Biodefense Research and the U.S. Regulatory Structure
Whither Nonhuman Primate Moral Standing?

ABSTRACT. Biodefense and emerging infectious disease animal research aims to avoid or ameliorate human disease and suffering arising from the natural outbreak or intentional deployment of some of the world’s most dreaded pathogens. Research to develop medical countermeasures to these diseases faces a difficult challenge since the products usually cannot be tested for efficacy in human beings. The U.S. Food and Drug Administration’s Animal Rule may be increasingly used to overcome this challenge by allowing researchers to translate animal data into medical countermeasures without human subject efficacy testing. Yet the Animal Rule also has significant implications for increased intensive nonhuman primate research. We argue that despite the common belief that nonhuman primates have a fairly high level of moral standing and the protections for animals that are crucial to the U.S. regulations guiding animal research, the Animal Rule specifically and the regulations generally raise serious problems for the attribution of moral standing to nonhuman primates. We argue, however, that the burden of proof is on a position denying all moral standing to nonhuman primates and compare the implications of the U.S. regulatory structure in this regard with some recent developments in the European Union.

Biodefense and emerging infectious disease animal research aims to avoid or ameliorate human disease, suffering, and death arising, or potentially arising, from natural outbreaks or intentional deployment of some of the world’s most dreaded pathogens. Top priority research goals include finding vaccines to prevent, diagnostic tools to detect, and medicines for smallpox, plague, ebola, anthrax, tularemia, and viral hemorrhagic fevers, among many other pathogens (National Institute of Allergy and Infectious Diseases [NIAID] priority pathogens). To this end, increased funding for conducting research, developing research fa-
facilities, and purchasing (stockpiling) developed vaccines, diagnostic tools, and therapeutics has been granted by the U.S. government since 2001.\(^1\) Research to develop these medical countermeasures faces a difficult challenge: for both moral and practical reasons, the products that the research aims to develop usually cannot be tested for efficacy in human beings. The pathogens of choice in bioweapons are precisely those that cause the greatest amount of human suffering and the highest death rates. There is wide agreement, at least in contemporary societies, that it is immoral to deliberately infect human subjects with these agents.\(^2\) In the case of biodefense threats that are also emerging infectious diseases, there may be some opportunities for field studies, but these may be practically difficult to undertake for a variety of reasons, including small numbers of infected persons, the sporadic nature of the outbreaks, and social factors such as remoteness from transportation networks or the lack of availability of health care facilities (Warfield et al. 2006).\(^3\)

The FDA regulations for approval of new drugs (FDA 2009b) and biologics (FDA 2009a), “When Human Efficacy Studies Are Not Ethical or Feasible,” commonly referred to as the Animal Rule, permits researchers to use animal data to develop medical countermeasures for humans to targeted pathogens without human subject efficacy testing and so may be increasingly relied on to overcome these challenges.\(^4\) However, the Animal Rule raises some serious issues with respect to animal moral standing (or status) and in so doing also provides the impetus for considering the moral standing implications of the U.S. animal research regulatory structure more generally.

In this paper, we adhere to the commonplace idea that beings with moral standing are members of the moral community whose interests, needs, and/or well being should be taken into account in appropriate ways by moral agents (Warren 2000, p. 1). An idea of moral standing underwrites, for example, a belief in morally significant (rather than simply legal) human rights. Moral standing is also commonly at issue in many contemporary debates, such as those over the moral legitimacy of abortion or fetal stem cell use, although public discussion may use different terminology. The concept of moral standing, however, is neither necessarily associated with rights nor necessarily limited to human beings (or human fetuses or embryos). We explore several different philosophical frameworks and issues for moral standing as these relate to nonhuman primates and other animals in the context of both the Animal Rule specifically and oversight of biomedical research with animals generally.

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We argue that the Animal Rule cannot be justified if we attribute moral standing to nonhuman primates. Yet it is a common assumption that nonhuman primates do have moral standing. Furthermore, when we look to the U.S. regulatory structure, we find a persistent tension with regard to animal moral standing. Certain aspects of the regulations, as well as the general culture of responsible conduct of research involving animals, make most sense if animals have moral standing. Yet, if animals do have moral standing, it is difficult to justify two key features of the regulatory structure. The regulations may consistently imply that animals have no moral standing and yet also promote certain nonmoral obligations toward them. However, even given this possibility, we suggest that the burden of proof lies with any view that excludes all nonhuman animals from moral consideration. Before we address these points, we overview the content of the Animal Rule and current uses of nonhuman primates in biodefense/emerging infectious disease research.

THE FDA ANIMAL RULE AND NONHUMAN PRIMATE USE IN BIODEFENSE/EMERGING INFECTIOUS DISEASE RESEARCH

The FDA's 2002 Animal Rule, sometimes called the “animal efficacy rule” or the “two animal rule,” provides a mechanism for approval of drug and biological products for human use whereby researchers can use animal data and not have to show efficacy in human subjects. The explicit reason for not demanding preapproval demonstration of efficacy in human subjects is that it would be unethical to deliberately expose healthy human volunteers to the relevant pathogenic agents because of the “serious or life-threatening conditions caused by exposure to lethal or permanently disabling toxic biological, chemical, radiological, or nuclear substances” (FDA 2002, p. 37989; FDA 2009a, 21 CFR 314.600). The rule applies only when it is not feasible to undertake field efficacy trials “after an accidental or hostile exposure” (FDA 2009a, 21 CFR 314.600; FDA 2009b, 21 CFR 601.90), but that is the case for many of the pathogens listed by the NIAID as research priorities.

Importantly, the Animal Rule addresses only efficacy testing; safety testing must still be conducted in human volunteers, according to the existing regulatory scheme, in order to secure FDA approval. Moreover, the rule does not bypass clinical efficacy testing in humans altogether; instead, it treats use of the product in response to an exposure as a clinical trial from which essential data can be gathered. Finally, if a product can receive approval (including accelerated approval using surrogate markers) based on existing efficacy standards, the Animal Rule cannot be used.
The Animal Rule requires (1) that the animal study endpoint be clearly related to the desired human benefit, “generally the enhancement of survival or the prevention of major morbidity,” and (2) that the data allow selection of an effective human dose (FDA 2009a, 21 CFR 314.610[a]; FDA 2009b, 21 CFR 601.91[a]), thus clearly linking the use of animals to human benefit. This linkage raises two important questions of relevance to the moral analysis of the Animal Rule: first, whether animal data will in fact translate to potential human benefit and, second, whether benefit might potentially also arise for other nonhuman animals. Since the Animal Rule assumes that medical countermeasures developed through animal studies alone could provide human benefit, it must also assume that animal studies have the potential to directly predict human response. Unlike a scientific justification of animal use for the sake of hypothesis generation, a justification based on direct prediction from animal to human response is controversial and perhaps untenable (Shanks, Greek, and Greek 2009). On the other hand, it may be that animal use under the Animal Rule could be justified on the basis of potential benefit for other nonhuman animals, such as the thousands of gorillas estimated to have died from the Zaire strain of Ebola virus between 2002 and 2003 (Bermejo et al. 2006).

In this paper we do not pursue these particular ethical complexities further. While we agree that if the scientific justification for the Animal Rule is untenable, then a moral justification fails as well, we assume, for the sake of argument, that a scientific justification for the Animal Rule is available. In the case of collateral benefit that may arise for some animals, we agree that a moral analysis of specific studies aiming at human-use approval under the Animal Rule should also take into account potential other animal benefit (though there is no regulatory requirement that this be done). However, in this paper we focus on the moral justification of the Animal Rule itself, which considers only human benefit and thereby neither assumes a need to show other animal benefit nor aims directly at such benefit.

