

THE LEGAL FRAMEWORK OF ANIMAL TESTING: CHALLENGES AND OPPORTUNITIES

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It's a delight to be here. I'm pleased to be talking to you about these difficult and important topics. I'm a lawyer and I'm going to be talking about animal testing, which means I need to grapple with the science, so I'll be talking about science from a legal perspective. I've had to go back and think about science—stuff I didn't pay too much attention to in college and before that—but I've learned a lot, and hopefully, I'll be able to translate the science for you as I've done for myself. I'm going to talk about how we got to where we are; where we are; science from the legal perspective; the legal framework; blending the law, the science, and ethics; and what's being done about that right now from a structural perspective. I'm going to be talking about the framework, so that hopefully, you will be informed about where we are, what structurally is problematic, how we can fix it, and where we can go.

So first question: Ethically, why should we care? Dr. Pippin just gave us many good reasons why we should care about this topic, because what we have is not working. We rely on animal testing to figure out whether our food, our drugs, our household products, and things we put in the environment are safe; and if it's not working, that's pretty important for us to know. Obviously, it's pretty important for animals as well. We're requiring an enormous nonconsensual sacrifice of hundreds of millions of animals each year. It's very difficult to get estimates on how many animals are used, but estimates range from what I consider conservative numbers to over a hundred million and even up to two hundred million animals used a

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year. Although you see a lot of different numbers, what you often see is that one million are used each year. That number relates to the animals that are covered by the AWA (Animal Welfare Act) used in federally funded research. So remember, that's only perhaps about two to five percent of all the animals being used. Also remember that that number does not include invertebrates, insects, or fish. People count those numbers very, very differently and it's hard to get a very good count. This enormous sacrifice needs to be taken into account, and we have to assume there's no reason to do it unless it's working. If it's not working, we need to stop. That's an ethical imperative.

So where did we start with this? We've been looking at animals since the second century when we started looking at animals scientifically for anatomy, physiology, and biology to try to figure out how structures work. We didn't really start using them as a proxy for humans until the early 1900s. We started testing industrial chemicals on animals in the U.S. in the early 1900s, and one of the things that's useful to know is why we do this and how, legally, we got to the point of using animals for testing. There was a cosmetic called Lash Lure, and women were going blind and a woman died because of the ingredients in these cosmetics. Now, we had used arsenic and other kinds of ingredients in cosmetics for centuries, but we started to do that industrially and people were being significantly harmed. So there was an outcry.

We talked about the tipping point early this morning. There was an outcry. How can we be marketing these kinds of things when they're unsafe and disproportionately harmful—mascara causing death? Not a risk you're willing to take. Beauty is not really worth the risk of death, right? That's when we began requiring testing on animals. And at the time, the scientists said to the legislature, "We don't know how to do this. We don't have tests in place that can help us figure out the safety and the efficacy of these ingredients in these products. All we have right now is some kind of rough approximation. So understand that this is not the gold standard and understand that it needs to change and improve." What did we do as a country, instead? We just said, "Okay we've got the model. We understand the scientists said we can use it. We're going to plug that into the regulation, and we're going to require everyone to use this testing." And it became the default. I'll come back to that in minute.

During the 1950s, we moved into a place where we had achieved better living through chemistry. We thought we could solve all problems and develop better products through chemistry, and animals were relegated to a part of that system. The idea behind animal testing is that animals are sufficiently close to us biologically that the results from testing on them are going to tell us something useful. Somewhat ironically, we now understand

this premise is not actually true. But all animal testing is predicated on that notion—that they’re close enough to us biologically that we’re going to learn something useful—but the ethical implications are really striking. They’re not close enough to us to warrant taking their lives into account. How can we hold those two concepts in our minds at the same time? This is a really interesting and important question. They’re either like us or they’re not. If they’re enough like us that we can test on them, it seems like they should also be enough like us that they deserve some significant protection.

Why do we do this? Obviously, safety is our goal, and there are some benefits to testing. Please don’t confuse what we’re saying here—we’re not against testing. Testing is really important. Product testing is very important. The question is not whether we test. The question is how we test. It appears the total societal consensus about testing is that we should test, so it’s really just a question about how we do it. We understand what the benefits can be, but we don’t fully understand the risks, although Dr. Pippin’s talk helped us understand more about the risks of testing. One of the risks that sometimes is not articulated is the value of the animals’ lives themselves, and that ends up being important for our conversation today.

