Philosophical Foundations and Animals in Testing: Concerns and Consequences

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Resumo: O presente *paper* busca, a partir da filosofia e da ciência moderna, demonstrar como são conduzidas as pesquisas cientificas nos Estados Unidos. A fim de abordar essa questão avança-se para entender a situação moral e legal dos animais na sociedade. Animais são vistos como uma propriedade em cada país do planeta, disponíveis para qualquer uso que os humanos considerem adequados. Para entender a situação atual, a autora propõe um olhar através da historia.

Palavras-Chave: Direito Animal; Abolicionismo; Testes em animais.

Abstract: This paper seeks, from the philosophy and modern science, showing how scientific research are conducted in the United States. In order to address this issue goes to understand the legal and moral status of animals in society. Animals are seen as a property in every country on Earth, available for any use that humans deem appropriate. To understand the current situation, the author proposes a look through the history.

Keywords: Animal Rights; Abolitionisim; Animal testing.

The first question we ask ourselves when discussing animals in testing is a philosophical one: "Why should we care about them?" Three reasons become apparent. First, this research

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relates to the safety of our food, medicine, and environment, thus concern for the integrity of the process is in order, and animals are part of that process.[1] Second, it is estimated that between 50 to 100 million vertebrate animals are killed in research each year.[2] Others suggest this is a significant understatement.[3] In order to continue, we should be convinced that this research is warranted and conducted properly, as death on this scale implicates our moral philosophy. And finally, what we do to animals who have no voice reflects on us and our societies.

The next question is a scientific one: "Is this good and productive science?" The current scientific assessment of toxicity testing from the United States National Research Council of the National Academy of Sciences is that animal testing:

- Is too expensive and time consuming;
- Does not yield good enough results or even a sufficient quantity of results; and
- Kills millions of animals a year without requiring the use of alternatives where they exist, or an exploration of where they might be possible. [4]

The ultimate question we consider regarding research on animals is, "Is it *right* to experiment on animals, and if so, under what conditions?" In order to address that question we need to understand the legal and moral standing of animals in society. Animals are currently conceived of as property in every country on the planet, available for any use humans deem appropriate. [5] How did this come to be? And how do we assess the outcome of this conception from a modern philosophical and legal perspective?

To understand our current perspective on animals in society, it is useful to look back through history. Originally, religious and philosophical thought framed our understanding of animals and delineated human relationship and moral responsibilities toward them. Subsequently, science has played an increasingly important role in this dialogue.

Beginning with a short history of religious thought, we see that some of the earliest religious traditions explicitly addressed our relationship with animals. Though it is hard to be certain when any religion began, it is clear that some of our oldest religious traditions grappled with questions about the human-animal relationship.

The Jain[6] and Buddhist[7] traditions have in common a deep respect for animals and a belief that animals and humans are part of the same family. Indeed, their belief in reincarnation suggests that humans may have been, or yet become, animals in another life.[8] Given this perspective, it is easy to understand the respect and significant protection animals are afforded under these traditions. Jains and Buddhists urge humans not to eat animals, or to use them for clothing, work, or entertainment. And they urge humans to have compassion, and to take responsibility, for the welfare of animals.

Some scholars think that the Buddhists and Jains developed in part as a response to the religious practices of their time, including that of the Hindus, a religion that developed from the older Vedic religion.[9] The Hindus both worshiped animals and sacrificed them, making it difficult to identify a single clear philosophy with respect to animals. Rather, it is more indicative of the ambivalence we continue to experience with regard to this question.

Several ancient religious traditions seek to place humans in harmony with nature and animals, rather than as masters over them. One example is Taoism. This tradition does not divide animals from the environment in which both they and humans live. This is similar to many of the Native American religious traditions, which sanctioned killing animals only when it was deemed necessary for human needs. A more holistic approach to human relationships with animals results from these traditions, while they maintain the role of the human as the primary decision-maker in the relationship.

In contrast with these traditions are the Jewish, Christian, and Islamic faiths. In these religious traditions, animals are deemed to have been explicitly created for use by humans, thus granting humans the right to use animals in any way they deem appropriate, with some obligations to treat them well and avoid unnecessary pain or suffering in certain circumstances. Animals in these traditions fall under the complete control of humans. Many, though not all, of the directives to treat animals humanely are for the preservation of the human soul or well being, rather than deriving solely from concern for the welfare of the animals themselves.[10]

No religious tradition is completely homogenous. For instance, some scholars believe that the Essenes, a Jewish sect, were strict vegetarians,[11] eschewing animal sacrifice and eating the flesh of animals, in keeping with their interpretation of religious practice.[12] This would have been a significant departure from Jewish tradition at the time.[13] There is some split in the Catholic tradition as well, with Thomas Aquinas describing the accepted wisdom that animals are for man's use[14], while Francis of Assisi urged the development of a more compassionate and caring relationship with animals rather than dominion over them.[15]

We can see that to some degree, attitudes towards animals as reflected in modern laws, evolved from these diverse religious traditions. And what do we learn from ancient secular teachings? Some of the ancient wisdom revered by the western world comes from individuals who scholars believe were vegetarian, including: Pythagorus, Plato, Aristotle, Socrates, and Plutarch.[16] What accounts for this strong representation of vegetarianism in a pantheistic society that did not specifically endorse those principles? It could be because the temples of certain gods were thought to be desecrated by meat and blood, and by those who ate animals. Thus, a Greek or Roman citizen devoted to a certain god might choose a lifestyle desired by that god.

