Animal Law Podcast: Transcript for Episode 92, Interview with Taimie Bryant

Mariann Sullivan: Welcome to the Animal Law Podcast, Taimie.

Taimie Bryant: Thank you. It's great to be here.

Mariann: It is such a pleasure to have you on. I've known you for a long time. You're such a gift to this movement, and now you get to be a gift to all of our listeners.

This is a little different because I don't often interview people about a law review article, but a lot of topics haven't yet been the subject of litigation that I can interview somebody about, and they're still really, really important. And I think many of our listeners are probably familiar, kind of, with this topic because of the controversy regarding the fact that Impossible Foods tested its products on animals, and people have different feelings about that. And this interview isn't about that particular situation, but the topic arose in many people's minds because of that situation.

And maybe, like me, they just had not thought, up until then, of animal testing as something that was done with foods. You think of pharmaceuticals and cosmetics and household products and plenty of dreadful things, but it seems kind of obvious when you think about it that if there's a new food, you would want to test it. When people want to test things, they tend to use animals.

So how did you come to be particularly interested in taking a deep dive into the legalities involved in this issue?

Taimie: Well, I think it was like other people's surprise, perhaps, to learn that Impossible Foods had tested one of its ingredients on animals.

There seemed to be not only controversy but a lack of clarity about whether that's required. So I began to look into that question, and when I discovered fairly early on that testing on animals is not required by the FDA, then I began

to wonder whether there was any other legal reason why an innovative company would test on animals.

I was also interested in this, not just because of Impossible Foods, but because I expect that there will be an increase in foods that contain bio-engineered ingredients. So I see it as something that is only going to increase and something that we may well want to see increase if it reduces reliance on farmed animals.

Mariann: That is something reading this article really brought home to me, the fact that this is not a simple case of what happened with Impossible.

We want there to be a lot of new foods. We want there to be replacements for a lot of foods that are out there right now, and so it's really important to be aware of what some of the obstacles are to getting those foods on the market.

And, as you said, you consider whether there's a legal reason to test on animals in this article, but also whether there's a marketing reason, which I think is another important question. You know, is it going to be easier for companies to sell these foods if they have tested them on animals?

You also consider if the answer to both of those questions is no, and I don't think I'm giving away secrets to say that's a possibility that's how this is going to come out, why is it going on, and why is it continuing? And why did Impossible Foods feel it was necessary to do this?

Let's start with legal requirements. A novel food ingredient. That seems to be the term at issue here. What is a novel food ingredient, and what are the FDA requirements for introducing a novel food ingredient?

It does make sense that the tests are required before something can be sold that hasn't been sold as food before. So what are those requirements?

Taimie: Well, my entry point into looking at this was to think about what is the legal definition of a food additive. And this is captured in 21 USC, section 321(s).

So it's a food additive if it's any substance the intended use of which results or may reasonably be expected to result, directly or indirectly, in its becoming a component or otherwise affecting the characteristics of any food. So this would include, Mariann, packaging chemicals, so it's an even broader scope than just what is actually in the food itself.

So a food additive is something that has not been found to be safe enough to be generally regarded as safe or GRAS. So let's say a company wants to market a food with a new ingredient in it, a new “food additive” under these terms, and it does the animal testing or non-animal testing necessary to ascertain its safety; then that food is not a food additive at all. It's GRAS; it's food. It can be marketed right away without any kind of FDA notification or approval.

On the other hand, if it's a color additive, then the FDA will do a review of what the company has done. And so the next set of questions would have to be for the company—Well, what constitutes the safety assessment that I need to do in order to be confident that my food ingredient is generally regarded as safe and not a food additive? What do I need to do? And for that, one doesn't turn to the FDA. The FDA could do the safety assessment, but the FDA delegates this or allows companies to decide how best to do the safety assessment, bearing in mind that the FDA requires it to be a scientific assessment.

Mariann: Yeah. And we'll get into what that means because that's a pretty obscure word, isn't it? Assessment. *both laugh*

Taimie: Right? It sure is.

Mariann: But this term GRAS, and I just want people to remember that it means generally regarded as safe, if we use the term GRAS, that's what we're referring to. I kept forgetting what it meant as I was reading this.

I found this all rather shocking, to tell you the truth! I'm all for them not doing animal testing, but it appears that it's kind of up to the company to decide most of this on its own. And their goals are, really, to get whatever their new thing is classified to their own satisfaction that it's GRAS, generally regarded as safe. Is that right?

And does it matter how the ingredient is going to be used? Is there any guidance for what kind of tests they have to use in different situations?

Taimie: Those are very good points. To start with your first one, I was surprised, too, at how companies are allowed to decide this question. Representative DeLauro introduced proposed legislation in 2021 that would place the responsibility on the FDA to do a pre-market review, whether the FDA does it as they're authorized to do or whether they at least review what companies do.