Aside from the directives regarding study endpoints and allowances for selecting human dosage, the rule itself provides no guidance on the permissibility of animal research when human research would be unethical. When investigators sought additional guidance on use of the Animal Rule in September 2008, the FDA’s Center for Drug Evaluation and Research produced a “concept paper”—a draft document preliminary to a guidance document—titled “Animal Models: Essential Elements to Address Efficacy Under the Animal Rule” (FDA 2008, p. 3). Subsequently, a draft guidance
with the same title as the concept paper and nearly identical content was
issued by the Center for Drug Evaluation and Research and Center for
Biologics Evaluation and Research (FDA 2009c). No final version has yet
been announced. The draft guidance, while it provides investigators with
some assistance in using the Animal Rule, says nothing relevant to the
morally appropriate use of animals in this context except that “studies
must comply with the Animal Welfare Act” (FDA 2008, p. 7). We discuss
the act and its implementing regulations in the last section of the paper.

At this point the reader may be wary of the very idea of a moral analysis
of the Animal Rule, given the rule’s own failure to address the ethical issues
related to animal use under it. Perhaps the Animal Rule is put forward
on purely pragmatic grounds and sets aside issues of moral justification
altogether. Of particular interest in this regard, as already mentioned, is
the fact that the rule does explicitly address moral justification regarding
human, but not animal, subjects: it applies when “definitive human efficacy
studies cannot be conducted because it would be unethical to deliberately
expose healthy human volunteers” (FDA 2002, p. 37995; FDA 2009a, 21
CFR 314.600, emphasis added). Thus the justification for the rule itself
is, in part, an ethical prohibition, which confirms that at least some ethical
claims are relevant to the rule. Yet even if the rule were justified on
purely pragmatic grounds, it would be important to investigate its moral
implications for animal moral standing as we do in this paper.

Primate Use and Demand in Biodefense/Emerging
Infectious Disease Research

In general, nonhuman primates account for a very small percentage
of the animals used in research.6 There are some forces moving biomedical
research away from the use of nonhuman primates, including the financial
and logistical burdens of properly housing and caring for the animals; a
broad agreement that animal subjects should be the least socially, emo-
tionally, and cognitively complex or advanced from among the species
appropriate to the study aims; and social pressures, especially in some
European Union countries.7 Yet despite these forces and low rates of use
in research generally, the scientific appropriateness of nonhuman primates
as animal models for a number of biodefense priority pathogens and the
potential for drug or biologic approval through the Animal Rule are likely
to both increase and intensify nonhuman primate use.8

To satisfy the requirements of the Animal Rule, efficacy for a drug or
biologic must be shown “in more than one animal species expected to react
with a response predictive for humans, unless the effect is demonstrated in a single animal species that represents a sufficiently well-characterized animal model for predicting the response in humans” (FDA 2009a, 21 CFR 314.610[a]; FDA 2009b, 21 CFR 601.91[a]). Thus, researchers may turn to nonhuman primate models as a way of establishing appropriate efficacy using a single-animal model. In either case, given the difficulty of extrapolating probable human efficacy from animal models alone, the biological relatedness of nonhuman to human primates makes nonhuman primates especially appealing for study of drugs or biologics that might gain approval through this mechanism. As one researcher puts it, “The FDA would prefer that one of the animal models be a nonhuman primate” (Drexler 2007, p. 99). Moreover, since the FDA requires that the animal study endpoint be clearly related to the desired human benefit—enhancement of survival or prevention of major morbidity—the potential increase in nonhuman primate use would no doubt also be highly intensive: that is, likely to involve high levels of suffering and death.

In biodefense/emerging infectious disease research, then, the apparent suitability of nonhuman primates as animal models for the human diseases studied and the moral and practical limitations on the use of human subjects for testing the efficacy of medical countermeasures combine to effectively promote nonhuman primate use. The large increases in funding directed toward, and the number of facilities engaged in, this type of research, combined with the factors of animal model suitability and human subject limitations, suggest that “the demand for nonhuman primates will undoubtedly increase to meet biomedical needs in this current age of biodefense” (Patterson and Carrion 2005, p. 15). Whether for these or other reasons, it appears that biomedical research use of nonhuman primates is in fact on the rise, at least in the United States.9

NONHUMAN PRIMATE MORAL STANDING AND THE ANIMAL RULE

The ethical tension inherent in doing research on animals because they are like us while at the same time being willing to do to them what we are not willing to do to humans has long been noted.10 In moral-standing terms, this tension reveals a discounting of the needs, interests, and well-being of nonhuman animals relative to human beings. What is striking about the Animal Rule is that it effectively calls for the use of animals most like us, specifies study endpoints that are likely to involve the suffering and death of the animals studied, and clarifies that this animal research is appropriate precisely when such research using human subjects would
be immoral (even with their consent). Thus, the Animal Rule brings this long-recognized moral-standing tension in animal research to a head.

In this part of the paper, we investigate whether the implications of the Animal Rule can be justified with respect to nonhuman primate moral standing. To accomplish this task, we investigate different views of moral standing to see how the Animal Rule would fare on each. Finding that, given a certain widely shared assumption, a moral justification for the Animal Rule escapes us, we turn, in the last part of the paper, to consider more generally the moral standing implications of the U.S. regulatory system governing biomedical research on animals. There we find remarkable interpretive instability regarding animal moral standing and yet argue that the conceptually coherent view implied by the regulations is that animals (including nonhuman primates) lack moral standing. At the same time, we maintain that this position bears the burden of proof in the debate over nonhuman primate moral community membership.

Narrowing the Question

In addressing moral standing, it is helpful to first distinguish two frequently conflated questions: the question of what sorts of beings are morally considerable and the question of the relative moral standing between those beings. The first question is about admission into the moral community. The second is about the relative moral value of the beings in the moral community. In this section of the paper we focus, for the most part, on the second question. We assume agreement on the claim that nonhuman primates have at least some moral standing (i.e., are morally considerable). We think this minimal assumption, while still somewhat controversial, is widely shared, even—or perhaps especially—among animal researchers. However, of particular interest, our investigation of the Animal Rule leads us to focus, in the last part of the paper, on the general implications of the U.S. regulatory structure governing animal research for nonhuman primate and other animal moral considerability (rather than relative moral standing).

Second, it is important to clarify further what we mean by moral standing. Moral standing is typically understood as the standing that an individual being has in virtue of its intrinsic properties, such that others are obligated in appropriate contexts to attend to the needs, interests, and/or well-being of that individual. Moral standing may be initially contrasted with attention owed to the needs, interests, and/or well-being of an individual or object merely as a consequence of its significance for
some other being(s) that is/are morally considerable. For example, I might be obligated to attend to the flourishing of an apple tree merely because it is an important source of nourishment for my family. In this kind of situation, the apple tree itself is not typically viewed as having any direct moral standing.

Examples of intrinsic properties that have been thought significant for moral standing include capacities for rationality and reason, sentience understood as the ability to feel pain or pleasure, and capacities significant for sociability such as the ability to communicate or to feel and express emotions. Each set of capacities has some immediate appeal as a basis for moral standing, yet which of these—or other—properties should ground moral standing and why is a matter of much philosophical debate. Other controversies regarding the intrinsic properties view of moral standing, which we consider in the section “Rejecting moral individualism?,” focus on the association of moral standing with individual capacities, either emphasizing instead capacities that are normative for a group rather than possessed by an individual or raising concern about the idea that capacities (which ground abilities, rather than, for example, vulnerabilities) should be the basis for moral standing.