However, there is also a very interesting concept identified in ancient Greek writing called the Golden Age myth. This concept describes a time in pre-history in which everyone was a strict vegetarian, there were no wars, and society was matriarchal. The Greeks lamented the loss of this golden era, and some strove for its return. Whether this Golden Age is a myth or a reality is not as interesting as the fact that a society believed:

- That it did exist,
- That such a lifestyle was possible, and
- That living in harmony with animals was considered an element of an ideal society.

Just as we lost touch with this Golden Age, so too did some of our more modern philosophers leave behind the concept that animals were sentient and entitled to any, much less full, moral consideration. In the western world, the work of René Descartes embodies this perspective perhaps better than that of any other philosopher.[17] Descartes wrote that animals are machines, and as such, can be disassembled without concern for an adverse reaction.[18] Though significantly well accepted, this theory of Descartes was not universally adopted.

Other philosophers responded differently to the questions of what duties humans owe animals and how to define the appropriate treatment of animals. François Marie Arouet de Voltaire wrote that animals have souls, feeling, and understanding.[19] Acceptance of this perspective gives rise to human responsibilities. Immanuel Kant explained that duties toward animals are duties to humankind, raising the concern that poor treatment of animals was bad for the human being and thus cruelty to animals was appropriate only when justified.[20] He used vivisection as an example of justified cruel treatment.

Charles Darwin took a different, scientific, approach and wrote that there is no fundamental difference between man and higher mammals in their mental faculties, that in fact humans are animals, and that non-human animals can reason.[21] Many

philosophers of his day felt that only those beings who could reason were deserving of moral consideration. Therefore, acceptance of Darwin's theories resulted in corresponding moral obligations toward at least some animals based on their perceived capacity to reason.[22] However, Jeremy Bentham wrote that the important question was not whether animals could reason, but whether they could suffer.[23] He believed that any being who could suffer should not be made to do so unnecessarily.[24]

Following in Bentham's philosophical footsteps are a number of vegetarian philosophers who believed that they had no moral authority to put animals to their own use. They include, Leo Tolstoi, whose vegetarian ideals related to his pacifism[25]; Mohandas Gandhi who wrote about the connections between vegetarianism, peaceful resistance, and the power of the truth force[26]; Albert Schweitzer who wrote of the need for an ethic of reverence for life[27]; and Henry Salt who wrote a book entitled *Animal Rights* in 1892, positing that animals had rights of their own and for their own sakes.[28]

More recently, philosophers and legal scholars have picked up on Salt's proposition and begun to analyze what rights and protections are due to animals, rather than focusing solely on what elements in animals, such as the ability to reason or feel pain, might provide the basis for moral consideration. These philosophers include:

- Peter Singer who authored *Animal Liberation*[29];
- Tom Regan who authored *Philosophy of Animal Right*s;
- Francis Moore Lappé, author of *Diet for a Small Planet*[30];
- Carol Adams who authored *The Sexual Politics of Meat: A Feminist-Vegetarian Critical Theory*[31];
- Steve Wise, author of *Drawing the Line*, [32] *Rattling the Cage*,[33] and *An American Trilogy*[34];
- Gary Francione who authored *Animals, Property and the Law*[35], and *Rain Without Thunder*[36]; and
- Marjorie Spiegel, author of *The Dreaded Comparison - Animal and Human Slavery*.[37]

This list is certainly not exhaustive and it expands each year to include authors who approach the question of the moral position of animals in our societies from increasingly expansive philosophical and legal perspectives.

It is useful to focus on two scholars in particular, one who receives a lot of attention for his work, Descartes, and another who receives attention from scientists, but not from legal philosophers or animal legal theorists, Darwin. The legacies of their work are important as we analyze animal testing and the philosophical developments relating to this field.

There are two categories into which the many kinds of testing fall and they derive from two different philosophical perspectives. The first is *in vivo*, which is testing within the organism, also known as live animal testing. *In vivo* testing evolves from and is supported by the work of Descartes.[38] Cartesian principles are premised on the notion that we can learn about human biology and physiological reactions by dissecting and testing on animals. This is the current standard in toxicity testing, and has been the norm, unchanged by scientific and other developments over the last 60 years. Because the main measure of scientific validity is based on replication, it is hard to shift away from these accepted methodologies. This has resulted in the tremendous entrenchment of *in vivo* methodologies.