This is a proposal, but the FDA has experience with this kind of mandate because, in 1969, then-President Nixon required the FDA to do an analysis of all the ingredients and the additives, generally regarded as safe. The FDA was overwhelmed by that assessment responsibility, and it's unlikely that they would be able to take on something of that scope now.

So yes, it is companies that do that, and they do not have reporting requirements. However, if a problem does arise with food, then they're going to have to show the FDA, and probably others as well, what their safety testing consisted of, and the FDA does require it to be a scientific assessment. Now, if you just go back to the same scientists all the time and those scientists are the ones trained in doing animal testing, then you're going to end up with animal testing as your safety assessment protocol.

If you go to scientists who are looking at other ways of doing assessments, what they're going to do is then check with the guidelines that the FDA has, and these are published in what they call the Red Book, 2000. It was most recently updated in 2000. And the FDA is very clear that they are just guidelines, but as examples, they give a number of animal tests.

So it would make sense for the company and for the product safety assessment company to decide to use the tests that are provided as examples rather than branch out into some alternative test that would not likely be accepted. So there is this pressure, and there is just continuity of the habit of doing things in the old way, without many incentives to produce something new, a new kind of testing protocol.

And if it greatly extends your approval process with FDA because you're a company that really wants the FDA to give you a stamp of approval, then you really have to think seriously about whether you're going to lose any kind of market advantage. Whether the delay is going to be significant enough to be costly to you. So it's a business decision that these companies will make.

Mariann: Let's talk about the business a little bit, the business of doing this testing.

You point out that there are very big companies that may do testing, and they do their own testing, and they do their own evaluations, but most companies, especially startups, which aren't that big, use testing companies that their entire line of work is doing product safety testing. Can you tell us a little bit about those companies and who staffs them, and perhaps what some of their policies are regarding animal testing?

Taimie: Well, I think their policies are really driven by wanting to provide a product to their client, which is a company that wants to be comfortable that they have met FDA requirements. And so they want to be able to go to a company and say, "We've dealt with this situation before. Even though the FDA requires the test to be specific to the particular substance that we would be assessed, so we can't just pull one of our previous tests off the shelf and use that. We can easily tailor, based on the models that we have already for what we've done, and then come up with the testing design that meets your needs as well."

If, instead, the company says, "Well, wait a minute, we do want to market to people who care about whether the product they purchase has been tested on animals," then the product safety assessment company has a real incentive to look at alternatives.

Now, they might not have the expertise to do that, and they may not know where to get that expertise. In which case, then the company that's seeking this assistance is really going to have to think about where else they could go. And this is where an organization like PETA has been so helpful because they have something like 35 scientists who will work, not just with the company, to come up with testing protocols that will meet FDA requirements, but they do work with FDA representatives about the reliability of these tests. And then whoever does the testing then can have the assurance that this will work.

And FDA welcomes, they say they welcome, and I've been told they welcome, this pre-assessment process, iterative process, with the company. So it's possible to do it. It's just it can be more time-consuming, and so some companies may not want to do it for that reason.

Mariann: So a really important factor is whether a company has a lot of incentive to be able to advertise that it doesn't test its food on animals. I would think since even I never thought about the fact that companies tested food on animals, we need a lot more consumer awareness about this issue because it's not something that even enters people's minds when they are buying food products to check whether it's tested on animals, even if they're somebody who cares.

Now, these companies that do a lot of product testing, I assume, have animal labs. I mean that they do their animal testing in-house, and they maintain these labs. So that's another incentive for them to continue doing it in this way?

Taimie: Right. I think that's true. I think that's one of the really exciting opportunities of the FDA Modernization Act 2.0 because it provides for the use

of non-animal tests prior to human clinical trials of new pharmaceuticals. So the FDA has several different divisions, and the pharmaceutical division is separate from the food division.

However, when product safety assessment companies now have the knowledge, and companies now have the knowledge, that these other tests could satisfy the FDA in the pharmaceutical context, then we might see more of an awareness about the possibility of a testing alternative to animal testing in the food context.

Now, one opportunity is the idea that if alternative tests are developed, and they can be altered in ways that meet FDA requirements in different kinds of contexts, then the scientific community and the product safety assessment corporate community have incentives to develop these new ways of doing things, and it won't be such a burden for the company to ramp up.

Now another source of pressure is what you have mentioned a couple of times, which is consumer awareness. So when I first started looking at this, I began to wonder if consumers really care about this as much. Maybe they think that food is different. Maybe they think that the personal care items that they purchase, that they're careful are cruelty-free; maybe they think that, in some way or another, those products are different.

So Professor Adam Felts at the University of Oklahoma and I did a nationally representative survey of consumers and asked them about different burgers, some of which had been tested on animals and some of which had not. And asked them, also, if they went out of their way to get personal care items that hadn't been tested on animals.