In this paper we do not argue for the association of any particular intrinsic properties with moral standing, nor do we argue more generally for the intrinsic properties approach to moral standing. Instead, we investigate whether, once we assume that nonhuman primates are morally considerable, the Animal Rule could reflect a justifiable view of nonhuman primate relative moral standing according to any plausible philosophical view of moral standing. In the course of considering these views, we do also end up pointing to both strengths and weaknesses of the intrinsic properties view. In addition, toward the end of the paper, we suggest a burden of proof claim regarding nonhuman primate moral standing that upholds modest tenents of the intrinsic properties view.

Speciesism and Moral Individualism

Biological relatedness does not necessarily correlate to relevantly similar needs, interests, and potential for welfare or harm. However, given the comparability of some nonhuman and human primates with regard to a variety of complex social, emotional, and cognitive capacities, a pointed question arises: can anything other than human prejudice support bio-defense research using the Animal Rule on nonhuman but not human primates? In his highly influential work Animal Liberation, first published
in 1975, Peter Singer used the term “speciesism” (originally coined by Richard Ryder) as a label for the practice of treating nonhuman animals as having lesser moral standing simply by virtue of not being members of the human species.

More recently, other philosophers have argued specifically for “moral individualism,” or the view that each being should be recognized as having the moral standing that befits its intrinsic moral properties, where these are usually understood as (loosely) psychological capacities, which might be held to include—among others—rationality, sentience, and sociability. Once one accepts the tenets of moral individualism, the attribution of full moral standing to all human beings regardless of whether they manifest specific morally relevant capacities, and the denial of this standing to those nonhuman primates with the relevant capacities, is clearly speciesism. Moral individualists simply point out that not all humans share certain seemingly morally relevant capacities, while many nonhuman animals do have these same capacities. As a result, the thought seems to be, we should be forced, on pain of contradiction, to extend the same level of moral consideration to those animals as we do to the human beings at issue (keeping in mind that “same consideration” does not necessarily translate to “same treatment” given variance in morally relevant interests). This so-called argument from marginal cases has played a central philosophical role in support of extending greater moral consideration to nonhuman animals.

If we accept the argument from marginal cases (and its conceptual roots in moral individualism), it is clear that the assumption evidenced in the Animal Rule regarding the relative moral standing of nonhuman primates is untenable. That is, not only can we not assume that it is morally permissible to do to nonhuman primates what it is morally impermissible to do to humans but we must start with the opposite assumption. Only if the particular nonhuman primates at issue either do not have psychological capacities relevantly similar to at least some humans, or if the impact on the animals does not in fact set back their interests in ways relevantly similar to what would be experienced by the exempted human subjects, can we justify nonhuman primate use. Neither of these potential justificatory routes is very promising. Whatever highly significant dissimilarities there are between human and nonhuman primates (and there are many!), it is no longer plausible to argue that at least some of the nonhuman primates most often used in the types of research in question (macaques, for example) do not have psychological capacities at least as complex as some human beings—for example, those who were born with conditions that
include profound intellectual and emotional disability. Likewise, the suffering and death that may attend the types of research in question would clearly be a serious setback to the interests of either type of primate. In practice, then, the thorough acceptance of a moral individualist position would exempt nonhuman primates from inclusion in deadly or painful experiments altogether as long as all human beings are similarly exempted.

It would be surprising if the moral assumptions underlying the Animal Rule could be rejected so easily, even given that we have initially assumed at least some moral standing for nonhuman primates. Further, some may be concerned that the logic of the moral individualist position is too radical in terms of its practical consequences for nonhuman primate use. What routes are left open, then, to justify the Animal Rule? One possibility is to argue that nonhuman animals have some moral standing, just not as much as humans. Another, more promising, route is to specifically reject some of the assumptions of moral individualism. Whichever of these routes is taken, problems remain for the Animal Rule.

Nonhuman Primate Partial Moral Standing

Suppose we claim that moral standing graduates along a hierarchical scale analogous to a “great chain of being,” with nonhuman primates next down the line from humans. Perhaps not surprisingly, given the deep roots of the idea of a divinely ordained hierarchy of nature in Western thought, this might be considered a popular view of animal moral standing. There are some aspects of the U.S. regulatory structure guiding research on animals that could indicate support for this kind of view. For example, in 1985, the Animal Welfare Act (AWA) added requirements that the psychological welfare of nonhuman primates must be given special consideration (Food Security Act 1985, sec. 1752[a]; Animal Welfare Act 1966). And in 1997, members of the National Research Council’s Committee on Long-Term Care of Chimpanzees concluded that chimpanzees should not be killed for population control purposes (Degrazia 1999, p. 28).

In some other countries, the idea that nonhuman primates have special, though it seems not full, moral standing is even more pronounced. Citing the fact that “the use of non-human primates is of the highest concern to the public” (2008, article 16, p. 15), the European Commission recently called for the use of nonhuman primates in research to be limited to essential biomedical areas for the benefit of human beings for which no other replacement alternative methods are yet available and only in cases
where the procedures are carried out in relation to clinical conditions having a substantial impact on patients’ day-to-day functioning as being either life-threatening or debilitating, or for the preservation of the respective non-human primate species. (2008, article 16, p. 15)

Although in its May 2009 vote on the commission’s report, the European Parliament rejected the position of the commission on nonhuman primates in general, it did agree to restrictions on the use of great apes (UK Office of the European Parliament 2009). Since no great apes are currently used in biomedical research in the EU (Vogel 2008), this agreement with the commission seems more symbolic than substantive. However, it also clearly mirrors the idea that among nonhuman primates, great apes may be perceived as having the highest moral standing.

If one takes this hierarchy approach to moral standing, two problems remain for justifying the use of nonhuman primates in keeping with the Animal Rule. First, the most plausible reason for supporting such a view would be that morally relevant characteristics of animals also generally are associated with a hierarchy of biological complexity, but if that is so, we are once again faced with the question of why individual nonhuman primates with the same morally relevant capacities as some individual humans should be subjected to treatment that is morally impermissible for these humans.14

Second, and more significant for the Animal Rule, if nonhuman primates have lower moral standing than humans but are still relatively high up—indeed, just next to humans—then what treatment of them is justified? Since the use of animals under the Animal Rule is promoted specifically when it would be unethical to use human subjects because of the extent of the foreseeable harm to them (harm so great that it would be wrong to cause it even with their voluntary and informed consent), and since the use of animals in these contexts is not tempered by any special requirements in the U.S. regulatory scheme (such as the need to show countervailing benefits to humans), it is hard to imagine the practical usefulness of any level of moral standing other than “full” in this context.15 Since moral standing that provides no grounds for practical protection is meaningless, the very notion that nonhuman primates might have some lesser moral standing under the Animal Rule self-destructs.16

Rejecting Moral Individualism?

Having eliminated the notion of partial nonhuman primate moral standing as a possible justification for the Animal Rule, we focus on views
of moral standing that specifically reject moral individualism. This rejection can take two forms: an emphasis on group, rather than individual, characteristics or a denial of the tie between moral standing and certain intrinsic properties.