One of the things that I’ll talk about, and on which much of my study about animal testing focuses, is the toxicity context. I will say in advance that toxicity is slightly different in each context, *in vivo* or *in vitro*. *In vivo* is in the body. *In vitro* is what we’re talking about moving to. From my perspective—a nonscientific perspective—*in vivo* is based on a Cartesian concept. We remember Descartes, right? In addition to some of the positive things he gave us, he gave us this idea that animals were these instruments that you could literally take apart and if there was some vocalization that was just how the instrument worked. There was no corresponding feeling of pain in the way that we understand. Therefore, there was no duty to avoid the pain. We could dissect them and it wasn’t a problem. Thus, we also have the opportunity to use them as a benefit for science. So that’s what the *in vivo* concept is based on, and I’m suggesting, along with other scientists, that we move on to this *in vitro* concept. It’s more of a Darwinian concept. Darwin did not separate the humans here and the animals there. It’s not as if we won the lottery on this evolutionary tree, “Yeah, we’re the humans, we’re on top.” It doesn’t work like that. We’re part of this structure of biology, and we’re interrelated. We’re all part of a biological family. There are distant cousins and close cousins, but we’re all biological beings. We’re all animals, and if we can stop and realize we’re all animals, that reframes the question for us. We need to figure out how to move from this *in vivo* model to an *in vitro* model.

Our goal is to reduce the overall number of animals used for testing. In the meantime, because these animal tests are considered the gold standard

within the scientific community—it's what we've been doing for decades—we are measuring any new scientific protocol against the current standard. Understand, we're taking a flawed standard and comparing new potential protocols against it by asking, "Does this give us at least as good or better results as the current standard?" What a confused mess, right? Who knows whether we're going to the right protocols?

The good news is that we do have new protocols coming up. We have computational biology, omics, and all kinds of things that I can't even begin to understand, but scientists have helped me understand that they're important and useful. These alternative methodologies use human tissue instead of mouse tissue—pretty simple, pretty straightforward.

In thinking about how we evaluate some of the scientific problems, consider the words of this postcard: "Science: if you don't make mistakes, you're doing it wrong. If you don't correct those mistakes, you're doing it really wrong. If you don't admit that you can be mistaken, you're not doing it all." That's kind of the framework I use when I think about this topic.

I want to elaborate a little bit on what Dr. Pippin said about some of the difficulties in using the bad science. Not only are we using these tests and then putting humans in harm's way, but there are other consequences. How many people in this room have dogs? How many people know that you don't feed chocolate to a dog? So we know that things that are bad for dogs aren't necessarily bad for people and vice versa. We also know that drugs that are tested on men aren't necessarily effective in women. As Dr. Pippin said, even among twins we don't have the same outcomes. Are we familiar with thalidomide? Thalidomide was a morning sickness drug that was developed, and successfully went through animal testing. The animals in this case were rats. Rats were resistant to the difficulties that Thalidomide presented in women; women were giving birth to children with severe birth defects. After the thalidomide problem, however, the response was not, "Maybe animal tests aren't working." The response was, "You have to do two sets of animal tests with different species." Well, that might work, but it doesn't always work.

Another thing that I found really interesting as a nonscientist was looking at how the scientists thought about these tests in the very beginning. How did they present them? It was fascinating to see that these tests were never scientifically validated. They just weren't. People said, "Well, let's try this." The scientific method would dictate that you try something, look at the outcome, see if it's predictive, replicate that, and then measure it. But we didn't do that with animal testing. When I say that to some of the scientists I encounter in my work, they say, "But it's been validated over fifty or sixty years." Well, it depends on which statistics you're looking at. Both the false positives and the false negatives are really important—saying

things are safe and putting it out there when it's not, and saying things are harmful that could actually be helpful and keeping them from the market. The failures are pretty stunning. Seventy percent of all ingredients in coffee fail animal toxicity tests. So you ought not to be drinking coffee. Penicillin is toxic to pigs and hamsters. Tylenol is fatal to rats. It's really sad because this is a huge economic waste. It's a huge waste in animal lives. It's a huge waste in human lives. And it really does, I think, indicate we're studying the wrong things or using the wrong methodologies, and we need to pay attention to that.