The second category of testing methods is *in vitro*, which refers to the technique of performing a given procedure in a controlled environment outside of a living organism. There are many techniques which fall into this category, including the relatively new field of computational biology. This is a Darwinian approach to testing. This approach both recognizes the autonomous value of animals and rejects the instrumental approach of using animals in order to learn more about human biology and physiological reactions. Scientists who choose these methods suggest that the data derived from *in vivo* animal testing is not sufficiently useful when applied in the human context. Darwinian theory suggests that we learn not only by dissection,

but through behavioral studies and other approaches. It further suggests that we best learn about humans by conducting research on humans, whether by testing human tissue or through observation and collection of data about human reactions to certain stimulus in their environments or bodies.

Regardless of the type of research a scientist engages in, all researchers, in theory, accept that experiments should be grounded in the same set of ethical principles. Interestingly, these principles guiding research have been accepted in both the scientific and legal communities for almost 40 years. These principles reflect the goal of achieving good scientific results with the least harm to animals. Ideally these principles should inform regulation and scientific practice.

It is helpful to know the origins of the principles and to consider the realities of their current application as well as the implications for their future use.

These principles are:

- Replacement - seeking to eliminate the need for whole animal experimentation by using non-animal models and techniques;
- Refinement - seeking to improve the design and/or efficiency of experimentation to eliminate or reduce the distress, discomfort, or pain experienced by laboratory animals; and
- Reduction - seeking to lower the number of animals necessary to perform an experiment so that the same quality of scientific information can be achieved by using fewer animals.

The "Three Rs" are referred to as "alternatives" in the scientific community and their origins derive from the work of two British scientists, William Russell and Rex Burch who wrote *The Principles of Humane Experimental Technique* in 1959.[39] Their work established the framework for the humane use of animals in science.[40]

The work of Russell and Burch both follow and precede developments in the moral philosophy relating to human experimentation. The most important of these is the Nuremberg Code which adopted guidelines for research on human subjects in response to the atrocities committed by Nazi doctors in World War II.[41] Additionally, the Declaration of Helsinki represents an evolving international effort of the medical community, guided by the World Health (Medical) Association, to regulate the use of human test subjects in research.[42]

Despite strong reaction to the acts of the Nazi doctors, there continue to be examples of abuse of human test subjects. These more recent realities continue to teach us of the need for the integration of the moral consideration of test subjects with the regulation of research.

One of the most well known examples of abuse in the United States is the Tuskegee Syphilis Experiment[43]. The United States Public Health Service experimented for 40 years on 399, mostly illiterate, African American men suffering from syphilis. These men received no medical treatment for their condition because the researchers wanted to study the autopsy data to learn the effects of syphilis on the brain.[44] Researchers told the men they were being treated for "bad blood" and gave them only aspirin or placebos. The results were that 128 men died from the untreated disease, and 59 relatives were infected, including some children who were born with the disease. Even after penicillin was discovered and known to be a successful treatment for syphilis, the men in the study and their families were denied this lifesaving treatment. The experiment ended in 1972, not because of concerns of the researchers, but because the experiment was exposed by a journalist. And even after that, the researchers did not admit any wrongdoing. Much has been written about this experiment, and many consider the outcome possible only because the researchers failed to give their test subjects full moral consideration.

What lessons have we learned from this, and in the human experimentation context more broadly? Certain guidelines must be followed which incorporate the moral consideration of the subject of the research.[45] These elements include:

- Voluntary and informed consent from the subject;
- The ability to withhold consent;
- Researchers have a duty to ascertain whether there is consent and must explore alternatives to the use of human subjects;
- The research must have a positive benefit unprocurable by other means and must follow generally accepted scientific practices;
- Researchers must avoid all unnecessary pain and suffering for the subject;
- The degree of risk should never exceed the importance of problem to be solved (in other words - a risk of death for a baldness cure is unacceptable); and
- No research should be conducted if researchers believe that death or disabling injury will occur.

Should the principles reflected in these guidelines, now enshrined in scientific standards and law for human experimentation, apply to animal research? This is a critical and timely question as the field of scientific research, especially toxicity testing, is in the midst of significant development, and also as societies increase their need for research data in greater amounts and with increased reliability and validity.

The Animal Welfare Act (AWA)[46] is the federal law in the United States that addresses the treatment of animals used in research. However, the AWA does little to protect animals. The lessons learned from the human research context were not imported to the AWA when it was adopted. Instead, the AWA focuses on minimal protections, setting requirements for cage size, ventilation, and the provision of food, water and pain relief, among other things. However, even that minimal protection

can be eliminated if it is deemed by the researchers to interfere with their study. Further, the AWA completely exempts from regulation all the mice, rats, and birds used in research.[47] These animals account for approximately 85-97% of all research animals in the United States.[48] Additionally, not all facilities conducting research are subject to the AWA.