An emphasis on group, rather than individual, characteristics may proceed by way of simply ignoring the core point of moral individualism and instead stressing capacities either generally shared or normative for a particular species or type of animal. For example, in a recent discussion of the moral argument for performing stroke research on monkeys, Michael Sughrue and colleagues focus on general intelligence distinctions between great apes and humans and between monkeys and great apes, claiming that “with regards to more complex thought processes, such as possessing the insight needed to understand the significance of having a neurological disorder or the nature of their confinement, current thinking suggests that it is unlikely that apes think in this manner, and almost impossible that monkeys do” (2008, p. 6).

Whatever one thinks about this particular summary of the myriad of studies on the relative intellectual capacities of primates, the point that there are significant species-typical distinctions in capacity between humans, monkeys, and great apes is well taken. Still, these general distinctions do not speak to the question of individual primate comparisons. For a moral individualist, the question of permissible research on any particular subject must address the relevant capacities of that subject (not of typical members of a species or other group). Thus, if an inability to understand the significance of having a neurological disorder provides a moral reason for using an individual in stroke research, on the moral individualist position it provides such a reason with respect to any individual lacking such capacities, regardless of species or other group membership.

Hence, in order to undermine the position of moral individualism, an explicit claim must be made: regardless of overlap in individual capacities, we are justified in treating nonhuman animals in ways that it is morally impermissible to treat humans, because the proper yardstick is not the individual but the group. Broadly speaking, it could be said that authors supporting this position reject moral individualism by explicitly embracing a form of “speciesism.” For example, in a widely reprinted defense of the use of animals in biomedical research, Carl Cohen writes that “persons who are unable, because of some disability, to perform the full moral functions natural to human beings are certainly not for that reason ejected from the moral community. The issue is one of kind. Humans are of such a
kind that they may be the subject of experiments only with their voluntary consent” (1986, p. 866). The problem with such a view, however, is that it is difficult to tell what the argument is supposed to be. Cohen asserts, but does not provide any particular reason for thinking, that humans as a group ought to be treated one way and animals another.

Still, it is important to be clear about the implications of this type of claim for the issue at hand, namely whether the Animal Rule can be justified if we assume nonhuman primate moral considerability. In this regard, it is important that the “group properties” claim we are considering here can take two forms. Both forms of the claim accept that moral standing is grounded in intrinsic properties and do not deny that we ought to extend moral standing to all individuals with the relevant properties. The protective form of the claim is simply that human beings as a group ought to be counted as having moral standing because the morally significant property at issue (whatever it is) is normative for them. Practically speaking, the protection of human beings generally against very painful or harmful research, which this view offers—and which we do not question—does not itself offer any justification for doing this research instead on nonhuman animals (and primates in particular).

The exclusionary form of the “group properties” claim starts from this protective position regarding human beings but goes farther by rejecting moral standing for nonhuman animals. Cohen holds a position like this, since he believes both that moral standing can be had only by beings with rights and that only moral agents have rights (1986, pp. 865–86). If we assume that no types of nonhuman animal are standardly also moral agents, then these claims, in combination with the claim that all human beings are rights holders, regardless of individual capacities for moral agency, does indeed lead to the position that we are justified in treating humans as a group in one way and animals in another. However, as already mentioned, the justification proceeds by rejecting the starting assumption of this section of the paper, namely that nonhuman primates have at least some moral standing.

Since the last part of the paper deals with the question whether the U.S. regulatory structure generally is consistent with granting nonhuman primates and other animals any moral standing, it is worth commenting here on the implications of a Cohen-type view for this broader discussion. As Cohen himself emphasizes (1986, p. 866), if we understand moral standing as being reserved for moral agents who are rights holders (although rights are nevertheless granted, under his view, at the group rather than
individual level), then a lack of moral standing does not imply a lack of all human obligations toward animals. For example, we may have a general duty to treat animals “humanely,” as well as contextually derived duties to particular animals—for example, obligations to promote the welfare of companion animals. Thus, whether or not animals have moral standing in the sense of being rights holders does not necessarily settle the question of whether the Animal Rule can be justified. After all, animals in these studies may suffer in ways that we cannot allow, whether or not they have a right not to be caused to suffer. Similarly, when one is in the position of researcher, one is responsible for the welfare of one’s animal subjects. There could be an unsustainable tension between carrying out this responsibility and causing the types of harm the Animal Rule permits.

At the same time, since moral standing under such a view is restricted to rights holders, none of these so-called obligations are moral obligations. This raises a crucial issue regarding the strength of an obligation to treat animals humanely and the like. In particular, we may wonder about situations in which a requirement for humane treatment conflicts with some other nonmoral end such as the advancement of science. As we highlight in the last part of the paper, the animal research regulatory scheme reflects precisely these sorts of tensions. It requires humane care and use in the absence of any clearer markers supporting the moral standing of animals.

On the one hand, then, we may question whether or not a Cohen-type view would necessarily support the use of nonhuman primates under the Animal Rule. On the other hand, if such a view did support the use of nonhuman primates under the Animal Rule simply on the grounds that only moral agents (as rights possessors) are exempted from such studies, we might rightly become quite anxious about the supposed exemption of humans who are not (or not yet) moral agents. In particular, we may worry about the weight placed on a successful defense of the idea that properties normative for a group can protect all members of that group regardless of any given individual’s possession of such properties. Instead of an absent justification for the supposed protection of the many by the some, one would want iron-clad support of this claim.

Alternative Approaches to Moral Standing and Alternatives to Moral Standing

Another challenge to moral individualism rejects the idea that moral standing is determined solely or mainly by the intrinsic properties of individuals. Philosophically, this challenge is appealing for two reasons. First,
as already mentioned, supporters of the intrinsic properties view are often unclear about the specific connection between these properties and moral obligations that are presumed to flow from the identification of a being as having moral standing. Although it seems indisputable that a variety of properties, like the capacity to reason abstractly and to have complex emotional reactions, are important in determining what interests a being will have, the connection between these interests and the level or kind of attention we owe them is less clear. Second, as we have just been discussing, the intrinsic properties view of moral standing seems inadequate for explaining the level of consideration we think that we owe other humans, let alone what we owe nonhuman animals.

So what are the alternative ways that we might think about moral standing? In particular, could these alternative hypotheses help to support the moral implications of the Animal Rule for nonhuman primate moral standing? We might think that the level of moral consideration we owe one another is rooted in the various kinds of relationships we have with one another. For example, beyond the specific role-related obligations and duties that parents have toward their own children, children may literally have moral standing for their parents because of their parents’ relationship with them. With respect to nonhuman animals, a relationship-based view of moral standing would suggest that our relationships with companion animals, for example, could themselves give them moral standing.

However appealing such a view may be in helping to ground the moral standing of those we care deeply about but who otherwise may appear “liminal” under the intrinsic properties view, it is implausible that relationships could be the sole source of moral standing. Under such a view, the moral standing of each being in a relationship depends on that very relationship. Thus, it is hard to see how such a view could support any individual’s moral standing generally (i.e., outside of the relationship). The more plausible view would be that some individuals have moral standing based on intrinsic properties and others can be granted moral standing on the basis of their relationship to those individuals. Such a model of moral standing, then, would depend on plural sources of moral value (intrinsic properties and relationships).