Scientists are beginning to talk about, write about, and acknowledge that animals are poor models for humans. One article I read acknowledged that mice really are the wrong model for cancer study, but then went on to conclude that we need to change the mice. We need to build better mice so they'll build better models. That was an interesting suggestion. Another article that I read made me much happier. This article from Europe said, "Based on empirical evidence and on well-established principles of evolutionary biology and complex systems, the animal model fails as a predictive modality for humans." This is mind-blowing and these are scientists saying this. These are not animal extremists. They are scientists.

One of the things that I find useful to remind people of is that some of the improved health outcomes and health benefits that we've experienced don't come from this work at all. They come from improved hygiene, sanitation, and employment conditions, as well as improved diet and lifestyle.

Another thing to point out is that it's not only the actual testing that's problematic for the animals in this situation. New York University is facing a lot of criticism because of the animals that died as a result of Sandy, the storm in New York. Some of them just drowned, and some of them were exposed to toxic fumes. Clearly there's a lot more to talk about when we discuss testing. So why am I, as a lawyer, talking so much about the science? Well, it's because the law doesn't know anything other than what it looks at. The law sits on top of other disciplines. It needs to look for evidence within a framework to decide what is appropriate in terms of regulation. In other words, the law defers to scientific experts. Going back to the statement that I made earlier—that we are trying to avoid unnecessary harm and suffering—that is a goal within the law that we adopted over a hundred years ago. It obviously doesn't apply in every context the way we'd like it to, but generically speaking, that is our goal—avoiding unnecessary harm and suffering.

How do we decide what is unnecessary? We look to the scientists. How do we decide what is harm and suffering? We look to scientists. And so, as Professor Cassuto said, scientists are now beginning to explore what

harm and suffering are. And recall that we're talking about people who, at one time, did not think fish could feel pain. They bleed, and yet we didn't think when you cut them open that it was painful. Now we're learning not just from what we think makes the most sense, but also from scientists. We're also learning about the suffering component, and not just physiologically. If you remove a young chimpanzee from his or her mother, there's a different kind of suffering there. And if the scientists are now recognizing it, then perhaps, legally speaking, that is a cognizable area of suffering. If we recognize that testing causes suffering, then we should be doing the analysis to decide whether it's necessary. Now that we have an expanded view of what can cause harm or suffering in animals, we need to pay close attention to that and to the fact that our view is still evolving. The scope of the problem is also quite huge, and it's difficult for the law to take that into account.

Hundreds of thousands of chemicals are in use in our environment without having been tested. Most people think we have the EPA (Environmental Protection Agency), the FDA (Food and Drug Administration), and the USDA (United States Department of Agriculture) testing everything, but that is incorrect. We have something called "TSCA" (Toxic Substance Control Act), which is a federal bill that, when it went into effect in the 70s, basically grandparented in all chemicals that were already in use at that time. We don't have an obligation to test any of those. Secondly, the act essentially states that the FDA will rely on what the industry says, unless you can prove that a chemical or chemical compound that's used in the environment is dangerous. Otherwise, the FDA and EPA aren't going to do anything about it. Thus, the default is that everything's safe, which is probably not how you thought regulation of chemicals worked in the U.S., right? But I'm happy to say people are working on TSCA reform.

The EPA has a backlog of 10,000 chemicals to be tested, and they can only test two to three a year. Why do they have a backlog of 10,000? I'll use an example. A simple two-generation toxicity test can take two years, use up to 2,600 rats, and costs just under half a million dollars. It takes a lot of time and a lot of money. They recognize that they're not going to be able to go through their backlog of 10,000. The TSCA registry has 86,000 chemicals on it and the REACH registry, which is in Europe, has somewhere between 60,000 to 75,000 chemicals on it.

Scientific methodology—when we do it right—can be very powerful. But one of the things we have to recognize is science is not neutral. Science is conducted by humans, and like any other field of human endeavor, it's affected by the biases that humans bring to it. I'll give you a couple of anecdotes that relate to the legal context. When women were pushing for

