Episode Title: Is There a New Chemical Bias? -- A Conversation with Richard E. Engler, Ph.D.

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

This week I sat down with Dr. Richard Engler, B&C's and The Acta Group's (Acta®), our consulting affiliate, Director of Chemistry, to discuss the new chemical bias. Our listeners know that Rich Engler has worked for decades reviewing premanufacture notifications (PMN) submitted under the Toxic Substances Control Act (TSCA). PMNs are applications to manufacture or import chemicals that are not listed on the TSCA Inventory and thus are considered new. Much has changed in terms of the new chemical review process since Congress revised TSCA six years ago. As we discuss in our podcast, however, one thing has not changed. The new chemical bias is as potent today as it was before Lautenberg was enacted in 2016. Rich and I discussed the new chemical bias, explain why it continues to confound chemical innovators, and what is being done to eliminate the bias and level the playing field. Now here is my conversation with Dr. Richard Engler.

Well, Rich, it's delightful having you back in the studio. It's always a pleasure to chat with you.

Richard E. Engler (REE): It's really nice to be back live. I've missed -- it's been a couple of years now.

LLB: I know. Me too. It's good to see you in person. Why don't you tell our listeners about your extensive background in TSCA and in new chemical review in particular?

REE: In my 17 years at [the U.S. Environmental Protection Agency] EPA, I was part of the group that reviewed PMNs and low volume exemptions (LVE). We would sit in biweekly meetings, chemistry meetings, hazard meetings, decision meetings. By my estimate, I probably looked at 10,000 notices in one way or another, worked on them either a quick review or more in-depth review, so I've seen a lot of new chemical notices in my career. And then since leaving EPA, about -- it's a little more than seven and a half years ago now that I joined B&C. We frequently assist clients with new chemical notices, PMNs, LVEs, and other types. Significant

new use notices (SNUN) as well, bringing those to EPA, trying to make them as robust as possible, and trying to get efficient decisions from EPA as promptly as possible. So lots and lots of PMN and LVE work in my many years.

LLB: And I know you well enough, Rich, to appreciate that, although you work on many aspects of TSCA, TSCA Section 6, Section 4 test orders.

REE: CBI.

LLB: Confidential Business Information (CBI), Export-Import Notifications. There's a special place in your heart, and I think that is probably derivative of your extensive work in green chemistry.

REE: There's no question. A lot of green chemistry is new chemistry. So if you're bringing green chemistry to market, there's a very good chance that it's a new chemical or it's going to involve a new chemical, and it may involve a number of new chemicals. If you're talking about building of complex molecules, you probably have a bunch of intermediates. And so it's very important for more sustainable chemistry that the new chemicals program work efficiently and recognize the benefits of those chemicals.

LLB: And when you say green chemistry, I know that means a lot to many of us in the community, but I think generally speaking, a lot of new chemicals are fundamentally greener and more sustainable than chemicals they may compete with in the market as existing chemicals. Is that a fair statement?

REE: Yes, I mean, I've always thought -- it's not really in the name -- but I've always thought of green chemistry as being really being green-*er* chemistry. It's pretty unusual that you have massive leaps in how much more sustainable a new chemical is. Incremental improvement is still improvement. There is that aspect of how -- we definitely need to improve. Can we improve in larger leaps? Maybe, maybe not. Depends on what the technology supports. But you're right, a lot of -- even back in my days reviewing PMNs at EPA, it was pretty clear, you could see the sort of progression to moving toward less volatile, less corrosive. The innovators were trying to design the hazard out, even if they were only making minor changes to the molecule.

LLB: Yes. And to allow our listeners to appreciate the big picture here, it might be good to go back and let our listeners, or just refresh our listeners' recollection with regard to existing chemicals. When TSCA was enacted originally in 1976, my understanding, Rich, is that there was no *de novo* review of existing chemicals then. They were simply listed on the Inventory and more or less presumed safe when used as intended. There was no independent review of their composition or safety when TSCA was implemented in '76. That's an important kind of background fact to talk about what we're going to talk about, which is the bias with regard to new chemicals. So why don't you to talk a little bit about that?

REE: Yes. I was not working in this space in the seventies when TSCA was enacted.

LLB: No.