However, even on a pluralistic view of moral standing, we are left with the problem of how to generalize the moral standing that is relationship based. If the standing of your companion animal is based on a relationship to you, why should I grant it moral standing? Or if I attribute moral standing to inappropriate objects, individual blades of grass perhaps, is...
there any reason you should respect this? Nel Noddings’s care-based ethic may offer a response to these concerns. On her view, appropriate objects of care are those whose reality could be a possibility for us. She writes, “When we see the other’s reality as a possibility for us, we must act to eliminate the intolerable, to reduce the pain, to fill the need, to actualize the dream” (2003, p. 14). While Noddings argues that it is impossible to actually care for everyone and that obligations toward those further removed from our “inner circles” of care will be less strong (2003, pp. 16–18), our ethical obligation is still to respond, within the constraints imposed by our other obligations, whenever we are faced with a potential object of care. Noddings herself has a circumscribed view of our capacity to see animals’ reality as a possibility for us and of the capacity of animals to appropriately receive and respond to our care (2003, p. 150). Moreover, she does not represent her view as being one particularly about moral standing. Nevertheless, this type of view could support relationship-based moral standing by granting moral standing to beings we might possibly relate to in a caring way (whether or not we actually do so). Hence, as long as your companion animal is a possible object of care for me, it could have moral standing of a sort on this type of view. Noddings’s view also requires reciprocity in the caring relationship; those cared for must “signal in some way that the caring is received and recognized as caring” (2003, p. 42). Since blades of grass presumably cannot respond appropriately to my care, they would not have moral standing.

Despite the promise of this type of view, however, a problem remains. Although it is “relationship based” insofar as the emphasis in considering moral standing is put on caring relationships, it also implicitly relies on an intrinsic properties view of moral standing. The appropriate objects of care must be capable of responding to that care and must be those whose reality can be seen as a possibility for us. What it means to be a being whose reality may be a possibility for us presumably has something to do with the type of being one is. Likewise, being capable of responding appropriately to care is clearly a property of individuals.

Whether or not a philosophically sound view of relationships as a source of moral standing is available, we suggest that an underlying problem in the dominant strain of philosophical discussions of moral standing is less how we understand the appropriate sources of moral standing and more the assumption that once we have solved problems of relative moral standing, our moral obligations will also largely fall into place. Some obligations follow in straightforward fashion from specific types of moral
standing (for example, the obligation to avoid interference with a being’s negative rights follows straightforwardly from the designation of a being as having those rights), but in many other cases, obligations are highly dependent on social and personal context (including, but not limited to, being a party to a specific relationship), and here matters of general moral standing may be irrelevant or nearly so.

Does either the consideration of relationships as a potential source for moral standing or the concern about moving too quickly from considerations of moral standing to a presumption of settled obligations help to support the Animal Rule’s moral suppositions? We think not. First, if moral standing is itself at least partially dependent on relationships, then it is most plausible that nonhuman primates used in research have heightened moral standing as compared with similar animals in the wild.22 But what if we think about the relationships that researchers hold with animals not as sources of animal moral standing but rather as contextual factors that may determine what in particular is owed to the animals (i.e., as researcher to animal subject)? Of course we might question, on the basis of animal moral standing considerations, the justifiability of such a relationship in the first place. However, if we set these considerations aside, what are the implications for the Animal Rule? As responsible animal caretakers, animal researchers arguably still have heightened rather than diminished social and personal obligations with respect to the well-being of the animals in their studies. While these heightened responsibilities take place in a context in which animal research is itself assumed to be morally acceptable, we should be reminded that even a Cohen-type view of moral standing, which issues a blanket denial of moral standing for nonhuman primates, would not necessarily support the Animal Rule (though certainly it would make the task easier).

More importantly, however, we must recognize that the obligations to humans that the Animal Rule reflects (i.e., not to expose them to agents that may cause extreme suffering and death) are obligations that are not considered dependent on social and personal context in the first place. Since the same general kinds of actions (with the same general types of foreseeable harms) are done to nonhuman primates under the Animal Rule as those that are morally impermissible to do to any humans, unless we deny nonhuman primates moral standing altogether, there is no reasonable argument for supposing that obligations in the nonhuman primate case alone are determined by personal and social circumstances. While in neither case is it necessary to suppose that it is in fact the moral
standing of the beings in question that upholds the obligations (it could be, for example, the researchers’ requirement to act in accordance with virtue in both cases), only an ad hoc move, or the denial of moral standing in the nonhuman primates case alone, could support dependence of the obligation on social or personal context only in the nonhuman primate case. Thus, although we might argue more generally for the significance of ethical obligations in research that are not dependent on moral standing, invoking these only in the case of animal research begs the significant questions regarding moral standing that we must instead address.²³

The Animal Rule and Nonhuman Primate Relative Moral Standing: Conclusion

If we approach questions of relative moral standing using the perspective of moral individualism, the effective promotion of the use of nonhuman primates where human subject participation is morally impermissible is straightforward speciesism. Despite problems with justifying species-relative gradations of moral standing, even a discounted approach to nonhuman primate moral standing seems unable to support the Animal Rule. Either the extent of harm involved in these studies is too great to be morally permissible given the relatively high standing of nonhuman primates or else the very idea of partial moral standing self-destructs in this context because it has no clear practical moral use. Finally, there are good reasons to be suspicious both of some of the implications of moral individualism and of the tight connection that is often presumed between ascriptions of general moral standing and prescriptions of specific duties or obligations; even so, none of the alternatives or correctives arising from these concerns is clearly capable of salvaging the moral suppositions of the Animal Rule. Even if we agreed that either moral standing or specific moral obligations were founded largely on relationships, for example, rather than on intrinsic properties, this would raise a host of new questions about the moral tensions between the role of researcher as animal caretaker and as scientist as well as about the move away from considerations of moral standing in the nonhuman animal case alone.

THE U.S. REGULATORY STRUCTURE AND NONHUMAN PRIMATE AND OTHER ANIMAL MORAL CONSIDERABILITY

We have been assuming that nonhuman primates have at least some moral standing. We think this assumption relatively unremarkable. Yet given this assumption, we have been arguing that the position of the
Animal Rule regarding permissible use of nonhuman primates is unjustifiable. It might seem that this result is bad for the Animal Rule. Common assumptions regarding the moral standing of nonhuman primates aside, we might think there is a clear tension between the general regulatory structure guiding care and use of animals in the United States and the Animal Rule, since the point of the U.S. regulatory structure appears to be, in no small part, to protect animals’ interests as sentient beings with various levels of significant social, emotive, and cognitive capacities. Yet the regulatory structure itself is silent regarding animal moral standing.

In this part of the paper, we extrapolate the implications of the U.S. regulatory structure for the moral standing of nonhuman primates and other animals, particularly focusing on the question of whether animals are morally considerable under the regulations. Significant aspects of the regulations, and of animal research practices generally, imply that nonhuman primates and other animals have moral standing, but there are key features of the regulations that imply otherwise when we “operationalize” the idea of moral standing. We consider the possibility that the regulations instead imply certain obligations toward animals in absence of moral standing. However, as nonmoral obligations, these requirements may be subordinate to other similarly nonmoral objectives such as the needs of science. Furthermore, as we have already indicated, within a regulatory structure that generally assumes moral obligations toward humans, the shift to nonmoral obligation for animal research alone begs precisely the question at issue, namely, why nonhuman animals should lack moral standing. Finally, we offer a modest positive claim that the burden of proof is on those who would exclude nonhuman primates in particular from moral standing altogether.