In reaction to growing pressure to provide real protections for laboratory animals, the AWA was amended to require Institutional Animal Care and Use Committees, known as IACUCs.[49] These committees are tasked with approving applications for research using animals. Instead of considering the Three Rs to determine if the protocol is necessary, and if it uses the fewest number of animals, the committees tend only to focus on the refinement principle and ask whether there is sufficient pain relief. [50]

It is no surprise that the committees do not fully consider the Three Rs for a number of reasons. The AWA does not identify any restrictions on what may be done during an experiment; in fact quite the opposite is true. Once a researcher asserts that a procedure is part of the test protocol, the IACUC has no authority to question the procedure.[51] Further, the AWA does not distinguish between types of experiments, or identify which ones have sufficient social utility to justify animal suffering. All experiments are treated equally, whether they seek to market a new color of lipstick, or find the cure for cancer. Likewise, the law does not require a researcher to prove that the research will be beneficial, that it is not redundant of other research, that it is necessary, or that there are no alternatives. Further, the committee process is not required at all for experiments that are classified as unlikely to cause more than minor pain and distress, despite the fact that the animals used in experiments are killed at the conclusion of the test if not before.

Because the principles underlying the Three Rs were not fully incorporated into the law, there is no mechanism to require their recognition, inclusion, or implementation. In fact, the United

States federal framework describes alternatives as those that accomplish one or more of the Three Rs suggesting that pain reduction alone satisfies the goals of the Three Rs. Given that animals cannot consent to being used in experiments, this lack of consideration of the need to protect them creates, or should, an ethical dilemma.

There are some recent positive developments in the United States toward the incorporation of the Three Rs into research policy, including the endocrine disruption program, the National Toxicology Program Interagency Center for the Evaluation of Alternative Toxicological Methods (NICEATM) and the Interagency Coordination Committee on the Validation of Alternative Methods (ICCVAM).[52] But the United States still lags far behind other jurisdictions, most notably, the European Union (EU), in implementing these principles.

One of the important aspects of the EU's commitment to the Three Rs is its Registration, Evaluation, Authorisation, and Restriction of Chemicals (REACH) legislation,[53] which calls for the use of non-animal tests. Another is the requirement to register and share testing data, which has already reduced the numbers of animals used in testing. The EU's Cosmetic Directive[54] contains both a marketing ban and a sales ban of cosmetics in the EU that have been tested in whole or in part on animals.

The creation of European Centre for the Validation of Alternative Methods (ECVAM)[55] is a significant step in toward a full implementation of the Three Rs and is based on EU Directives that state:

- An [animal] experiment shall not be performed if another scientifically satisfactory method of obtaining the result sought, not entailing the use of an animal, is reasonably and practicably available.[56]
- The Commission and Member States should encourage research into the development and validation of alternative techniques which could provide the same

level of information as that obtained in experiments using animals, but which involve fewer animals or which entail less painful procedures, and shall take such other steps as they consider appropriate to encourage research in this field.[57]

Animal welfare is now an explicit value in the EU as evidenced by adoption of the Animal Welfare protocol to the European Commission Treaty.[58] This protocol requires the EU and its member states to pay full regard to the welfare of animals when drawing up agriculture, transport or research policies.

As a result of the adoption of Three Rs principles into regulatory policy in the EU, we see that scientific advancement continues, the protection of human health and the environment remain central to the work of research at the same time that animal welfare is taken seriously. For instance, the number of animals used in testing in the United Kingdom alone has been cut in half compared to the number of animals used in 1970.[59]

The work of many countries with respect to the implementation of the Three Rs is now being supported by an international movement to coordinate the development of alternatives to animal testing.[60] The International Cooperation in Alternative Test Methods (ICATM) was signed April 27, 2009, by the United States, the European Union, Canada, and Japan[61]. The agreement seeks to:

- Reduce use of animals in toxicity testing worldwide;
- Further the optimal design and conduct of validation studies to support national and international regulatory decisions on the usefulness and limitations of alternative methods;
- Further high quality independent scientific peer reviews of alternative test methods that incorporate transparency and the opportunity for stakeholder involvement;
- Enhance the likelihood of harmonized recommendations by validation organizations on the usefulness and

limitations of alternative test methods for regulatory testing purposes;

- Achieve greater efficiency and effectiveness by avoiding duplication of effort and leveraging limited resources; and
- Support the timely international adoption of alternative methods.[62]

As we increasingly recognize the reality of our global community, international harmonization of standards becomes more important.[63] Moreover, good scientific practices know no geographic boundaries. It is important to develop consensus among the many stakeholders involved in animal testing. Once we reach common ground, we can begin to share information and research tasks. The mandatory sharing of test data between researchers reduces unnecessary duplication, an important element of the Three Rs - reduction.[64] Even in the early stages of partial information sharing, it is estimated that this saves 8-12 million animals killed a year for toxicity testing in the United Kingdom, almost a quarter of the total number.[65]

Another benefit of sharing data internationally and working cooperatively across the globe relates to another of the Three Rs - replacement. The development of new scientific methods increases with regulatory and financial support, as well as the cooperation of scientists working across the globe and across disciplines.[66] Much work remains to be done. As most scientists now recognize, there are almost no other scientific fields relying so heavily on experimental protocols that have remained nearly unchanged for more than 40 years.[67]

We can see that adoption of the Three Rs into scientific and regulatory policy will spur the development of new scientific methods, reduce the numbers of animals used in testing, and achieve greater protections for those who are used. However, the Three Rs do not complete the task of achieving full moral

consideration for animals as test subjects.[68] The Three Rs have some limitations.