And these consumers said…they were nationally representative, so we had only about 2% of them were vegan/vegetarian. But something like 74% of our respondents said that they care about this issue, and they care about it with food. They also care about knowing about it and labeling, and this is where consumer awareness can be really important because something like 67-68% of our respondents said that they were surprised that food ingredients are tested and that they are tested on animals specifically.

So, if one stops to think about it, I think one is less surprised, as you mentioned in the beginning when you said when you stopped to think about it, you thought, “Well, you know, it makes sense we have these new ingredients, it can confer a sense of safety in consuming it if it's been tested in some way.”

But these respondents in our survey said that it would be a hindrance to their willingness to purchase a product if they knew that it had been tested on animals. And that was true of whether it was the manufacturer or a supplier.

The opportunity is there for companies to advertise, to put it on their packaging that it's cruelty-free. The opportunity is there for organizations that regularly let people know what personal care items are cruelty-free for them to maintain lists of food companies that also don't test on animals. So letting consumers know, I think, is a really important piece of this.

Mariann: Yeah, I totally agree though I've always found it so perplexing how people who are not vegan or vegetarian, who don't really think about the problems involved in consuming the bodies of animals, might nevertheless be very concerned with products having been tested on animals. But I've consistently found, particularly with my students because that's a group of people whom I get to go into this and talk about things more deeply. And so many of them are horrified, more and more every year, that products are tested on animals and go out of their way to buy cruelty-free cosmetics and whatever, and are not vegan. And even though it perplexes me, we've got to go with the way people are; we don't necessarily understand it.

And if this is something that does have salience for consumers, it's certainly something we should be paying attention to. And I buy it. I think your survey makes total…it doesn't make sense to me, but it sounds totally right to me…that people could be persuaded to care about this if they ever thought about it. Which, you know, I didn't, so I don't blame them for not thinking about it as well.

It all seems very simple. You don't have to do animal tests; PETA will figure out what other tests you can do, and the FDA will work with it. So why did it go so wrong? I don't want to pile onto Impossible, but they are our example, and they are the thing that kind of brought this to mind. So let's talk about what went wrong there.

Tell us the situation about the testing that they did, why you think they did it, and what happened with the FDA once they did do it.

Taimie: You know, I very much agree with your idea that this isn't really about Impossible Foods and the Impossible Burger, although it really was my entry point, and it was convenient in the sense that the survey Adam and I did could focus on plant-based burgers with tested or not tested ingredients because 92% of our respondents eat burgers.

So it had a big impact, in terms of the educational value that could have occurred if Beyond Meat, for example, put on its packaging that it does not test on animals. I think one of the reasons that a company like Beyond Meat might not do that is that it can seem really gimmicky in an environment in which the consumer thinks, “Well, no food product is tested on animals. So that's just a cheap attempt to get me to buy the product.”

So consumers would need to know more about this. In Impossible's case, I really don't know exactly. They gave some reasons for why they did it that had to do with their marketing opportunities, and they maintained that the FDA did require this, and I don't really know where that came from, but they're not alone.

So one of the things that puzzled me was why consumer food safety organizations also would not be aware of this and the lesser reliability of animal testing. So if they care about consumer safety when it comes to food, they ought to be wanting the very best tests available. And a lot of those tests don't involve animals at all.

So the Center for Food Safety brought suit against the FDA for having approved Impossible Foods’ GE, genetically-engineered heme, the ingredient at issue, on the basis of the animal tests that Impossible Foods did, and argued that Impossible Foods should have done more animal testing than they did.

And this puzzles me because if they want safe foods, we should be looking at the best and most reliable tests, not more animal tests. So it is this lack of information on the part of these consumer protection organizations that also puzzles me. Now, the judicial response to that was the Ninth Circuit decided this and said that the FDA had the discretion to decide what kind and how much of the testing was sufficient because the Red Book 2000 is really just guidelines.

And this brings home the point that they're just guidelines. And the FDA says in that book, the Red Book 2000, that they are just guidelines because science evolves, and we need to look for the very best tests that we can use. And so most likely, the reason that companies do this is, first, working with the FDA can be perceived as time-consuming, and if one wants to use the same product safety assessment companies that others use or that they have used in the past, they are most likely just, out of habit, going to do that. So I think the pressure really has to come more from consumers, from nonprofit organizations working not just with companies that are the food producer companies, but also working with the product safety assessment companies, and getting consumer safety organizations involved as well.

Mariann: Let's talk a little bit about the problems, because you do in your article and I think it's a really important point, and I'm not sure, as you said, what Impossible was worried about. Apparently, they had some reason to be worried because they got sued for not even doing more animal testing than they did.

So they weren't completely wrong about having something to worry about. But, aside from getting FDA approval or not running into FDA problems, what are the legal risks that companies might try to avoid by testing on animals? Can they get sued down the road?