In the United States, the care and use of animals in biomedical research is regulated by the AWA, administered by the Animal and Plant Health Inspection Service (APHIS) within the U.S. Department of Agriculture (USDA), and by the U.S. Public Health Services (PHS) Policy on Humane Care and Use of Laboratory Animals (in compliance with the Health Research Extension Act of 1985), implemented by the Office of Laboratory Animal Welfare (OLAW) under the National Institutes of Health (NIH). The PHS Policy on Human Care and Use includes the U.S. government Principles for the Utilization and Care of Vertebrate Animals Used in Testing, Research, and Training. Both the AWA and the PHS policy require oversight by institutional animal care and use committees (IACUCs).
Many features of both the U.S. regulatory structure guiding animal research, and of animal research practices generally, seem to imply that animals used in research have moral standing. For instance, the AWA (7 USC 2131) requires “that animals intended for use in research facilities” be “provided humane care and treatment” (7 USC 2131). “Humane” is not defined in the legislation or implementing regulations, and a general obligation to treat animals humanely may be consistent with denying them moral standing. However, we think that, on its face, the assumption that animal welfare is to be promoted and harm minimized for the sake of the animals themselves appears as the most plausible interpretation, not only of the general ethos of responsible conduct of research with animals, but also of many of the particular requirements guiding animal research. Examples include the requirements to minimize pain wherever feasible, reduce numbers of animals used to those necessary for the research, and kill animals painlessly. Indeed, the very term “sacrifice,” used by animal research scientists to describe the killing of animal subjects, implies that animals are themselves morally valuable. Additional requirements implying an assumption of moral standing apply only to nonhuman primates: the ban on killing chimpanzees for population control purposes and the AWA’s requirement that researchers attend to the psychological welfare of nonhuman primates. Finally, there are requirements of “thorough” justification for the use not only of nonhuman primates but also of dogs and cats as animal models (NIH OLAW 2009, p. 4).

Yet there are two features of the U.S. regulatory structure and guidelines in particular that, taken together, imply instead that nonhuman primates and other animals used in research are not morally considerable. The first feature is a lack of any principled moral limitation on permissible animal use with respect to core harms such as pain and suffering. The second feature is a lack of any robust requirement to balance animal harms in research against probable human benefit. While either a limit to permissible harms or a requirement to balance harms and benefits would arguably be a way to give practical credence to (i.e., make operational) the view that animals themselves are morally considerable, a lack of either commitment undermines the idea that the dedication to animal welfare apparent in the regulatory structure is based on the moral value of the animal research subjects. In what follows, we consider each point in more detail.
Moral Standing and Limits on Permissible Pain and Suffering

Since an individual with moral standing must have its interests, needs, and/or well-being taken into account, providing an upper limit on the extent to which these may be undermined (in the case of interests and well-being) or not responded to (in the case of needs) seems to be one obvious way to respect that standing. It is important in this regard that the U.S. regulations do restrict animal use in a large array of circumstances in order to limit animal pain and suffering. For example, the regulations implementing the AWA call for the establishment of institutional animal care and use committees (IACUCs), which are analogous to the institutional review boards (IRBs) established by the federal Common Rule for the protection of human subjects in research (HHS 1991). IACUCs are required by regulation to review activities related to the care and use of animals and ensure, among other things, that “procedures involving animals will avoid or minimize discomfort, distress, and pain to the animals,” that “procedures that may cause more than momentary or slight pain or distress to the animals” will “not include the use of paralytics without anesthesia” and that animals must be euthanized after experimental use if they would otherwise experience “severe or chronic pain or distress” (USDA 2009, 9 CFR 2, subpart C, 2.31[d][1][i, iv, v]). Principles 4–7 of the guidelines for the care and use of vertebrate animals in testing specify further that animals should be assumed to experience pain where human pain would be probable and require that researchers aim to minimize the pain experienced by animals and painlessly kill animals when pain cannot be minimized (NIH OLAW 2002).

Yet, despite these and other important regulations and guidelines aiming to minimize animal pain and distress, it is highly morally significant that there is no limit to permissible pain and suffering where these are either necessary to the scientific research itself (e.g., in studies of pain or suffering/distress) or a necessary product of interventions or protocols critical to the scientific research (e.g., in vaccine or therapeutic studies involving lethal agents, such as in biodefense research). IACUC review must either ensure that appropriate analgesics are employed when procedures cause more than minimal pain or else approve a scientific justification for withholding such pain relief (USDA 2009, 9 CFR 2, subpart C, sec. 2.31[d][iv][A]; Karas and Silverman 2006, p. 244). Alternative methods to those causing more than momentary pain or distress must be considered and a scientific justification for the failure to use alternatives must be given (USDA 2009, 9 CFR 2, subpart C, 2.31(d)[ii]Karas and Silverman 2006,
Animal researchers are required by the AWA regulations to include in their proposals “a description of procedures designed to assure that discomfort and pain to animals will be limited to that which is unavoidable for the conduct of scientifically valuable research” (USDA 2009, 9 CFR 2, subpart C, 2.31[e][4])—a standard that by its own terms subordinates animal welfare to scientific value. Since we do not ordinarily think of scientific progress as trumping moral requirements, such as the requirement to protect research subjects, it is fair to say that the current U.S. regulations place no principled moral limit on permissible animal pain and suffering.26

The U.S. regulatory position on pain and suffering (or distress) may be contrasted in this regard with potential regulatory shifts in the European Union. In its November 2008 proposal, along with the limitations on nonhuman primate use it put forth, the European Commission also called for an upper limit to allowable animal pain and distress (European Commission 2008, article 22, p. 16). While the European Parliament rejected the limitations on the use of nonhuman primates, except for great apes, it has accepted setting an upper limit on pain and distress for animals used in research generally (Humane Society International 2009).

Moral Standing and Benefit-Harm Trade-offs

Many will think that recognizing the moral standing of another being necessarily requires placing an upper limit on the pain and/or suffering that it is permissible to knowingly inflict or cause to be inflicted (at least nonconsensually) on that being. Others will argue that what is crucial for moral standing is not necessarily that individuals are protected against extreme harms but rather that harms to some individuals’ interests or well-being are appropriately offset by benefits to others. In some rare circumstances, it may be argued, such careful balancing of harms and benefits may even allow extreme harms to be inflicted on, or allowed to befall, a limited number of individuals with moral standing. In both domestic and international policy and regulatory statements, broad appeal to human (and sometimes animal) benefit appears to be offered as a justification for undertaking biomedical research on animals.27 Thus, perhaps, the U.S. regulatory structure could support granting animals some moral standing while still justifying some quite extreme setbacks to their interests.

Interestingly, however, the U.S. regulations guiding animal care and use in research offer no clear guidance regarding specific permissible trade-offs between animal harm and sought-after human benefit. Indeed, there
is no definite requirement to balance proposed human benefit against animal harm at all. While principle 2 of the guidelines pertaining to care and use of vertebrate animals in testing states that “procedures involving animals should be designed and performed with due consideration of their scientific relevance to human or animal health, the advancement of knowledge, or the good of society” (NIH OLAW 2002), this is a far cry from a requirement to compare any specific animal harms with sought-after human benefits. In principle, though not necessarily in practice, “due consideration” of “scientific relevance” with respect to benefits so broad as “knowledge, or the good of society” could be thought to justify even the most serious harm to animals for the most minor or improbable of human benefits. Furthermore, IACUCs are expressly prohibited from prescribing methods or setting research standards in any manner that is not specifically authorized by the regulatory structure (USDA 2009, 9 CFR 2, subpart C, 2.31[a]). Thus, they may not impose a different, more substantive, requirement for balancing animal harm and human benefit.