suffrage in this country, we had scientists explaining why that was a bad idea. I'll read you couple of quotes that I find entertaining. A nineteenth-century brain specialist, a Dr. Hammond, said, "A woman's brain involves emotion rather than intellect, and whilst this feature fits her admirably as a creature burdened with the preservation and happiness of the human species, it painfully disqualifies her for the sterner duties to be performed by the intellectual faculties." That's a brain specialist—a scientist—going on the record saying that that's how women's brains work. From the recent election, we have some other comments about women's physiology that I won't rehash, but this is not the only context. So this is when women were arguing, "We're legal persons" and some scientists were saying, "No, you can't be." Not that they were not, but that they couldn't be. This is an example of scientific sexism. There's also scientific racism. We had lots of people in the antebellum and postwar eras talking about the different natures of white and black people. There were five scientists in particular who aimed to scientifically prove that "Negroes" (using their words) were a human species different from the "white species," that the rulers of ancient Egypt weren't African, and that mixed-raced offspring tend to be physically weak and infertile. These were scientists. So we're all affected by the culture in which we live and grow up.

Think about that now in the context of animals. If there's scientific sexism and scientific racism, I would suggest that there is also scientific speciesism. We make assumptions about animals, and we don't even do the due diligence scientifically to answer simple biological questions about who they are as beings and how they relate to us as human beings legally. In addition to what Dr. Pippin said about the Animal Welfare Act, this is the main law. One thing that's really interesting to know is that there are tons of laws that relate to or affect the context of animal testing, but they don't regulate it. The other thing that's really interesting is that none of those statutes require animal testing, not one.

When I went into this focused research a little while ago, I got pretty nervous because I thought, "How are we going to statutorily protect animals?" As a question was posed earlier, "How do you weigh human interests against animal interests?" You're not going to win if you have to do this at the statutory level. There are no protections required for animal testing at the statutory level. There are in the regulations, and certainly in the guidelines, but none statutorily speaking. There are some other regulations that require additional protections above the Animal Welfare Act, but they're not enforceable at law so I'm not talking about them. We have these things that say you should do more than the Animal Welfare Act, but you can't sue on them so I don't really discuss them. The Animal Welfare Act exempts ninety-five to ninety-eight percent of all the animals

used for testing. All the invertebrates like birds, fish, reptiles, insects, and amphibians are not included. Note that we're only focusing on federally funded research facilities. We're only talking about the pain, housing, dietary provisions, and veterinary care of the small percentage of animals that are covered. And we're only talking about the minimal level required to care for these animals, and prohibitions against mistreating them or causing harm without analgesics. Anything that's prohibited can actually be allowed if it's required as part of the scientific protocol. So imagine for a minute, if your study is pain—What happens when someone feels pain? What are the physiological reactions? Then you may cause pain in the animal without analgesics because that's what you're studying. The law does not distinguish between types of experiments. Nor does it require a proof of benefit. It does not seek to reduce any replication that's unnecessary. It doesn't seek to ask whether the experiment is necessary. It doesn't require seeking alternatives. It doesn't require much protection, and as we know, it doesn't require protection for very many animals. So it's not a very helpful law.

Another question is—If we have all this failed science, shouldn't there be some human remedies? One would think so, but no. As long as the scientists, the pharmaceutical companies, and other companies follow whatever protocol is in place—if they follow the rules they've told the IACUC (Institutional Animal Care and Use Committee) they're going to follow—then even if the drug fails or causes harm, they are protected from liability, period. You can imagine that any kind of change in this regime that doesn't give this kind of protection to these companies is going to be met with significant resistance. There are a couple of things they want. They want intellectual property protection, and they want protection from liability. You can sue them, but the suit will likely be dismissed. So all the successful cases that you see, the ones that are not dismissed, like Fen-Phen, that's when they actually lie. That's when the company didn't follow the protocol or they lied about the results. As long as they follow the protocol, you have no remedy even if you are harmed.

One of the other fundamental problems about the Animal Welfare Act is that there's no citizen-suit provision. You heard this morning about environmental claims, and one of the reasons animal folks use environmental law is because you have citizen-suit provisions. You can actually sue somebody. You can get in there and have your argument heard in court. There's no citizen-suit provision to enforce the Animal Welfare Act.

So what does that mean? That means that we can make requests for records, and we can file complaints with the USDA that this lab or that lab is violating the law. And maybe they'll investigate, maybe they'll

eventually send a note or a letter, and maybe they'll fine them, but we can't directly sue them. There have been efforts to improve the regulation, and as was already discussed, those efforts have tended to backfire.

Rats and mice are warm-blooded animals and as such, should have been covered under the statute, but they were excluded by the Secretary of the USDA. In fact, they are, biologically, animals. Thus, they should be covered by the statute, but when challenged, the statute itself was changed to exclude them. How can we say, biologically, these groups of animals are not animals? It's stunning.