Most importantly perhaps, the Three Rs do not by themselves allow for challenges to the purpose of the experiment. They do not provide a method to determine if the experiment is socially or scientifically necessary. Additionally, application of the Three Rs to new and emerging technologies is unclear. Many new test methods will be first tried on animals. This is the validation method we are most familiar with, and will be the way which new test protocols receive approval. Further, even in vitro tests may use animal cells in the culture process.

And of course, the Three Rs principle do not challenge the presumption that it is appropriate for humans to determine when and how to use animals in research. Though the Three Rs suggest more care be taken in the exercise of animal research, it is a principle which further entrenches this human privilege.[69] It does not allow consideration that any animal, no matter its level of sentience or ability to reason and communicate, should have the right to withhold consent to be used as a test subject.

Ultimately, implementation of the Three Rs represents a significant improvement in animal welfare in the research context. But this protection is limited. It stems from the motivation to encourage appropriate human behavior. It is does not represent a paradigm shift in which we would return to a much earlier conception of animals as family, deserving respect, rather than property, deserving protection.

Notes

[1] See generally, C. Ray Greek and Jean Swingle Greek, Sacred Cows and Golden Geese: the Human Costs of Experiments on Animals (Continuum 2002). Kevin Dolan, Laboratory Animal Law: Legal Control of the Use of Animals in Research (Wiley-Blackwell 2d ed. 2007) (2000).

[2] Helga Kuhse and Peter Singer, A Companion to Bioethics, 400 (Wiley-Blackwell 2001) ("This wide range indicates how poor the record-keeping is.")

[3] See Debra Durham, Toxicity Testing: Is Animal Testing Still Viable? At the 2009 Animal Law Conference: The Links, http://lawlib.lclark.edu/podcast/?p=2582.

[4] Committee on Toxicity Testing and Assessment of Environmental Agents, Toxicity Testing in the Twenty-First Century: A Vision and a Strategy (The National Academies Press 2007)

5 *See Pierson v. Post*, 3 Cai R. 175 (N.Y. 1805) (seminal U.S. Supreme Court case involving property rights over animals). See also 4 Am. Jur. 2d *Animals* §6 (2006) (discussing branding cattle "as a means of identifying their property"); Gary L. Francione, Animals, Property, and the Law (Temple University Press 1995). See also, Joyce Tischler, *The History of Animal Law, Part I (1972-1987)*, 1 Stan. J. Animal L. & Pol'y, 1 (2008). David S. Favre, *Equitable Self-Ownership for Animals*, 52 Duke L. J. 473 (2000). Sonia S. Waisman, Pamela D. Frasch, Bruce A. Wagman, Animal Law: Cases and Materials (Carolina Academic Press 3d ed. 2010) (2000).

Taimie Bryant, *Animals Unmodified: Defining Animals/defining Human Obligations to Animals*, 2006 U. Chi. Legal F. 137 (2006). Animals and Their Legal Rights, a Survey of American Laws from 1641 to 1990 (Animal Welfare Institute 4th ed. 1990). *The Legal Status of Nonhuman Animals*, 8 Animal L. 1 (2002).

[6] Natubhai Shah, Jainism: The World of Conquerors, Volume $_1$ 222 (Sussex Academic Press 1998).

[7] *See* Christopher Chapple, Nonviolence to Animals, Earth, and Self in Asian Traditions 22 (SUNY Press 1993).

[8] Marvin W. Meyer and Kurt Bergel, Reverence for Life: The Ethics of Albert Schweitzer for the Twenty-First Century 222 (Syracuse University Press 2002).

[9] Natubhai Shah, Jainism: The World of Conquerors, Volume 1 158 (Sussex Academic Press 1998).

[10] For example, Immanuael Kant stated that "he who is cruel to animals becomes hard also in his dealing with men. We can judge the heart of a

man by his treatment of animals." Immanuel Kant, Duties in Regard to Animals, in Animal Rights and Human Obligations 23, 24 (Tom Regan & Peter Singer eds., 2d ed 1989).

[11] Raymond W. Bernard, From Chrishna to Christ 39 (Mokelumne Hill Press 1966)

[12] Upton Clary Ewing, The Prophet of the Dead Sea Scrolls 115-116 (Philosophical Library 1963)

[13] Louis A. German, Vegetarianism and Jewish Tradition 22 (Ktav Pub. Inc. 1975) ("[I]t is necessary to keep in mind two facts about the world of ancient Israel: 1. The tribes of Israel were a pastoral people and therefore a flesh-eating people. 2. They inhabited a world in which blood sacrifices, both animal and human, were widely practiced."). *See also* Upton Clary Ewing, The Prophet of the Dead Sea Scrolls 122-123 (Philosophical Library 1963).

