



Episode Title: Animal Testing and New TSCA

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Richard E. Engler (REE): It's not reasonable to say we will develop something that no one's ever seen within time certain. That's not the way science works.

Lynn L. Bergeson (LLB): Hello and welcome to *All Things Chemical*, a podcast produced by Bergeson & Campbell, P.C. (B&C[®]), a Washington, D.C., law firm focusing on chemical law, business, and litigation matters. I'm Lynn Bergeson.

In each episode, we are going to try very hard to bring you intelligent, insightful, and engaging conversation about everything related to industrial, pesticidal, and specialty chemicals and the law and business issues surrounding chemicals. Our incredibly talented team of lawyers, scientists, and consultants keep you abreast of the changing world of both domestic and international chemical regulation and provide analysis of the many intriguing and complicated issues surrounding this space. This week we convened a roundtable discussion with several of my colleagues here at B&C to discuss the U.S. Environmental Protection Agency's (EPA) Strategic Plan to diminish animal testing.

The plan, as you probably know, was released by EPA in June of this year and its goal is to diminish animal testing. This is an issue on which most stakeholders are aligned and obviously very supportive. In keeping with Congress's commitment as outlined in the 2016 amendments to the Toxic Substances Control Act, what we call TSCA, EPA proposes in its Strategic Plan several so-called new approach methodologies or NAMs. The hope is that EPA will be able to develop these NAMs and one day reduce, and even better for our furry friends, eliminate animal testing.

Weighing in on this really interesting subject are my colleagues here at B&C: Dr. Jane Vergnes, Director of Toxicology; Dr. Rich Engler, Director of Chemistry; and Dr. Oscar Hernandez, one of our Senior Chemists. I really wanted to have Rich and Oscar with me this week because of their significant experience on the EPA side of the equation. Rich is a 17-year veteran of EPA, having served as Senior Staff Scientist in EPA's Office of Pollution Prevention and Toxics, what we call OPPT, and was the leader of EPA's Green Chemistry Program. Oscar is former Director of the OPPT Risk Assessment Division. Jane's insights

as a toxicologist and her significant experience, having directed corporate toxicology programs at Ashland, ISP [International Specialty Products] Texaco, and Union Carbide before joining our team, offer an invaluable real-world kind of “gut check” on EPA’s very good, but aspirational, Strategic Plan. We had a great conversation, and I’m really excited to be able to share it with you now.

Here’s my discussion with Jane, Rich, and Oscar about EPA’s approach to reducing animal testing and the complex issues this laudable goal raises.

On June 22, 2016, we found many reasons to celebrate. Core among them was Congress’s enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act (Lautenberg). Embedded in that law is a Section 4 provision that really addresses a commitment, a Congressional commitment, to reduce and replace animal testing, a topic that I think many of us have long wanted to see happen before 2016, but we see it now embedded in the law, a Congressional commitment to reduce animal testing. What we’re going to talk about today is EPA’s plan, Strategic Plan to give expression to that Congressional commitment. Specifically on June 22, 2018, EPA issued the Strategic Plan to Promote the Development and Implementation of Alternative Test Methods (Strategic Plan) within the TSCA program.

My first question -- going to throw it to you, Rich -- is what exactly is this plan, and how does it relate to the law?

REE: The law specifies that EPA has to develop a Strategic Plan to develop and promote alternative test methods, non-vertebrate test methods, that give EPA the information that it needs or give *part* of the information that EPA needs to do risk assessments under TSCA. The test methods have to be reproducible, they have to be fit for purpose to supply that particular -- whatever the particular endpoint is, or the particular information that EPA is going to use it for in terms of assessing the hazard, or the exposure, for the risk assessment. The law lays it out very broadly and required EPA to develop a Strategic Plan within two years, and that’s what EPA published on June 22 this year.

LLB: Oscar, animal testing has been first and foremost in chemical testing sectors for many, many years. You, as former Director of EPA’s OPPT’s Risk Assessment Division, must have pretty strong views on the relevance of animal testing, probably the continued need for animal testing, but also our commitment to reduce and diminish animal testing. What are your thoughts on what this plan does and what it doesn’t do?

Oscar Hernandez (OH): In reference to your initial comment, definitely that this strategy is not presumed to displace animal testing entirely. It is not a one-to-one replacement. It is bringing in new tools, new approaches, that in combination, eventually and successfully, will reduce the use of animals in toxicity testing.