We can talk about the IACUC later, but we need to understand that what the AWA does is promote bad science. And it's doing it against society's interest and against animals' interests. The other thing that's important to note about the AWA, which is another reason I don't think it can be usefully amended, is that it was predicated on the proposition that we should be using animals in testing. So not only is it about testing animals, among other things, but it's predicated on the notion that testing animals is a fine thing. It's not even a question of how to change that paradigm. It's really only a question of how to refine it and do animal testing a little bit better.

With these difficulties presented in the law and in science, where else can we look for help? Moral philosophy is a place that the law sometimes looks to for direction. First is the Nuremberg Code, which was developed after World War II after horrific human experimentation. We came up with a protocol for obtaining informed consent concerning testing in the human context—that is, using humans as test subjects. Of course, part of that analysis concluded that we should be testing on animals rather than humans, given the atrocities that happened there. Then we have the Declaration of Helsinki, which gives us a little bit of framework for—again—regulating human test subjects. We also have something called the Five Freedoms, which was developed in the agriculture realm in England. I think this also supports, and is useful to, our conversation here. The Five Freedoms are freedom from hunger and thirst; from discomfort; freedom from pain, injury, or disease; the freedom to express normal behavior; and the freedom from fear and distress. These were freedoms that scientists in England thought were appropriate for us to consider for animals in the agricultural context, and I would suggest it's appropriate for us to consider them in the testing context as well.

We also develop our moral philosophy by lessons that we have learned over time from making mistakes. I'll relate to you one quick story. How many people are familiar with the Tuskegee syphilis experiments? They were pretty horrific. For those of you who aren't familiar with them, the U.S. Public Health Service experimented for over forty years on 399 mostly

illiterate black men. 128 died. These men had syphilis, and they weren't being treated because the researchers wanted to see how it affected their brains, which meant that they had to wait for them to die to autopsy their brains. In addition to 128 men dying, fifty-nine of the men's wives and children were infected because they didn't tell the men they had syphilis. They told them they had "bad blood" and told them that's what they were testing. So even after Penicillin was tested and determined to be effective in treating syphilis, none of them were given the treatment and they were kept from getting it elsewhere. This protocol ended in 1972, and even then, people didn't say this was a mistake. The reason it ended was that a journalist uncovered what was going on.

Thus, we learned more lessons about the need for voluntary and informed consent. Consent may be withheld. There's a duty on the doctor's part to ascertain consent and to explore alternatives. Research must also have a positive benefit unprocurable by other means and it must follow generally accepted scientific practices. In our context, that's not especially helpful. The research should avoid all unnecessary pain and suffering and the degree of risk should never exceed the importance of the problem to be solved. For example, it wouldn't make any sense if there's a risk of death for an allergy cure. These are the lessons we pulled from Tuskegee.

We also have something called the Three Rs principle, which blends the moral philosophies of law and science. Two researchers in England developed the principle of the Three Rs in the testing context. The three Rs are: first, replacement, which is seeking to eliminate the need for whole-animal experimentation. In other words, replacement means trying to find alternatives. The second is refinement, and that's to improve the design or efficiency of the experiment to eliminate or reduce the distress, discomfort, or pain experienced by the animal. Finally, there is reduction, which means to lower the number of animals that we use in each experiment and still have the same quality of scientific information. So we're trying to eliminate the need for experimentation, and when we have it, to reduce the animals' pain and suffering and to reduce the number of animals that are subjected to it.

Interestingly, this is a principle that's adopted and accepted around the world. As I've been studying and traveling, it's phenomenal to me that I talk to researchers in Brazil, I talk to them in Japan. I talk to them in Zurich, and in the U.S., and people know what this means. Scientists know what it means. The question is only how it is implemented. In the U.S., we don't really implement it. Because all we have for implementing legislation is the AWA. And even with the amendments to the AWA, we're only looking at refinement. We're only looking at reducing the pain and suffering, which is still a good thing because we didn't do that in the past.

But in the EU, they have a very different situation. The EU has something they call the European Center for the Validation of Alternative Methods, and that's all they do. We have one in the United States too. We are party to international cooperatives dedicated to seeking and developing alternative test methods. But in the EU, the Animal Welfare Protocol is adopted as part of the European Commission. It requires the EU and member states to attend to the welfare of animals when drawing up all kinds of policies.