[14] Aquinas: Political Writings, 251-252 (R.W. Dyson ed., Cambridge University Press 2002). For more on Aquinas and animal souls *see* Andrew Linzey, Christianity and the Rights of Animals, 36-39 (Crossroad Pub. Co. 1987).

[15] For a thorough account of Saint Francis's life and work in regards to animals, *see* Roger D. Sorrell, St. Francis of Assisi and Nature: Tradition and Innovation in Western Christian Attitudes Toward the Environment (Oxford University Press 1988).

[16] *See generally* Ethical Vegetarianism: from Pythagoras to Peter Singer (Kerry S. Walters & Lisa Portmess eds., State U. of N.Y. 1999); and Rynn Berry, Famous Vegetarians and Their Favorite Recipes: Lives and Lore from Buddha to the Beatles (Pythagorean Books 1993).

[17] Rene Descartes, Discourse on the Method and Meditations on First Philosophy (David Weissman, ed., 1997) (1637).

[18] Animal Rights: Current Debates and New Directions 110 (Cass R. Sunstein & Martha C. Nussbaum eds., Oxford University Press 2004) (Descartes maintained that animals are not conscious because the do not possess a soul, which was vested only in human beings). *But see* Tom Regan, The Case for Animal Rights 3-6 (1983) (questioning the extent that Descartes really held this extreme view).

[19] Voltaire, Philosophical Dictionary 112-113 (P. Gay trans., 1962) ("How absurd, to say that beasts are machines, devoid of knowledge and feeling, which perform all their operations in the same manner, which learn nothing, which perfect nothing, etc! ... Barbarians seize this dog, which surpasses man so greatly in his capacity for friendship; they nail him to a table, and dissect him alive to show you the mesenteric veins. You discover in him the same organs of feeling that are in yourself. Answer me, machinist, has nature arranged all the springs of feeling in this animal in order that he should not feel? Has he nerves in order to be unmoved? Do not suppose such a pointless contradiction in nature.")

[20] Immanuel Kant, Critique of Pure Reason (Penguin Classics 2008) (1781).

[21] Charles Darwin, The Descent of Man 319 (Encyc. Britannica, Inc. 1952) (1871) (The difference between humans and non-human animals is "one of degree and not of kind,").

[22] Nuffield Council on Bioethics, *The Ethics of Research Involving Animals*, 4.4 (2005) *available at* http://www.nuffieldbioethics.org/go/browseablepublications/ethicsofresearchanimals/report_230.html.

[23] Jeremy Bentham, An Introduction to the Principles of Morals and Legislation (Oxford University Press 1996) (1970). *See also* Ruth Payne, *Animal Welfare, Animal Rights, and the Path to Social Reform: One Movement's Struggle for Coherency in the Quest for Change*, 9 Va. J. Soc. Pol'y & L. 587, 593 (2002) ("Many writers believe that the true founder of the animal welfare movement was the renowned utilitarian Jeremy Bentham. As a utilitarian, Bentham believed that the correct moral action is discovered by noting which action produces the most social benefit, even if that benefit comes at a significant cost to a few.").

[24] Peter Singer, Animal Liberation 7 (rev. ed., Ecco 2002) (1975).

[25] Arthur Herman, Gandhi & Churchill: The Epic Rivalry That Destroyed an Empire and Forged Our Age 132 (Random House, Inc. 2008) (stating that "Gandhi had read Tolstoy's *The Kingdom of God Is Within You*" and had been 'overwhelmed' by its message that God's greatest gift to man was the power of universal love to overcome all conflict and hatred. (Many years later Gandhi would say that it was reading Tolstoy that made him a believer in nonviolence.")).

[26] *See generally* M.K. Gandhi, For Pacifists (Bharatan Kumarappa ed., Navajivan Pub. House, 1971) (1949) (a selection of Gandhi's writings and speeches on the general principles of pacifism within the framework of his philosophy of non-violence); Social and Political Philosophy: Readings from Plato to Gandhi (John Sumervill & Ronald E. Santoni eds., Doubleday & Co., 1963) (representative collection of Gandhi's writings on non-violence resistance covering civil disobedience, passive resistance, non-cooperation, and Satyagraha, or truth-force); Mahatma Gandhi, The Moral Basis of Vegetarianism (Ramachandra Krishna Prabhu ed., Navajivan Publishing House, 1988) (1959) (compilation of Ghandhi's writings on vegetarianism.).

[27] *See generally* Marvin W. Meyer and Kurt Bergel, Reverence for Life: The Ethics of Albert Schweitzer for the Twenty-First Century (Syracuse University Press 2002).

[28] Henry S. Salt, Animals' Rights: Considered in Relation to Social Progress (1892) (Soc'y for Animal Rights 1980).

[29] Peter Singer, Animal Liberation (rev. ed., Ecco 2002) (1975).

[30] Frances Moore Lappe, Diet for a Small Planet (20th Anniversary Edition) (The Random House Pub. Group 1991) (1971).