The strategy from EPA was to incorporate all of the available tools in their repertoire and name all of them NAMs. Perhaps this has to do with the fact that NAMs narrowly could be identified as hazard-only methods, but EPA incorporated exposure, chemical characterization, so it is really more of a risk context, which is very appropriate for the program.

LLB: Jane, maybe you can help us understand what is a core tenet of the Plan, which is something called the New Approach Methodologies. We’re going to talk more about that at length, but

what are they, why is TSCA interested in NAMs, and how does the plan address their development?

Jane S. Vergnes (JSV): NAM is very broad conceptually. The legislation itself does specify the use of computational toxicology and bioinformatics, procedures or processes such as high-throughput screening methods, predictive models. Basically, it involves the use of some of the techniques that EPA has developed over time, plus the application or the introduction of new approaches as EPA finds them to be both relevant and reliable. Basically, again this represents a combination of traditional approaches plus some new approaches to bring as much relevant and reliable scientific information as possible to the process that EPA must conduct under the regulation.

REE: Can I just add that, we're trying here -- we're trying to address the tension between the increased need for information. Part of the impetus for TSCA reform was the perception that there were many thousands of chemicals that were in commerce, that little was understood about these substances. There is additional authority for EPA to use its testing authority to require testing on new substances in addition to the requirement for EPA to review *all* existing chemicals. With the many thousands of chemicals that were potentially going to be subject to testing, there was concern about a significant increase in the use of animals for that testing. Trying to balance that tension between animal welfare and the need for data is -- the NAMs help fill that data gap. This is really part of the negotiation that we saw during the development of Lautenberg, where, yes, there's a need for data, but can we find ways to fill those data gaps without additional vertebrate testing?

LLB: Your comment, Rich, raises an important kind of jurisdictional issue. What we're talking about here is simply industrial chemicals, the area of the law that EPA regulates under TSCA. I want to make sure I get this right. This plan only addresses animal testing, and chemical testing generally, as it relates to industrial chemicals. Pharmaceuticals and cosmetics, does this plan have any relevance to those other products?

JSV: It doesn't apply to those products. It applies strictly to chemicals that are regulated under TSCA.

REE: Yes, the methodologies might apply across, but the authority and the requirements relate exclusively to TSCA. If EPA identifies particular methodologies that might apply to a pesticide, the Pesticides Office might consider incorporating these in its consideration under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). They might be more broadly accepted in the scientific community, and industry might use them to support safety evaluation of cosmetic ingredients, but the requirement is exclusive to TSCA, and so it is exclusive to the uses that are under TSCA jurisdiction, which are not cosmetics, food, drugs, pesticides. It really is limited to the TSCA authority.

LLB: Okay, so does that mean that the U.S. Food and Drug Administration (FDA) and the Office of Pesticide Programs are similarly committed, because this is a Congressional law that expresses a Congressional intent, as it were? But is animal testing unbridled in those other programs? I guess I'm still struggling with what is the relevance of this one plan for one aspect of the EPA program offices, and how does it relate to testing across the board by the federal government?

JSV: I think even though the legislation itself is restricted to industrial chemicals under TSCA, that the methodologies that may be developed, the techniques that may be developed, are not only applicable to those substances, that because of the relationships that are set up,

because the information is likely to be shared with other existing agencies, such as the Interagency Coordinating Committee on the Validation of Alternative Methods (ICCVAM), for example, or the NTP [National Toxicology Program] Interagency Center for the Evaluation of Alternative Toxicological Methods (NICEATM) that these other methodologies, if they prove to be reliable and relevant, they could be applied in these other areas that are under other legislation. There are those opportunities.

OH: Though there is one limitation or restriction for the Office of Pesticides, and for FDA as well, that the regulation requires, specifies, certain number and types of tests, animal tests, to be conducted in order to process the registration. That's very difficult to avoid at times, so it's going to be a different challenge for the Office of Pesticides to expand alternative methods into their active ingredients program, for example. I see that as a very difficult proposition at this point.

LLB: But I think it's probably fair to say that the federal family is generally committed to diminishing animal testing.

OH: Yes, that for sure, yes.

LLB: That is a societal mandate. It's a commitment now that the federal government at least articulated in this 2016 law with respect to industrial chemicals. But the fascinating tension that I think I see, and that we've chatted previously about, is trying to achieve the best set of data that is predictive of human and environmental harm, and doing so in a way that spares animal lives consistent with Congress's intent, but also elicits high-quality data that will really make products and the world a safer place. Who can help me understand how, logistically, this is going to be done? Who are the stakeholders? Who is going to be spending the money? And over what period of time?