The EU also has something called the REACH program, which deals with the registration, evaluation, authorization, and restriction of chemical substances. This is another thing that we have difficulty doing in the United States. We don't share information. The testing that goes on is proprietary. It doesn't really help a pharmaceutical company to share their information if someone's going to beat them to the punch development-wise based on their research and their investment. We've seen significant amounts of money—millions and millions of dollars—invested. We don't share it beforehand, we don't share it afterwards, and we don't even share it when we're talking about cosmetics. We just don't share information. The European Union decided that doesn't make any sense.

REACH is a registry where all the people who are producing chemicals have to register the kinds of chemicals they are using and it is put into a database. This database will be available to researchers around the world, and the idea is that we can learn a whole lot of information based on the testing others have already done. There's one estimate that the sharing done in the UK alone means that animal testing has dropped by half since 1970, just in England. This REACH protocol is very new. It was contested but it is proceeding. It is something for us to consider, but it would be very expensive. Sometimes I get excited about what's happening in Europe and say, "Let's do it like they're doing it." Then my scientist friends say, "Wait. Calm down. It's not perfect there either." So we have to see how it continues to go.

One estimate is that it will reduce the animals killed each year from forty-five million to eight to twelve million just by sharing information. This is not from stopping animal testing. This is just sharing information about what people are already doing. The EU also has the cosmetic ban. In 2004, they banned animal testing on finished cosmetic products where there were alternatives. Then in 2009, they stepped it up and said not just finished products, but products that have ingredients that have been tested on animals. Finally, by March of this coming year, 2013, it is supposed to be a total ban.

Now, the interesting thing is some of the scientists say, "We don't have enough alternatives that have been validated so that all these cosmetics

can be tested using alternative methodologies.” So this is going to be something for all of us to watch. What it means is that we have lots of cosmetics that can now be tested through alternatives and will be able to be sold through the EU. However, we have some that can’t be tested because we don’t have validated alternative models of testing.

The question is, is the EU going to say, “Well, let’s slow it down then. Let’s wait until we have all of these scientific alternatives available and validated.” Or are they just going to say, “It’s cosmetics. You can sell the ones that are tested appropriately, and you can’t sell the ones that aren’t.” I’m not a betting person. I don’t know how it’s going to go. My scientist friends don’t think the EU is going to hold the companies’ feet to the fire, and they’ll extend the ban. This is a really interesting paradigm-shifting kind of moment in the EU to see whether the principles of animal welfare they’re proposing are going to go much further than they are right now.

Now let me talk about some of the other things that are going on and explain how you can be thinking about this. We need to have all the stakeholders at the table. It used to be animal people talking to each other saying, “This is awful. Animal testing is awful.” Well, obviously, it’s awful. Great, that got us really far, right? What has changed is that the scientific community now says it’s possible to do things differently. As long as it is just the animal folks saying that this is bad, that’s never going to win the day as far as I can see. It hasn’t so far. But when the scientists say it doesn’t have to be either/or, instead we need better science and we can develop alternative science that also saves animals, then everybody should be happy. Thus, by having the scientists and animal advocates working together and talking to each other, things are moving much more quickly than they have in the past. But we also need consumers, we need the industry, we need the government, and we need the public health and environmental advocates involved.

I’ll just give a quick anecdote about why. We were thinking, “Public health people and environmental health people—we’re all together on this.” We want a safer, cleaner, and healthier environment for everybody, but the environmental and public health people basically said, “We really don’t agree with you. We want more animal testing.” Wait—what? This doesn’t make any sense. However, after stopping to talk to them, it made perfect sense. They’ve been pushing the government for decades to get rid of PCPs, Dioxins, and similar toxins, but the government says, “We can’t even prove it’s dangerous, so we’re not going to ban it. We’re not going to regulate it.” So they don’t want to have to argue about alternative tests. They want tests that are already accepted, they want these chemicals to be tested, and they want it to happen now. They don’t want to wait for alternative methodologies. So it makes sense. They’ve been struggling with that battle

for a very long time, but it puts us somewhat at odds. And so we do need to come to the same room and get to a common point.