By contrast, comparing animal harm and sought-after human benefit is part of many European countries’ research review processes, though how these comparisons function in practice is not clear (FELASA 2007, p. 41). And in significant contrast, U.S. human subjects research regulations require the balancing of risks of harm to subjects against potential benefits to society—even though little guidance is provided as to how to accomplish this: “The IRB shall determine that . . . [r]isks to subjects are minimized” and “are reasonable in relation to anticipated benefits, if any, to subjects, and the importance of the knowledge that may reasonably be expected to result” (HHS 2005, 45 CFR 46, subpart A, 111(a)[1, 2]). Moreover, foundational guidance documents for the ethical conduct of research with human subjects, both domestic (such as the Belmont Report) and international (such as the Declaration of Helsinki), emphasize the importance (as well as the difficulty) of assessing risks of harm to subjects and balancing those risks of harm against benefits to society. Although it is true that history amply demonstrates how often this balancing has failed in practice, it is nonetheless also true that IRBs are specifically directed to attempt it, whereas IACUCs are not.

Thus it is apparent that the U.S. regulatory structure for animal care and use offers only a vague appeal to human benefit as a potential justification for animal use in biomedical research and no requirement to balance specific animal harms and potential human benefits. In addition, it places no upper limit to permissible pain and suffering where these are
necessary to specified scientific aims. However, it is reasonable to think that recognizing other beings’ moral standing requires placing a limit on what types of harms can be visited upon them (as specified in the Animal Rule regarding human subject use) or at least requires balancing harms to them against probable benefits to others (as called for in the U.S. regulations generally guiding human subject protection). Since the U.S. regulatory structure guiding animal care and use requires neither of these conditions on animal use, we must conclude that rather than being in unsustainable moral tension with the U.S. regulatory system more generally, the Animal Rule is the logical expression of the moral implications of the regulations, namely that nonhuman animals, including nonhuman primates, are not morally considerable. Instead, on this understanding of the regulatory structure, the obligations that researchers do have toward animal subjects would be nonmoral requirements of general humane treatment or specific obligations incurred through special relationships to them. Only under this kind of model could we say consistently that we are obligated to treat animals humanely but permitted to use them in any way necessary for the advancement of science.

Our task in this paper was to ask (1) whether the Animal Rule is justifiable if we make the relatively uncontroversial assumption that nonhuman primates have at least some moral standing and (2), given the negative answer to the first question, to consider what the implications of the regulatory structure more generally are for animal moral standing. We have argued thus far that the most coherent interpretation of the regulatory structure is that animals are not morally considerable but that certain nonmoral obligations toward them still hold. As we have discussed, this position—while coherent—both allows that other nonmoral objectives may, in certain circumstances, supersede the obligations to animal subjects and, moreover, begs precisely the question over animal moral standing that is at issue.

What should we make of this perhaps breathtaking conclusion that nonhuman animals, including primates, have no moral standing under the U.S. animal research regulatory structure? After all, we have not set out to fully tackle the complex philosophical question of whether animals do in fact have moral standing. Although we make no claim to a full argument for nonhuman primate moral considerability, we propose modest versions of two core claims discussed in the second part of this paper that we uphold, despite worries about the more robust versions of the claims and associated views on moral standing generally. In particular, a modest objection to
speciesism and a modest version of moral individualism together identify the burden of proof in this debate over moral community membership as belonging to those who would not include nonhuman primates. The modest objection to speciesism holds that it is unjustifiable to rule a being out of moral community membership on the basis of morally irrelevant factors and that species membership alone is a prima facie morally irrelevant factor. The modest version of moral individualism holds that, before ruling a being out of moral community membership, we ought to consider the morally relevant properties of individuals over and above group norms, noting that many nonhuman primates share cognitive, emotive, and social capacities that we recognize as at least sufficient for including humans in the moral community. We might add to these two claims a third, regarding moral risk, that we have not yet discussed. Specifically, if we think that failing to include members of the moral community as such is morally wrong, whereas inappropriately including some individuals as members of the moral community is only prudentially inconvenient, then, given a state of epistemic uncertainty regarding nonhuman primate moral community membership, we will want to err on the side of caution in drawing moral community boundaries.

These three claims together give powerful initial reasons to reject the idea that even those animals closest to us with respect to a host of complex emotive, intellectual, and social capacities could reasonably be denied all moral standing. While we have not ruled out as a conceptual possibility the idea that nonhuman primates might have some lesser moral standing than humans, we have shown that positing such lesser moral standing for nonhuman primates cannot help to justify the Animal Rule. Hence the Animal Rule is justifiable only if nonhuman primates have no moral standing, and we have argued that although this position is potentially compatible with the larger regulatory structure guiding animal research in the United States, it is a position that itself shoulders a burden of proof that has not been met.

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in those forums for helpful feedback. We are particularly grateful to Warren Whipple for editorial and research assistance.

NOTES

1. To give just a few examples: Project BioShield, signed into law in 2004, set aside $5.6 billion for the purchase and stockpiling of medical countermeasures and other biodefense efforts (U.S. Department of Health and Human Services, n.d.). NIAID oversees grants that support research focused on countering threats from bioterror agents and emerging infectious diseases at 10 regional centers of excellence (RCEs) (NIH NIAID 2008; NIH NIAID n.d.). Finally, according to a U.S. Government Accountability Office (GAO) report on high-containment biosafety laboratories, the number of the highest biosafety level (BSL 4) labs increased in the United States from a total of 5 before 2001 to a total of 15 either planned, built, or in the works by 2007 (2007). These labs contain the most dangerous pathogens and must meet very strict safety and security regulations, as well as facility structure requirements.

2. Nevertheless, history is replete with just such experiments, often state sponsored. Martin (2006) offers a brief summary. Edward Jenner, for example, tested the first successful smallpox vaccine for efficacy on an eight-year-old child (Selgelid 2003).

3. See also Jester et al. (2006).


5. We thank an anonymous reviewer for suggesting we discuss these issues and directing us to consideration of the specific resources mentioned in this context.

6. According to a 2004 review of studies published in 2001, nonhuman primate use is estimated at 100,000 to 200,000 animals worldwide, which is approximately 0.1 percent of animals used in experiments. Notably, however 50 percent of use was in the United States (Carlsson et al. 2004).

7. These forces are especially salient with respect to the use of great apes. A 2007 Science article notes that “fifteen years ago, the United States was one of a half-dozen countries that had captive chimpanzees available to biomedical researchers. Today it stands alone” (Cohen 2007, p. 450). However, even in the United States, a National Center for Research Resources moratorium on breeding federally supported chimpanzees, instituted temporarily in 1995, is now permanent (NIH, National Center for Research Resources, n.d.). Things
are somewhat more complex with regard to other primates. In specific cases, the use of primates has been restricted in the EU (see, e.g. Abbott 2008). See also the discussion in the second half of this paper regarding the European Commission’s 2008 proposed limits on both great ape and nonhuman primate research.


9. In 2007, the number of nonhuman primates used in “research, experiments, testing, and teaching” was reported by the USDA to be at 69,990 (U.S. Animal and Plant Health Inspection Service 2008, p. 13). In 2006, the number reported was 62,315 according to the American Society of Primatologists (2008). Because the 2007 USDA report is the first comprehensive report publicly issued since 2001, it is difficult to ascertain the precise rates of increase in use. However, the Humane Society of the United States reports a 29 percent increase between 2001 and 2007 (2009). How much of any increase in nonhuman primate use is due to biodefense/emerging infectious disease research is unclear.