Taimie: So this was a direction that I took because I really was interested in this question about what legal justifications would there be for a company and were those realistic worries that the company should have?

So one was FDA regulations, and I decided early on that wouldn't be an obstacle. But then I wondered if companies could be concerned about being sued by consumers if the consumer argues that they have been harmed by an ingredient in a particular food that they've eaten.

So when I first started looking at that area, I realized that most of our food safety laws are at the federal level, and they have preemption clauses in them. So food safety and also food labeling would let a consumer know. And so all of those avenues, those aren't open to consumer lawsuits, they are agency driven. And so consumers can complain to the FDA, but it's going to be the FDA that does this.

So then I looked more closely at the preemption clauses, and there are some vulnerabilities there as concerns labeling, as concerns particular kinds of ingredients. But it's very limited because, Mariann, the problem is causation.

If you're going to sue the company for one of that company's product ingredients making you sick, you're going to have to show that, but for your exposure to that chemical or substance, you wouldn't have gotten sick. And in this case of food, the evidence has been digested and is gone. And so it's not easy to do this.

So when I started looking at this area of law, I really didn't find any food additive cases except for one. It's a 2011 case involving microwave popcorn. Diacetyl is the additive in microwave popcorn that gives it a buttery flavor and aroma. And it was known to the company that employees working in these microwave popcorn manufacturing facilities had a disproportionately high

number of lung impairment problems and, nevertheless, did not put a warning on their microwave popcorn packaging for consumers.

So there's a consumer who consumes a lot of microwave popcorn, and they're not breathing it in, but they develop health problems because of it, even though they are consuming it orally. And the court said, “You know what? You knew that diacetyl poses safety concerns, so it should have been on the packaging.”

Now, in that case, there was animal test data submitted, but the court didn't find it very helpful at all and instead relied on epidemiological data. So I wanted to know how courts think about this. So suppose you've got a company worried about that little tiny possibility of a lawsuit like the microwave popcorn lawsuit. And so, would it help you to test on animals?

So that took me into this whole case law search about how courts look at animal study data in what I'm thinking is an analogous context of pharmaceuticals. And certainly, there's been a lot of litigation about that, and courts are skeptical when a company comes and says, “Look, we did all this animal testing to get FDA approval, and it showed that it was safe."

So courts have said, “Well, the pre-market situation is not going to be sufficient if you've got epidemiological data. You’ve got humans who have actually consumed this product, and they've gotten sick from it. You should be showing us data that's coming from the human population rather than showing us data from animals you've intentionally sickened with this.”

So massive doses of drugs that humans would not consume wouldn't be exposed to in those amounts, courts have been very skeptical. This is not to say that courts would not admit the evidence from animal studies data from animal studies. It is to say that a company that's thinking about this very small risk, and addressing that very small risk with animal studies, should think differently about it.

The risk is very small, and doing the animal study will not adequately protect them if it turns out that people actually get sick from the product. So I really could not see any legal reason for doing this.

I thought maybe it was that the companies producing food are thinking that, especially in the case of Impossible Foods, this is a burger intended to be like a meat burger. It's intended to appear to bleed like a beef burger. And the targeted audience is not the vegan/vegetarian community; it’s really people who would not eat a plant-based burger unless it was almost a perfect replica of a beef

burger. And if that's the case, and you assume that your target consumer audience is not that concerned about animal protection, then you might take the easiest path to satisfying FDA requirements.

Mariann: One of the things that I found most fascinating about your article is that the attitudes of the courts regarding this evidence of animal testing that had been done pre-market really meant very little to them. And as you said, they wanted other kinds of evidence. So what can a company do pre-market to make sure that their product is safe and that they will have evidence to show that they tried to make it safe if down the road they are sued by…I mean, in your case, it was just one person…but if they're sued in a class action or something, and there are a lot of people who seem to have been injured, they could be entirely liable. What do they do to keep themselves?

Taimie: I think it's a two-part process. I think that getting FDA approval and protecting yourself downstream from consumer or agency lawsuits, actually, because you have an unsafe product on the market, those are two different steps.

So at both of those junctures, you're gonna want the most reliable tests. What's so exciting in this area is that scientists have been developing those tests and the possibility of getting pre-market approval, even if your ingredient is reviewed for safety by the FDA, right? It's not just GRAS, generally regarded as safe, and you don't have to show them, but you show them. And the ability to convince them with reliable tests is greater now than it's ever been, and I think it's because of the science being so strong. Not everywhere we need to go. But because the science is so strong, this is why something like the FDA Modernization Act 2.0 could be possible. Nobody's talking about sacrificing human safety for the purpose of protecting animals from these terrible experiments.

But because we can have really reliable tests, then everyone wins, and it's understood that everyone wins. So reliability is something that can be tested all by itself. So if we take this gruesome test, the LD 50, I use this as an example. This is a test where animals are subjected to a substance in increasing amounts until 50% of the population will die.