Another good thing that happened is that when the EPA realized it wouldn't be able to go through its 10,000-chemical backlog with the current methodologies it had, the EPA went to the National Academy of Science and told them the EPA needed some help. The EPA asked them to study this and figure out what they needed to do. The National Academy of Science published a report in 2007. In it they concluded that the EPA needs to switch to *in vitro* testing, and that they could do it in twenty years. Note that this concerns toxicity testing, not all other fields of testing, but there's a lot of work being done as a result of this report to try to find, push for, and implement alternatives. So this provides some hope.

International harmonization is another focus that is hopeful. Because things are happening differently in Europe and because U.S. companies that sell cosmetics and pharmaceuticals want to participate in that market, it makes sense for them to meet the standards that are established in the EU. They want to be able to sell things in the U.S. and the EU, but they don't really like the idea of having to meet different standards. The idea of international harmonization suggests that the scientists of the world should get together and say, "Here's the standard. If you do this test and it passes, then it's safe." There really ought to be one safety test. After all, the biology is the same around the world.

The legal overlays are also important. Will the United States recognize a testing protocol that has been validated in the EU? Anyone want to guess what the answer is right now? The answer is no. Scientifically, we're working toward international harmonization, and even the industry is working on it because it's in their interest. And frankly, the individual entities are working on alternative tests as well because they're much faster, cheaper, and much more predictive. But we need the law to kick in and say these alternatives are good enough. We need to make these the gold standard. We need to say, "If you use these tests, then you get the intellectual property protection—to a lesser degree—and you get legal liability protection." But the government's not willing to do that yet. Why not? They say, "Well, we don't have enough data on these tests." We've asked the companies that are using the tests to share the data with the government, but they refuse to share it until they get the protection they seek. We go back to the government and say, "Well, they've got it. They want to share it. They just want the protection." But the government refuses to give the protection until it has the data. So we have still a lot of work to do.

We've got a few other things happening that make us hopeful. Dr. Pippin has mentioned a few. We've got the NIH (National Institute of

Health) suspending their funding of chimpanzee research right now. They haven't said they're done with it, period, but we're happy they're taking a pause. They're reassessing the information they have saying that chimpanzee research is not helpful. There are also efforts to permanently retire the chimpanzees that have been used in research.

Additionally, there's something called the Cambridge Declaration on Consciousness that just came out within the last couple of months. Although this hasn't really been picked up very much in the mainstream media, an international group of scientists have said that they support the idea that animals are conscious and aware to the same degree that humans are. I'm going to say that again. Animals are conscious. They have consciousness, and they are aware to the same degree as humans. Typically, we say, "Well, they don't feel pain the same way we do and they aren't self-aware." Scientists are now saying they are, and this includes all mammals, birds, and some cephalopods. This is pretty ground-breaking, and again, it has both legal and ethical implications. If this is true, and the scientists are now saying it is, then this should affect our legal analysis when we're talking about causing them harm and suffering, and determining what is necessary.

I already talked a little bit about TSCA reform. There are a lot of scientific methodologies being developed across various systems, and there's a lot more interdisciplinary conversation between scientists across jurisdictions—that is really promising. There are also more hopeful developments, including personalized medicine. Each person has his or her own DNA sequence, and the personalized medicine will be designed for that person's own DNA. So it will work for your specific genetic makeup. How brilliant is that? We're not yet at the point where this is affordable and available to everyone, but people are working on it, and that makes me hopeful.

We need to implement some changes. We need to insert an ethical conversation into our discussions on policy design. We need to include considerations of animal welfare. We need to think about economic viability for the industry. It needs to be manageable for regulators. We need to figure out our goals and determine if those goals can be met using good science rather than just animal testing. We need to move away from the Cartesian principle that we've been following. We also need to have a paradigm shift based on ethics and it needs to be empirical, but that is going to be difficult thing to do, both under the law and with science. We need to look at it after we've asked ourselves these ethical questions, and I think we'll get a lot farther than we have.

And so my suggestion is that we need to value animals for their intrinsic being, and acknowledge that they have intrinsic value and not just

instrumental value. This conception of animals is biological. They are part of our biological family and deserving of respect rather than treatment as property. They deserve protection.

I'll end with two quotes from George Bernard Shaw, who has a lot to say on ethics. He said, "If you cannot attain knowledge without torturing a dog, you must do without knowledge." And he said, "Vivisection is a social evil because if it advances human knowledge, it does so at the expense of human character."

Thank you.