REE: EPA, through its Office of Research and Development (ORD), has already been working on high-throughput screening, Tox21, ToxCast. This research has been going on at EPA for a fair amount of time. The law here makes that continued research a much higher priority because it is mandated, so EPA is going to have to continue to do that sort of research. It really puts greater pressure on the EPA Administrator to make sure that that aspect of EPA's ORD continues to be funded and continues to progress so that the research related to this can't just be left on the wayside.

Whether the resources are going to be there is really going to be a political question: Are the funds going to be appropriated to continue to do this? That's something that really remains to be seen, although research has been not cut as drastically as some of us might have feared. But the fact that it's mandated in there will -- at least within the Agency -- will mean that the research into these new approaches will continue to occur at least at a higher priority than other research that EPA might undertake.

LLB: I'm guessing, though, that there is an expectation that private stakeholders, industry, public-private partnerships, and others outside of the EPA federal family will be participants in this initiative. What is the duty, if not the obligation, of the private sector to facilitate identifying NAMs and funding them in a way that works collaboratively with government resources to get to a better place?

JSV: This at least provides incentive and support to corporations, for example, to members of the stakeholder community, to develop and deploy alternative methodologies and approaches, which in the past may not have been as well received as they might be under this

framework. In that respect, it provides additional options to corporations or to stakeholders that are developing new chemical technologies to bring forth new approaches to the evaluation of their potential effects on human health and the environment.

- REE:** Another key set of stakeholders that is underappreciated is the testing labs. Who are the groups that will be doing the testing? They are generally contract labs. There are a handful of companies that have their own testing facilities, but most of that's been outsourced. And so, the labs are going to have to -- I mean, not only do we need to develop the methods -- but the labs are going to have to develop the expertise to do these methods in a reliable, reproducible way. Their experience with the challenges of testing under *any* methodology is going to be an important input into making sure that we get a practicable and reliable set of methods.
- OH:** I think there are some opportunities in the office -- that is, the OPPT has a good record in working collaboratively with industry. We had some programs in the past that produced conventional information, but nonetheless, it was a big effort and eventually was taken to the Organization for Economic Cooperation and Development (OECD), where it was memorialized as part of their programs. A similar approach I think could be followed here: that once EPA finishes its retrospective analysis to identify the most frequently requested animal tests, that they could identify a couple of targets for development. I think at that point then, it would be important to engage industry.
- LLB:** Before we get into some of the timeframes that are laid out here, I think there are two terms that are a very, very relevant step forward under the Strategic Plan, and that is: What NAM can be demonstrated to be relevant and reliable? At the end of the day, who decides what is relevant, and how is relevance defined, and how are data determined to be reliable, presuming that means predictive of a particular endpoint of toxicity? Who decides that, and what does the Strategic Plan say about documenting those terms in a way that will be helpful for purposes of regulatory standard setting?
- REE:** There are a couple of issues there. One is what are the criteria for reliable -- but who decides? In my view, it's the Agency, in consultation with their advisory committees, so that discussion, both the scientists within the Agency (ORD and OPPT), as well as the external advisors -- whether it's a science advisory board or a specific advisory committee to OPPT -- will be the ones providing that advice to management in OPPT and the Office of Chemical Safety and Pollution Prevention (OCSPP), to make that formal decision. "Here are the methodologies that will meet these particular endpoints." Presumably, as they have with the other OCSPP harmonized guidelines, those will be published in the *Federal Register* so that there'll be broader stakeholder engagement as well. But in terms of what's reliable, I'm going to have to defer to Jane and Oscar as to how will those groups judge -- how will the internal scientists and the external advisory groups judge reliability and predictive -- will those methodologies be sufficiently predictive?
- JSV:** We know that the Plan does talk about the creation of this TSCA-NAM team, which they call the TNT, which right now is composed of representatives of the various agencies within EPA. But at this point in time, we don't know what EPA might do in terms of the addition of any external stakeholders to that team, and that remains to be seen. But according to what EPA has provided to us, they have made a commitment to making this process open, transparent, available to the public. And in the past, as these methodologies have been explored and developed, there has been -- both with the Interagency Coordinating Committee (ICCVAM), as well as its European counterpart, as things have been advanced to OECD methods development, there has been this general understanding that there would

need to be some sort of validation of the method, that it would need to be reviewed, that both its ability to predict the specific endpoint it's designed to address, its reliability, its sensitivity -- How often does it reliably predict the effect? How often does it give you a false positive for the effect? How reproducible is the methodology? All of those things are aspects that, from what we've seen, the Agency already incorporates into this thinking and intends to practice as it goes forward to develop these new methodologies and new approaches.