And it isn't just that at some point, 50% of them just keel over. It's a terrible process of increasing physical infirmity that involves all kinds of hideous manifestations of exposure to toxicity. So bleeding from all parts of the body, convulsion, seizures, all of this. Well, it's one thing if we get reliability from this, but it's another thing when we don't.

So this test, the LD 50, is actually quite a poor predictor when compared to human cell line tests, of this substance's toxicity. So the LD 50 test that causes all this grotesque suffering has only a 65% accuracy rate, whereas the human cell line tests have a 75 to 85% accuracy rate. Which tests should we be using?

We should be using the more accurate one. Since the science is here now that justifies this use, it becomes even less justifiable to use animal testing at all, for any reason like habit, or timing of FDA review, if that's pursued by the company.

Mariann: So you think there's a likelihood, even if there is a problem down the road and there is a class action, and there is an argument that a food has been put into the market, even though it has problems with it, there's a likelihood that these new tests will actually be admissible to help accompany proof that they weren't negligent if it's a negligent cause of action.

Of course, if it's for product liability, there's a strict liability facet. So, it's unclear exactly what they have to prove anyway. But these tests, assuming that they are allowed to bring in expert testimony, these tests might be admissible to help them show that they're much better than the animal tests that they're doing now to show that they took precautions.

Taimie: Well, as I mentioned before, I think it's two parts. So a company should be not only testing for safety before it markets the product in order to meet the generally regarded as safe requirement from the FDA, they should be using the best tests that are out there, and scientists should be available to help a company sort that out.

But then the second piece of this is that after you've been marketing the product for a while, if you start getting consumer complaints about it, if you start hearing about people in the company, like take the microwave popcorn case, people in the company, the manufacturing facility getting sick from exposure to this ingredient, this additive, then what you really need to do is do the testing sufficient to determine whether that is the cause of the problem and how to mitigate this kind of situation.

And at that point, too, relying on what the very best science will tell us is important to the company. It's important to the consumers; it's important to the employees who are exposed to the chemical. So, there are two opportunities for the company to ensure that their product is safe, so it isn't just a matter of getting it out there so people will purchase it.

In the case of Impossible Foods, they did sell this burger before they got the no-questions letter from the FDA. They sold it in some restaurants and fast food places, but also in some very upscale restaurants. And there were no problems with this.

Mariann: I think I ate one myself in the very early times.

Taimie: Yeah. In the very early times, I think I did too. There was so much excitement about these burgers when they came out, and they've been through different iterations trying to match up with consumer preferences. So the first of their burgers didn't have a very high nutritional value. Tasted like beef but didn't have a lot of nutritional value, and they have since increased the nutritional value.

Impossible Foods has been responsive, as have other plant-based food products. They want their products to be valued by consumers. So it had been sold in a lot of places. There were no complaints, and there were no obvious problems with it, but the FDA was not satisfied with that because it isn't systematic study.

And I think this underscores one of the problems that has plagued animal testing generally, which is that what we believe to be good scientific testing involves having controlled populations. It has all of these indicia of scientific rigor that we can't always perform when it comes to human populations.

So, now that we have these, just to give you an example, organs on a chip. These are very small, thumbnail-sized chips. The grooves on this chip can be lined with human cells from different organs with different processes. It's possible to see how those human cells will react to different kinds of substances.

So that's just one example. There are many, many others, and it's really the scientific community that should be praised for making a lot of this happen because now it's possible to do this kind of testing. This is not to say that we have tests for everything. So there isn't just toxicity testing; there’s efficacy testing.

Suppose you want to test a new antidepressant, or you want to test the effect of psilocybin, magic mushrooms, on relieving treatment-resistant depression in humans. These tests, pre-marketing, pre-clinical, pre-human tests, may still be done on animals with these tests that involve conditioned depression, desperation, and despondency in animals, and then see if, in the case of psilocybin, it relieves this suffering that has been inflicted on these animals. It's not going to take care of everything, because of efficacy, because of the nature

of what the substance is supposed to do. But we are certainly a lot farther along than we were, and it's an exciting time to see how much we can carve out for non-animal testing purposes and then deal with the really difficult cases from a number of different perspectives.

Mariann: Yeah, it really does seem like so much is possible. I just want to go back to one thing, which I wasn't totally clear on. It's a detail, but you mentioned that Impossible got a no-questions letter. And then you've also talked of pre-market approval, and then we've also talked of GRAS.

Can you just define the difference between those three categories?

Taimie: So a company can satisfy the FDA safety assessment requirement by simply doing the safety assessment that it thinks is appropriate for the product and not notify the FDA at all. Now, suppose they do want to notify the FDA for some particular reason.