10. Harry F. Harlow’s highly controversial psychological studies of maternal deprivation in infant rhesus macaques in the 1950s offers an especially poignant example of this tension in animal research: “The macaque infant differs from the human infant in that the monkey is more mature at birth and grows more rapidly; but the basic responses relating to affection, including nursing, contact, clinging, and even visual and auditory exploration, exhibit no fundamental differences in the two species. Even the development of perception, fear, frustration, and learning capability follows very similar sequences in rhesus monkeys and human children” (1958, p. 674). Harlow used macaques because of their psychological similarities to human infants, while much of the biodefense research relevant to the Animal Rule is focused on the physiologic and immunologic similarities of human and nonhuman primates. The features of nonhuman primates that Harlow was interested in studying thus themselves arguably implied the moral standing of the research subjects, whereas the rationale for nonhuman primate use in biodefense research does not rest on nonhuman primate features that are so clearly morally significant.

11. This distinction follows that made by Kenneth E. Goodpaster (1978).
12. For example, in aiming to justify their use of nonhuman primates for stroke research, Sughrue and colleagues (2009) address their argument to a principle of equal consideration of human and non-human primate interests (p. 4). Yet, as we discuss, they fail to consider that their argument applies equally well to some intellectually disabled human beings. Some animal ethics authors suggest that animal researchers may tend to disvalue animal moral standing because these researchers are willing, in certain contexts, to use animals in ways that conflict with their well-being. We think the picture is more complicated. Successful animal research with advanced species such as nonhuman primates is likely to entail developing relationships with individual animals and certainly necessitates a clear sense of the animals’ capacities. Relationships formed in research thus may lead researchers to attribute moral standing to the relevant individual animals and we discuss the potential connection between relationships and moral standing in what follows. In addition, knowledge of animal complexity and capacity may raise researchers estimation of moral standing for the animals generally. Finally, as we address in the last part of the paper, the general ethos of responsible conduct of research with animals foregrounds researcher responsibility for animal welfare, which translates easily, in the context of the meticulous animal care required to meet these expectations, to the inference that animals are themselves morally valuable.

13. As noted by an anonymous reviewer, James Rachels coined the term “moral individualism” in Created from Animals: The Moral Implications of Darwinism (1990, p. 5). More recently, Jeff McMahan (2005) has argued most specifically and thoroughly for this view; however, its basic tenets are arguably shared by many prominent philosophers writing about moral standing.

14. An example of such a scale of biological complexity with associations of increasingly heightened moral significance might progress from nociception, to pain sensations, to consciousness, to complex social interactions and expectations, to self-awareness, to rationality in ranking organisms.

15. A requirement to show countervailing human benefit would make controversial, for example, the fact that the Animal Rule may be used to seek approval for drugs and vaccines for pathogens, such as smallpox, currently causing no human mortality or morbidity.

16. More broadly, since we want to say that a moral obligation is a very serious sort of obligation, problems of practical application may raise concerns about the very idea of partial moral standing. Other authors have argued explicitly against the notion of degrees of moral standing (see, e.g., Harman 2003). In contrast, David DeGrazia has argued explicitly for the possibility of unequal moral standing (see especially DeGrazia 1993); however in his construction “moral standing” is a way of summarizing salient moral differences between
animals and humans that he takes to be compatible with equal consideration of relevantly similar human and animal interests (1993, p. 28). In this paper we do not aim to resolve the general question of whether animals might have some “discounted” moral standing relative to humans.

17. Mary Anne Warren discusses variants of this kind of view in some detail (2000, pp. 122–47).


19. Elizabeth Harman argues specifically that attribution of moral standing cannot itself endow moral standing, despite the fact that it often seems to do this work. Her claim is that there is no principled way of making the distinction between cases where attribution does seem to be a reason to endow an object with moral standing and cases where it does not, and that it is “deeply controversial” to claim that it always so endows (2007, p. 63).

20. Warren (2000, pp. 137–47) interprets Noddings as offering a perspective on moral status, but Noddings’s focus on descriptive aspects of caring relationships and her concern about reliance on moral principles and rules generally may be in some tension with Warren’s interpretation.

21. This point is inspired by Elizabeth Anderson’s (2004) work.

22. While one could argue that the relationship of research animal to researcher itself could lower the moral standing of an animal, we are at a loss as to how this claim might be philosophically (as opposed to pragmatically) justified.

23. It is important to be clear that our argument in this section of the paper is not that all research conducted using nonhuman primates with the aim of eventual approval of medical countermeasures through the Animal Rule is unjustified. Rather, it is that the moral assumptions of the Animal Rule itself are not justified once we assume that nonhuman primates have some moral standing.

24. Some might prefer the term “distress,” but we think the term “suffering” is more fitting given the cognitive capacities of nonhuman primates in general and some of the more extreme types of harms at issue in this paper. “Distress” is used in the regulatory framework, so we also use this term in the context of describing the regulatory framework.

25. These features track, respectively, what would be needed under a rights- or utility-based framework in reflecting moral standing for animals. However, we do not think it necessary to invoke these broader philosophical frameworks in making our point and worry that doing so might be distracting.

26. While the AWA requirements we have mentioned regarding euthanizing animals and prohibiting paralytics without anesthesia are not similarly qualified by any consideration of scientific justification, it is fair to assume that there could be no scientific need for failing to comply with either of these requirements.
27. See, for example, the introduction and preamble to Council for International Organizations of Medical Sciences international guiding principles for biomedical research involving animals (1985), the *Guide for the Care and Use of Laboratory Animals* (Institute of Laboratory Animal Resources 1996, p. 1), and the U.S. Government Principles for the Utilization and Care of Vertebrate Animals Used in Testing, Research, and Training (NIH OLAW, 2002). Sometimes appeal is also made to the potential for animal benefit.

28. Still, it is worth recalling that philosophical positions denying animals any moral standing have been repeatedly critiqued on those grounds in particular. A standard interpretation of Kant’s view, as expressed, for example, in his *Lectures on Ethics* (2001, 27:710), is that nonrational animals have no moral standing. This has been a sticking point for many who admire Kant’s normative moral theory. For a nuanced interpretation of Kant’s view on animals and nature in general see Wood (1998). A version of the view that animals have no moral standing is also supported by Carruthers (1992). David DeGrazia offers a neat summary of various philosophical views (including Carruthers’s view) challenging the idea of equal consideration of animal interests (1996, pp. 53–74).

29. In particular, worries about the treatment of intrinsic properties as the sole source of moral standing and the assumption that moral standing determination resolves more about moral obligation than we think may be warranted.

30. It is worth noting that our claim here is exceedingly minimal. To contrast, DeGrazia (1996, pp. 49–53) argues quite convincingly for a much stronger claim, namely that the presumption should be in favor of equal consideration of relevantly similar animal interests.

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Submissions should be 8000 words or less, and prepared for blind review. All submissions should be received by November 1, 2011, and submitted via e-mail to both rkukla@gmail.com and kiejournal@georgetown.edu, with the subject heading, “Submission for Special Issue on Science, Expertise, and Democracy.”

We think this will be an excellent issue and we very much hope you decide to submit your paper!

Special Issue Coeditors
Kevin Elliott
Rebecca Kukla
Justin Weinberg
Narrative Inquiry in Bioethics (NIB) provides a forum for exploring current issues in bioethics through the publication and analysis of personal stories, qualitative and mixed-methods research articles, and case studies. Articles may address the experiences of patients and research participants, as well as health care workers and researchers. NIB is dedicated to fostering a deeper understanding of bioethical issues by engaging rich descriptions of complex human experiences. While NIB upholds appropriate standards for narrative inquiry and qualitative research, it seeks to publish articles that will appeal to a broad readership of health care providers and researchers, bioethicists, sociologists, policy makers, and others.

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