LLB: Maybe it's me, but this sounds like super complicated stuff, and it sounds like this could take a really long time, especially since, as you just noted, Jane, this has been going on literally for decades, not just domestically, but all over the world. Does the plan anticipate benchmarks against which reasonable further progress is going to be measured? What is the timeline here?

REE: Yes. The timeline is not clear to me. The statute does require five-year reporting to Congress, but that's a progress update. It's not necessarily "EPA must develop this many alternative methodologies in this timeline." I don't think that's a reasonable requirement to expect when you're talking about research. Some of this is really -- some of it is implementation of promising methodology, some of it's going to be entirely new, and you cannot force a timeline on entirely new research. It's just, it's not reasonable to say, "We will develop something that no one's ever seen within time certain." That's not the way science works.

LLB: True, but, if I recall, the plans suggest some near-term and immediate goals, and then the ever-elusive long-range -- right, long-term goals.

OH: Open-ended.

LLB: Right. Many of us are of the view that some sort of hard stop might provide incentive to achieve metrics by date certain. But I think in this context, that would be asking a lot. It may well be a bridge too far. But what are some of the immediate near-term goals that EPA is expected to achieve within the next, say, three years?

OH: I think some of the immediate successes would be the application of the use of NAMs to identify candidates for prioritization for further evaluation. This is not even to characterize the chemicals, just to identify candidates that should be further explored. I think that could be one of the first very accessible projects that they can initiate. In the ecological area, they're probably almost there. It's certainly the type of information that is needed for at least a basic ecological assessments are fairly accessible right now using non-vertebrates: fish, in this case. I think they can claim an early success there, but beyond that, it's very, very tedious and very slow. But mostly they need to start using what's available.

LLB: Jane, your comments went to just the inherent complexity of the task. We can all get wrapped around the axle in trying to figure how best to do this, but I think you aptly illustrated just how really, really tough this is. People have been trying to achieve this goal literally for decades. You had mentioned the event, what 20, 25 years ago, the Doris Day?

JSV: Oh, when the Doris Day Animal League basically brought activities at the Department of Transportation to a grinding halt over the use of rabbits for corrosivity testing for Department of Transportation (DOT) transportation classification. Basically, there was outreach at the time from DOT. They were just flooded. This is from a source within DOT that came to an industry group and said, "We need help. We need to find a different way to

do this, because we're getting so much incoming e-mail and correspondence that it shut down our servers."

LLB: None of it good.

JSV: None of it good. It did lead to -- there was significant progress on that endpoint. It's still not perfect, but certainly a great deal of progress and change. One of the challenges that we face going forward is that the multinational companies, the company that wishes to operate in commerce outside of U.S. space, needs to provide the information and comply with the regulations that are necessary to do business in other nation-states and other territories that have other regulations. We've seen a great deal of progress in a number of parts of the world. Europe, for example, is a leader in this area of moving toward alternative ways of assessing things and of chemicals, and including that in their regulations. But we have other parts of the world where there is still a heavy reliance on these traditional animal tests and testing paradigms, so you are left with this duality. If the United States and Europe move very quickly in this direction and other trading partners in other parts of the world don't come along, we still have a situation where we may be doing testing for two different purposes, where the animal testing won't really go away. That's a challenge for a number of reasons: It doesn't help us meet the goal of basically replacing animal testing to the extent that we would like, it creates additional cost, which is not as important as the welfare issue, but we need to keep it in mind.

LLB: It's a reality with which all companies must deal.

JSV: Right. That imposes greater costs on the companies that wish to put these new technologies into commerce. We need to recognize that a lot of the goals of these new technologies are to provide safer alternatives that are safer for people and for the environment, that are better, that are improvements than what the existing technology is. This creates an additional barrier, in addition to the challenges that any regulatory agency faces in terms of what it must do to achieve those goals of protection, its mandate to protect human health and the environment. It's costly, it's time consuming. It takes a great deal of expertise to do this well. It's always a challenging space for any government agency to work in because there is this constant tension of differing societal priorities and goals.

LLB: Within that, there is the constant tension, as you just alluded to, Jane, which is federal agencies and, in this case, EPA with respect to industrial chemicals, must ensure the safety of chemicals when used as intended.