Impossible Foods, for example, said that they wanted to get FDA actual approval, such as it is, from FDA because they wanted to use that in order to market with some large chain stores. So, they wanted what is called a no-questions letter. So, in this case, the company submits their safety assessment to the FDA, and the FDA reviews it, and if they agree that this was completely satisfactory, they can issue a no questions, that is, they have no reason to question the scientific assessment that determined the safety of this product.

What they can also do is say no basis. They can review this and say that they don't think that there was a basis for the company's assertion that this is a safe product because the testing didn't meet what the FDA thought it should be. What the company can do then, in the face of this possibility of getting a no-basis letter, is they can withdraw the request altogether and simply go ahead and market the product.

If they don't want the no-questions letter, then they can stop there. If they want the no-questions letter, they do not have to test on animals to get that no-questions letter. But they do have to spend time with the FDA to assess what more reliable or better testing would be appropriate there. So it's at that point that Impossible Foods could have said, “We're not gonna test on animals. We're going to do these other things.”

And so Impossible did have that option and chose to satisfy the requirement with as little animal testing as possible. And in fact, got sued because it was less

than what the guidelines even said, but nevertheless did have that choice because they wanted the no-questions letter.

Mariann: That's a little complicated. And then, to be honest, even though, sure, I would want that situation to come out factually, I find it unbelievable that you can ask for a no-questions letter, and then they would say, "Oh, wait, no, we have some questions." And then you can say, "Oh, never mind, I don't want a no-questions letter anymore." *both laugh*

That's a crazy process!

Taimie: Right.

Mariann: But, the other term that you've used that I don't completely understand in this context is pre-market approval. Is that the same as a no-questions letter?

Taimie: Right. So it would be, in the case of the situations we've been talking about, it would be the no-questions letter.

But suppose it's a color additive. If it's a color additive, then you do have to go through a formal FDA review, which means you do have to submit the tests. And this also came up in the Impossible Foods situation because Impossible said that the ingredient, the GE heme, was not really for color. It wasn't to create the bleeding burger effect. Instead, it was for the smell and the flavor, the meaty flavor of beef, that they put this in the product. So they argued that they did not need formal review, but ultimately they did the animal testing because they wanted the no-questions letter, not because it was a color additive that did require pre-market approval from FDA.

Now, Representative DeLauro would like for all ingredients, all additives, to go through pre-market approval, like the color additive situation.

Mariann: Yeah, it certainly does seem to make sense.

All right, let's talk about next steps. What would you like to see at the regulatory level? What would you like to see the FDA do, within the feasible?

Taimie: Well, if it's within the feasible, then we should move on to the next point. *laughs*

Mariann: For you and I to talk about what we really want, as opposed to what's feasible, might get out a little too far field, but *kind of* feasible.

Taimie: Well, in my article, I talk about the possibility of the FDA requiring justification if a company is going to rely on animal testing to meet its GRAS requirements. And so if you're going to do a safety assessment, which you have to do, if you're going to do that with animals, then you're gonna have to get that approved before you do the test.

Right now, that isn't required. You do have to do that because the science justifies having the FDA take that step. If, on the other hand, you're going to do non-animal testing, then the situation would stay the same for you. Your company, if you're using non-animal tests, the assumption could be you're using the most reliable test, the best predictors of human toxicity, then you don't have to notify the FDA about this.

So the reason for this proposal was that I think the science justifies it. And there may be some companies that can say, "No, actually, we don't have a test yet, a non-animal test, that enables us to do this." But, the fact that they have to do the justification will increase the time that it takes for them to get moving with their product, and so they will really look hard for an alternative to animal testing, is my thinking.

It was also kind of a compromise in the sense that I really don't think the FDA has the resources or the desire to do a pre-market review of absolutely every ingredient. So this is a way of saying if you're not going to do it for every ingredient, at least do it for the ones that are using outdated methods of safety testing.

So the FDA, I saw as being a good place for change because it's a kind of top-down signaling to everybody, all the actors in the environment. So it sends the message to the product safety assessment companies at the same time as sending it to these food producers, and so I would've expected a percolation of these new alternative testing strategies.

I think that based on an investigation by Politico that they published, a report of this in April 2022, it would seem that the food division of the FDA isn't a place where you go for prompt changes. My sense is that right now, that isn't the primary lever that could result in some significant change.

I think that nonprofit organizations…and PETA isn't the only one doing this work; it's the one that I gave as an example in the paper, but there are other

organizations that are focused on making alternative tests available and understood by companies and others who are interested in using alternative testing for a variety of reasons: pharmaceuticals, food, whatever. And so I think that sector should continue to assist companies.

I think that is an area where there's already attention being paid. However, in these two other areas, I think there's work to be done. And one of those is the nonprofit organizations whose mission is to protect animals. And those organizations could do a better job of informing consumers so that consumers can put their consumption dollars where their values are.