[31] Carol J. Adams, The Sexual Politics of Meat: A Feminist-Vegetarian Critical Theory (The Continuum Int'l Pub. Group Inc. 2006) (1990)

[32] Steven M. Wise, Drawing the Line: Science and the Case for Animal Rights (Perseus Pub. 2002).

[33] Steven M. Wise, Rattling the Cage: Toward Legal Rights for Animals (Perseus Pub. 2000).

[34] Steven M. Wise, An American Trilogy: Death, Slavery, and Dominion on the Banks of the Cape Fear River (Da Capo Press 2009).

[35] Gary L. Francione, Animals, Property, and the Law (Temple U. Press 1994).

[36] Gary L. Francione, Rain Without Thunder: The Ideology of the Animal Rights Movement (Temple U. Press 1996).

[37] Marjorie Siegel, The Dreaded Comparison – Human and Animal Slavery (Heretic Books 1996) (1989).

[38] Namely that since animals do not have souls or consciousness, they are a sort of *automata* and cannot "experience pain, pleasure, or any other sensation or emotion." Gary L. Francione, Introduction to Animal Rights: Your Child or Your Dog? 104 (Temple University Press 2000); *see also* Tom Regan, The Case For Animal Rights 3 (1985).

[39] W.M. Russell, R.I. Burch, and C.W. Hume, The Principles of Humane Experimental Technique (Hyperion Books 1992) (1959).

[40] "Russell and Burch did not seek the abolition of animal experimentation, but only the 'removal of [its] inhumanity' through implementation of the Three R's --a goal consistent with the animal welfare approach." Darian M. Ibrahim, *Reduce, Refine, Replace: The Failure of the Three R's and the Future of Animal Experimentation*, 2006 U. Chi. Legal F. 195, 197 citing *id*. at 64.

[41] Nuremberg Code, *Directive for Human Experimentation*, http://ohsr.od.nih.gov/guidelines/nuremberg.html (last visited Nov. 29, 2009) *reprinted from* Trials of War Criminals Before the Nuremberg Military Tribunals Under Control Council Law No. 10, Vol. 2, 181-182 (Washington, D.C.: U.S. Gov't Printing Office 1949).

[42] Declaration of Helsinki 1964, adopted by the 18th World Medical Assembly, Helsinki, Finland, June 1964, amended by the 29th World Medical Assembly, Tokyo, Japan, Oct. 1975, and the 35th World Medical Assembly, Venice, Italy, Oct. 1983. World Medical Declaration of Helsinki, British Medical Journal (7 Dec. 1996) 313 (707):1448-1449 (recommendations guiding physicians in biomedical research involving human subjects).

[43] *See generally* James H. Jones, Bad Blood: The Tuskegee Syphilis Experiment (Free Press 1993) (general account of the Tuskegee Syphilis Experiment); and Harriet A. Washington, Medical Apartheid: The Dark History of Medical Experimentation on Black Americans from Colonial Times to the Present (Anchor 2008) (documents the use of African-Americans as unwitting or unwilling human guinea pigs including the Tuskegee Syphilis Experiment);

[44] *See* Jones, at 5-10.

[45] National Research Act, Pub. L. No. 93-348, 88 Stat. 342 (1974); 4 Encyc. of Bioethics 2357 (3d ed. 2004) (documenting the initial regulations created by Congress concerning research on human subjects).

[46] Laboratory Animal Welfare Act of 1966 7 U.S.C. §§2131-2156 (2007).

[47] Section 2132(g) states in relevant part: "(g) The term 'animal' means any live or dead dog, cat, monkey (nonhuman primate mammal), guinea pig, hamster, rabbit, or such other warm-blooded animal, as the Secretary may determine is being used, or is intended for use, for research, testing, experimentation, or exhibition purposes, or as a pet; but such term excludes (1) birds, rats of the genus Rattus, and mice of the genus *Mus*, bred for use in research, (2) horses not used for research purposes, and (3) other farm animals, such as, but not limited to livestock or poultry, used or intended for use as food or fiber, or livestock or poultry used or intended for use for improving animal nutrition, breeding, management, or production efficiency, or for improving the quality of food or fiber. With respect to a dog, the term means all dogs including those used for hunting, security, or breeding purposes." 7 U.S.C. § 2132(g) (2000).

[48] Darian M. Ibrahim, *Reduce, Refine, Replace: The Failure of the Three R's and the Future of Animal Experimentation*, 2006 U. Chi. Legal F. 195 at 105, 214, citing HSUS, *Overview of the Issues*, available at http://www.hsus.org/web-files/PDF/ARI/Overview_of_the_Issues.pdf (last visited Nov. 27, 2009); Orlans FB, *Data on Animal Experimentation in the United States: What They Do and Do Not Show*, 37(2) Perspective Biology and Med 217, 218 (1994) (noting that the AWA does not apply to mice, rats, and birds, which make up between 80-90% of all animals used in experiments); Francione, *Introduction to Animal Rights* at 34 ("[T]he Animal Welfare Act does not cover rats and mice... which, according to the federal government, account for approximately 90% of the animals used.").