That goal, it seems to me, trumps all else, because that is the Congressional mandate, and that is the burden that all chemical manufacturers must satisfy in having, for example, new chemicals approved or existing chemicals remain on the market. If testing is necessary to ensure that that goal is demonstrated and achieved, then the ability to find alternative test methods that lack reliability, that might lack demonstrated reliability and relevance, is going to be a legal challenge that I think we lawyers tend to focus on.

These test methods, their validation, the confidence building, the ability to demonstrate unequivocally that a new test that does not rely upon animal testing absolutely gives the public confidence that these products are safe when used as intended. And when you think about it for more than a nanosecond, that is a very tall order, because we've been doing the same thing for decades. The will is there. I think we see the political will is there, but the know-how and all of the pieces of EPA's plan: the identification of these methods, the confidence building, and the implementation in a way that is regular, predictable, and

reliable. These are really, really complicated issues, and part of our discussion here is intended to demonstrate why, yes, of course we all want to stop using bunnies in research, BUT the reality is, the public also wants clearly demonstrated safety in the products that they purchase and use.

JSV: We all expect that, and this speaks also to that difference between defined approaches, such as we have when we have an OECD guideline, and some of the other approaches that this regulation really permits EPA to practice, as long as they are relevant and reliable. That does place the burden on EPA that may not have previously existed, but it also opens opportunities for EPA to use other information to inform its decisions, as long as it's relevant, reliable, and they can defend how that particular information and that particular science informs Agency decisions.

LLB: I'm guessing if we had other stakeholders in the room -- I mean we clearly are representatives, largely, of industry. We have two of our colleagues here who worked for many years with EPA. But that relevance and reliability, those terms are going to be defined very disparately, depending upon the stakeholder defining the term. If we had representatives from the [non-governmental organization] (NGO) community in here, for example, or PETA (People for the Ethical Treatment of Animals), how might those terms be defined by them, as opposed to by us, looking through a lens of a more private industrial chemical perspective?

REE: That's a good question. The relevance is perhaps the easier question to ask. Does the alternative method indicate something about the endpoint that it's being used to predict? The sensitization testing has -- the *in vitro* methods have developed a correlation between a result in the *in vitro* method and *in vivo* --

JSV: -- Key event. A key event in the *in vivo* disease process, or toxicity process.

REE: Right. So there is that correlation designed, or essentially built into the method. Is that reliable? Then the question is: "Are we seeing false positives? Are we seeing false negatives? What are those rates? What is the group of chemicals for which it applies? Is that sufficiently broad that you can use this in a general way?" I think that's a much harder question to answer, but even if there is a narrow set, it's still -- if it's an opportunity to reduce some animal testing, it's helping EPA achieve its statutory mandate, maybe not as broadly as we would hope, or as the statutory language envisions, but some is better than none.

JSV: We all know that there is not one position among the NGO community, that there are likely to be disparate, and in some cases conflicting, views. To some, the changes might represent a path toward information they believe is more relevant and more reliable because in the view of certain NGOs, animal models are not reliable predictors of what is going to happen to humans.

LLB: Period. Under any set of circumstance?

JSV: Right.

LLB: Interesting.

JSV: Then on the other hand, there are NGOs whose position is going to be that we have had reliable methods. They have not been practiced to the extent that we wish to have seen them

practiced for this broad spectrum of chemicals. If I don't have the information, all of this information on each of these, I don't have a really good basis for assessing the risks.

LLB: And hence they shouldn't be marketed? That would be a logical outcome of that.

JSV: That might be. I don't think there's going to be any one perspective, and there is going to be this tension. I think that's part of what the education mission and the communications mission of EPA will be.

LLB: And the transparency, right?

JSV: And the transparency. But there will always be this dynamic tension between going from what we know into new territory and exploring in new ways. This dynamic tension has existed throughout human history. Whenever we move toward new science, new paradigms, new anything, there's always this dynamic tension between what is and what we know, and that future state --

LLB: -- or that transitional state --

JSV: -- what we don't know and what we're trying to learn, and how we apply. We live in a world where, to be very honest, when I started in the field in genetics, when I was looking at basically how genes are structured and how their regulation is controlled, and we were starting to do molecular genetics, and we were starting to look at DNA sequencing and using techniques. This was before the polymerase chain reaction and before the widespread availability of what all of us have in our homes now: laptop computers, computers that were affordable that anyone could have that had this ability to store huge amounts of information and programs to analyze it.