And I think more should be done with that. If PETA has a leaping bunny or a cruelty-free symbol for cruelty-free products, or a listing of such products, they really ought to be thinking about that when it comes to food as well. And I think that consumer safety organizations should get on board with the greater reliability of non-animal tests in many of these situations so that we actually have a win for everyone: for consumers, for animals.

So those are the changes that I think can create greater incentives to move the alternatives picture forward.

Mariann: Do you see any possibility for legislative reform?

I mean, we've spoken of the FDA Modernization Act, which is, of course, in a completely different context, but normally legislative reform at the federal level, I would say there's no possibility of anything ever happening, but that happened. And do you think that there are also people working legislatively on the food testing issue, or are we not there yet?

Taimie: I think the work that could be productively done would be at the regulatory level rather than the federal legislation level because it's really what the FDA expects in terms of validating safety that becomes important here.

So it's actually not clear to me yet how much the FDA Modernization Act 2.0 really changed the actual situation of what the law said before. So there's the language that is being replaced said something like, “including animal tests had to be reported.” So preclinical trial test data had to be reported to the FDA, including animal tests. And I'm not sure how that was interpreted.

So it's been interpreted, I guess, as saying “including animal tests” means you have to have animal tests, but “including animal tests” could mean that if you did animal tests, you would submit those as well as everything else. So, I think

we need to see what actually happened with the FDA Modernization Act 2.0 and learn from that because I don't see change in this area of food happening in the same way.

I think a lot can be done at the regulatory level, and I really don't think that a lot needs to be done because the FDA has said repeatedly that animal testing is not required. So unlike the pharmaceutical areas where the sense is that the FDA does require it, and I think in the food area, if you're not going to show this, that the alternative to animal testing is better, or as good, then the FDA could say, "No, you don't get your no-questions letter unless you do animal testing."

So in both contexts, the FDA can still push for animal tests. The FDA Modernization Act 2.0 does not prohibit the use of animal tests. And the FDA could still require it and still put pressure on companies to perform it.

So we haven't really seen what that law does. And in this area, when it comes to food, we already know that we don't have to test on animals. So the real effort should be in incentivizing companies to use non-animal tests for reasons of animal welfare and consumer safety.

Mariann: Is there potential litigation if, in a certain circumstance, the FDA refuses to issue its no-questions letter unless there are animal tests or something like that?

The only other kind of litigation I can think of that might result would be defensive if people don't want to put a product out there and get sued just to see whether their decision not to do animal testing was a good one.

But is there any proactive kind of litigation that's possible? Do you see a possibility for that? Or is this all going to be a consumer campaign?

Taimie: If a company wants to get a no-questions letter, that is, the FDA has no questions about the safety assessment that the company has done, and the company wants to be sure not to use animal tests for whatever reason—the company may believe that the non-animal test really is more predictive and they don't want the delays associated with an animal test that they think is duplicative or worse, would be falsely suggesting toxicity, when in fact it's just in that range where it's not a good predictor. And the non-animal test was actually better and showed that the ingredient is safer.

So suppose the company is wanting to stick with non-animal testing, then they could sue the FDA for not using their discretion in a way that permitted the

company to get the no-questions letter. The problem with that is that it's not clear to me that anybody actually needs a no-questions letter. And so, the solution is just to withdraw it and sell the product anyway. So the FDA is not really a gatekeeper of what products get on the market and which new ingredients do. So you have to be injured in some way.

And it's not clear to me that a company would be injured because I went through the idea that a no-questions letter was necessary for shelf space in large retailers, and that didn't bear out. Or selling it in foreign countries that wasn't born out by what I could find in the background searching that I did. So, what benefit do you get? Well, you get to say to consumers, “Oh gee, our product is so novel that it had to be tested and approved by the FDA in order for us to bring it to you.”

It's a sort of marketing strategy that goes to the novelty of the product. It could be that some companies will want to get a no-questions letter because then the ingredient is listed as GRAS. So it's actually on a published list of generally regarded as safe ingredients. They're associated with that. So, there could be some of these reasons, but you don't need that letter in order to market the product.

So if DeLauro's legislation were to become a reality and the FDA did do a pre-market review, and they did prevent a company from being able to market a product because of the use of an alternative to animal testing, well then we'd more realistically see litigation, I believe.

Mariann: Yeah. That would certainly increase the incentives for litigation. Really interesting and a little shocking. I'm almost always shocked about the law’s implications for animals, but I'm actually pretty shocked about how little oversight there is over what goes into the food system.

It was a really, really instructive read. Thank you so much for sharing it with us, Taimie.

Taimie: I think the one thing, too, that I would say is the problem of these unreported safety assessments leaves us in the dark about how much animal testing is actually going on. It would be gratifying to know if there is less of it going on.

If these product safety assessment companies are actually ramping up in ways that enable less of this animal testing going on. We don't actually know, and it would be very helpful to know. So some form of transparency, maybe some

form of legislation that makes that sort of assessment more public, would be helpful.