[49] *See* 9 C.F.R. § 2.31(a) (any institution that conducts research on animals must establish an international IACUC "to oversee and evaluate all aspects of the institution's animal care and use program."

[50] For example, at least once every six months, the IACUC must evaluate the institution's standards for humane treatment of animals and inspect the institution's animal facilities. *Id*. at §2.31(c). Methods of experimentation must minimize any discomfort, distress, and pain the animal may experience. *Id*. at § 2.13(d)(1)(i). The principal investigator must demonstrate that no alternative procedure was available when an experiment might cause more than transient or minor pain and must prove experiments are not unnecessarily duplicative. *Id*. at 2.13(d)(1)(ii)-(iii).

[51] 9 CFR § 2.31(a) (2005) (The Chief Executive Officer of the research facility shall appoint an Institutional Animal Care and Use Committee (IACUC), qualified through the experience or expertise of its members to assess the research facility's animal program, facilities, and procedures. Except as specifically authorized by law or these regulations, *nothing in this part shall be deemed to permit the Committee or IACUC to prescribe methods or set standards for the design, performance, or conduct of actual research or experimentation by a research facility*.) (emphasis added).

[52] Paul A. Locke, *The Revolution in Toxicity Testing: Are We Ready for an In-Vitro Future?*, AV Magazine 20 (Summer 2008) *available at* http://www.aavs.org/images/AVSummer08.pdf (In 2008, ICCVAM and NICEATM published a five year plan to advance "alternatives for those regulatory test methods that can involve significant animal pain and distress and case use large numbers of animals.").

[53] Regulation No. 1907/2006 of the European Parliament and of the Council of 18 Dec. 2006, Registration, Evaluation, Authorisation and Restriction of Chemical Substances, 2006 O.J. (L 369).

[54] Council Directive 76/768/EC 1976 O.J. (L262) (amended 4. Feb. 2009) (Concerning Cosmetic Products).

[55] *About ECVAM*, http://ecvam.jrc.it/ (last visited Nov. 27, 2009).

[56] Council Directive 86/609/EC of 24 Nov. 1986, 1986 O.J. (L 358) 7.2 *available at* http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:31986L0609:EN:HTML (on the approximation of laws, regulations and administrative provisions of the Member States regarding the protection of animals used for experimental and other scientific purposes).

[57] *Id*. at Art. 23.

[58] *Id*.

[59] Alan M. Goldberg and Paul A. Locke, *To 3R is Humane*, The Environmental Forum (July/Aug. 2004) *available at* http://caat.jhsph.edu/publications/articles/To_3R_Is_Human_J-A_20041.pdf.

[60] Allison Guy, Clement Gauthier and Gilly Griffin, *Adopting alternative methods for regulatory testing in Canada*, 14 AATEX Special Issue Proc. 323-327 (2008) *available at* http://www.soc.nii.ac.jp/jsaae/WC6_PC.html (Publication serves as an archive of the conference: 6th World Congress

on Alternatives & Animal Use in the Life Sciences, that was held in Tokyo, Japan from Aug. 21-25, 2007). Melvin E. Andersen and Daniel Krewski, *Toxicity Testing in the 21st Century: Bringing the Vision to Life*, Toxicological Sciences 107 (2), 324-330 (2009).

[61] Memorandum. of Cooperation, *International Cooperation on Alternative Test Methods*, signed April 27, 2009 http://iccvam.niehs.nih.gov/about/icatm.htm (page last updated Sept. 3, 2009).

[62] Framework for International Cooperation on Alternative Test Methods (ICATM) http://www.fda.gov/InternationalPrograms/HarmonizationInitiatives/ucm114518.htm Oct. 2008 (last updated Apr. 30, 2009).

[63] Thomas Hartung, *A Toxicology for the 21st Century – Mapping the Road Ahead*, Toxicological Sciences, Vol 109 No. 1, 18-23 (2009) *available at* http://toxsci.oxfordjournals.org/cgi/content/full/109/1/18 (arguing that "[w]hen lobbying for programs to identify pathways of toxicity… project, the aim should be for a global program from the start, for example, similar to the human genome project.).

[64] Larry Greenemeier, *Fed Agree to Toxicity Tests That Cut Animal Testing*, Scientific American Feb. 15, 2008 http://www.scientificamerican.com/article.cfm?id=feds-agree-to-toxicity-test.

[65] *See* Hartung, *supra* note 66

[66] Thomas Hartung, *Toxicology for the Twenty-First Century*, Nature, vol 460, July 9, 2009 *available for a fee at* http://www.nature.com/nature/journal/v460/n7252/pdf/460208a.pdf.

[67] Daniel Krewski, *Without Changes, Testing Will Evolve Slowly*, Environmental Forum (Mar./Apr. 2008).

[68] David S. Favre, *Judicial Recognition of the Interests of Animals - A New Tort*, 2005 Mich. St. L. Rev. 333 (2005).

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