We've come so far in so many areas over the past 30 years or so, and even before that, let's say in the last half of the 20th century into this one, that it's sometimes difficult to fathom how many changes we've gone through. Integrating all of that information and applying it and moving forward, it's a challenge. If we go back. I mean if we really go all the way back, there are many who say that the father of toxicology, Paracelsus, was one of the first to espouse the use of animal models. The history of toxicology has relied on a number of these, although they've been changed and refined over the years. We are really moving into a newer paradigm. It does affect so many areas, not only the Agency's mission, but, as you've noted, some of the concerns that the legal profession has about this, and that a number of stakeholders have about what this means.

LLB: Maybe we can have a last discussion just on when we all looked at the plan when it came out, what were our preliminary responses to it, in terms of adequacy? Did it give full expression to the mandate set forth under the Lautenberg Act? Now that we've studied it a little bit more and we've seen it a little bit in action since it came out a few months back, are there things that we think EPA got just right, or are there things that we would like to see tweaked a little bit differently? Anybody have a view on that? Oscar, your brow is furrowed.

OH: Yes, I think it's kind of early. I think we have to look at the initial outputs, and that will give us an indication, particularly performance of the TNT.

LLB: What is the TNT?

OH: TNT is the TSCA NAMs Team that is supposed to be --

LLB: What a great acronym!

OH: It *is* great. It's explosive. So that's supposed to be the focal group.

LLB: Who's on the TNT?

OH: It is chaired by OPPT, and it will have membership coming from Pesticides, Office of Research and Development, mostly I believe.

LLB: Office of Science Policy, too, I think.

OH: Office of Science Policy as well. Correct. That's going to give you an idea of the direction they're taking and the level of effort that has been invested. That will forecast how this program may or may not grow.

LLB: Rich, any thoughts?

REE: Yes, I think it's -- for me, the difference is going to be: here's the concept, but where's the execution? How does EPA as an agency take this forward? Will there be the necessary coordination between the program offices, and OPPT, and the Pesticides office, and the Office of Research and Development? Internally, there's going to be that need for coordination. But then also, externally, making sure that they're getting good input from external stakeholders, from a variety of points of view. Is EPA getting the resources necessary from Congress to implement? I mean, a plan is a plan, but if EPA is going to limp along with dribs and drabs of funding, then there's not much that they can do with -- not much *more* that they can do with what they have. I think that we're going to have to wait and see how this is -- when the rubber meets the road, how does this come together?

JSV: I think that was my principal concern. I was pleased to see the plan. I didn't expect that it would have more specifics and would have been concerned if it had been more specific and had promised to deliver on certain specific endpoints at a specific time. My principal concern is that this will take a level of scientific knowledge, expertise, and sophistication that is beyond what has been available to the Agency in the past. I share Rich's concern: Is this going to be funded adequately? Is EPA going to be able to attract the scientific expertise it really needs to fulfill this mission?

LLB: I share that concern as well, for a variety of reasons. But I also recognize that this is an opportunity for shared ownership. EPA, the federal family as a whole -- Congress needs to do a really good job of funding, and EPA needs to be very mindful of deploying its limited resources to achieve the goals of this Strategic Plan. Of course, industry has an obligation to step up and engage with EPA to ensure that *its* best and brightest are informing the judgment of EPA on NAMs and how best to ensure that they are reliable, relevant, and reflective of all that this plan anticipates.

I think we all here institutionally applaud EPA's efforts in timely meeting its obligations under Lautenberg. The Strategic Plan came out exactly two years from the date President Obama signed Lautenberg into law, and EPA has been very, very consistent in meeting those metrics. We are hopeful that EPA will be equally successful in meeting the interim challenges anticipated in this somewhat aspirational timeframe under the plan.

With that, I just want to thank my colleagues here -- Oscar Hernandez, Richard Engler, and Jane Vergnes -- for what I thought was a very stimulating and, we hope, informative

discussion about what on its face might seem like a very simple concept: Golly, let's get rid of animal testing. Little bit harder than I think we all anticipated, but we applaud Congress and EPA's efforts to achieve precisely that goal. Thank you.

All right. Our thanks to Dr. Jane Vergnes, Dr. Rich Engler, and Dr. Oscar Hernandez for being here with me today to discuss animal testing alternatives. I hope our listeners learned a bit about EPA's efforts to reduce animal testing and the many intriguing scientific, legal, and policy issues surrounding this effort. If you'd like to learn more, check out our regulatory blog at lawbc.com, where we have an entire section devoted to keeping up with just TSCA.

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