So that's a direction in which more information could really enable further action on the basis of an educated guess about where we should be looking to improve.

Mariann: Yeah, absolutely. It is quite extraordinary that there is no transparency about that and that it's something that so many of us in this movement, or at least maybe I'm blaming everybody else where I'm at fault, have really never thought about it and are very unaware of it.

So yeah, we could be participating in all sorts of animal testing with our consumer dollars without being aware of it in any way.

Taimie: Right. I think the fact that Impossible Foods sought a no-questions letter and this became known enabled us as a movement to really become more aware of the extent of secretive amounts of animal testing going on.

So we could be consuming a lot of products, not just Impossible Foods' Impossible Burger, but a lot of products that contain ingredients that have been tested on animals. And this is truly worrisome, in my view.

Mariann: It really is. And I'm really grateful to you for clarifying so much of it because I wasn't aware of this even just having been aware of the Impossible situation.

The impossible situation. *both laugh*

Can you just share with me what's happening at UCLA when it comes to animals? Because I don't think I'm up to speed.

Taimie: You mean at UCLA law?

Mariann: Yes.

Taimie: When you say UCLA, Mariann, the first thing that comes to my mind is the challenges we have had on campus protecting our trap neuter return program for campus cats, for feral cats.

Mariann: I've heard so much about this program in the past. I'm really sad to hear that.

Taimie: It is a huge success story in the sense that it took us 15 years to bring the feral cat population down. And now, 30 years after we started this thing, we are at something like 15 individuals on a 419-acre campus.

I mean, it has been very successful in relieving the suffering of cats abandoned here, being able to find homes for newly abandoned ones, and maintaining the ones who can't. Yet there are regular problems about this activity in a campus that also values birds and a belief that it's a disruption of the ecosystem. So when you say animals at UCLA, I think that's the first thing that comes to my mind.

And here at UCLA, we have these two courses now, we have the Potentially Dangerous Dog Administrative Hearings clinic, and I decided to switch that to a simulation course. We had some difficulties with our agency partner.

Right now, they're in a transitional period with interim leadership and lots of staffing problems, and this opportunity to switch it to a simulation course is really exciting because it could serve as the basis for training hearing examiners in other jurisdictions in how to up their due process procedural aspects in these potentially dangerous dog hearings.

I'm very excited about that new development. And then I am very excited that the Topics in Animal Law seminar that I'm offering this semester has a waitlist. And the reason that this is not something that I would expect is because UCLA law has gone in the direction of a lot of specializations with heavy requirements for getting that certification on one's transcript and degree. And so, between taking bar courses and taking certification requirement courses, there really isn't a lot of room for some courses that don't fit neatly in any one of those specializations.

And I think the students that come into that class have increasing knowledge about the world and how animals are living in that world. And so it's much more exciting to be talking with them. It's much more of an exchange.

Do you find that in your classes, too, more knowledgeable students and students who really care?

Mariann: Yeah, I think that every year there is more awareness. I mean, there is still an alarming lack of awareness about many things.

I'm always thinking, “Well, everybody knows about factory farming; they’re just terrible people.” But of course, that's not true. It's just even in this day and

age, people can still be very naive. But I do find that every year I have students who are more and more aware, more and more troubled.

And you're exactly right; it adds to the conversation so much when I'm not just telling people what's going on as it used to be in the old days. There's a shared awareness.

Taimie: I do have a student who does not believe that animals have consciousness or sentience.

Mariann: Why would they take that course?

Taimie: Well, it remains to be seen if it's a course that they want to continue taking because so much of what we do is premised on the exact opposite. There's this uneven permeation of beliefs about animals as conscious and sentient, and what does it mean to be sentient? And we can talk about it more meaningfully now than in the past.

So I'm grateful, actually, that these kinds of ideas surface, and education isn't just about preaching to the choir that turns up in the classroom. So, that I find kind of encouraging that people are much more open about what their underlying premises are, presumptions are.

Mariann: I totally agree that students, I think, are much less cautious about revealing how they think about these issues because they've actually started thinking about these issues before they've entered the class and have some ideas.

I've never had anybody who didn't think that animals were conscious. That's a new one. I'm not sure what that even means.

I'm taking it you just started the course?

Taimie: Yes. We just started.

Mariann: Yeah. I haven't yet started my course for this semester.

Taimie: And this is a student who wrote to me before the semester started and engaged me on the subject. So I was able to have a number of email exchanges that just asked more about what the thought process was that was underlying the belief and asked about specific examples, and they asked me about specific examples. It was a very productive exchange.

Mariann: That's great. I'm excited for you this semester. It sounds like you have wonderful stuff going on, and I just want to thank you for sharing all of this with us today.

I never would've gotten such a depth of knowledge about what's going on here without this article and without this interview. So thanks, Taimie.

Taimie: Thank you, Mariann.