REE: Yes. The initial task under TSCA was for EPA and industry to develop a list of chemical substances that were in commerce when TSCA was enacted. And that became the original Inventory. And it was some 60-odd thousand substances were listed on the original Inventory. You're right. They were not -- at that time, they were not reviewed for safety. They were just

-- these were things that were in commerce. But EPA had the authority in TSCA to review those. Section 6 gives EPA authority to review existing chemicals. Section 4 gives EPA authority to gather information on chemicals, new or existing. And I think the original intent was for EPA to go and look at those 62,000, pick and choose, and do risk evaluations for existing chemicals and regulate, as appropriate. Of course, that got --

LLB: That didn't happen.

REE: Well, that got disrupted when with the *Corrosion Proof Fittings* decision where EPA sought to regulate asbestos. But some of its actions were deemed to have gone too far, that they had to use the least burdensome method to protect against risk in the environment. And the Supreme Court said, you went too far with this. And so some, not all, some of the proposed asbestos regulations were rolled back. And that really made, in my view, made EPA gun shy about going after existing chemicals. They're just like, "Oh, now we can't regulate existing chemicals." Or arguably they *could*. They just -- it would -- it certainly increased the burden on EPA to take action. But I think it was more a matter of being gun shy than not being able to do it right.

LLB: And whatever the reason, at the end of the day, despite TSCA's original enactment in '76 all the way up to 2016, there were relatively few existing chemicals that were reviewed under TSCA.

REE: Well, there were attempts. There was the high production volume chemicals effort where EPA was trying to gather information about the very high production volume chemicals, using that to help inform risk decisions. EPA brought out a list of what they called the Action Plan Chemicals, which quickly morphed into the Work Plan chemicals. So there were activities within existing chemicals. There were a handful of significant new use rules (SNUR) for existing chemicals to try to bound what could be done with existing chemicals. If EPA could identify specific conditions of use that weren't ongoing, EPA could use a SNUR to regulate an existing chemical, regulate new uses of an existing chemical. So there were some efforts, but there was nothing -- there was not extensive effort, maybe is one way to put it.

LLB: TSCA, although many of us love TSCA -- old and new -- one of its many failings was the inability of the law to direct any systematic review of existing chemicals. TSCA was heavily criticized for a whole host of reasons, one of which is it was aspirational. It didn't provide structurally a mandate to review any one or number of chemicals by a date certain. That, of course, was remedied in 2016 when Congress said, "No, you're going to review existing chemicals, and you're going to do it according to this schedule." So that review is underway, but it will take quite a long while for Congress or for EPA pursuant to Congress's request to review all high-production and active existing chemical substances. We won't go into just how long that review will take, but I know I won't be around when that review is completed. And it's going to take many, many, many decades. But at the end of the day, I think Congress did a pretty good job of remedying the major criticisms of the old law when it enacted Lautenberg in 2016. But one of the issues it didn't remedy was something called the new chemical bias. And maybe for our listeners, you can tell us in a relatively straightforward, simple way what the heck does that mean?

REE: You're right. The new chemicals bias does predate Lautenberg. And in a way, it was -- it may have been in part reaction to the perceived lack of authority over existing chemicals. The new chemicals reviewers felt that the review during a PMN was the *only* opportunity to regulate a chemical if regulation were necessary. And so what was not unusual is that you have a new chemical that's very much like an existing chemical and would nevertheless be regulated in a

way the existing chemical was not because the existing chemical was largely being set aside by OPPT [EPA's Office of Pollution Prevention and Toxics] to not take action. And it was not unusual for submitters to say, "But this is just like this substance that's listed on the Inventory." And EPA back then was relatively indifferent to that. I mean, the argument was then -- and arguably still is -- that while that existing chemical hasn't been reviewed for risk and the presumption was if it was reviewed for risk, it would receive a similar sort of regulation as the new chemical. But you had this bias against new chemicals. They were receiving regulations, whether through consent orders or SNURs or both, that weren't imposed on existing chemicals. And that is the essence of the new chemical bias. The new chemical is regulated more stringently than the existing chemical.

LLB: Why can't EPA simply regulate an existing chemical on the same regulatory pathway as a new chemical if they're found to be structurally identical?

REE: Well, it's been -- EPA has to follow the law. And they have to actually go through the evaluation of the existing chemical. I guess EPA could try to stand up an existing chemicals program that looks a lot like the new chemicals program where they're trying to go through these -- go through substances more promptly. I think EPA could try to regulate with SNURs. If they have a new chemical that's very similar to an existing chemical, they could seek to impose a similar sort of restriction on the existing chemical. And then if that is an ongoing use, that significant new use is an ongoing use, that could be defeated. But then somebody would have to come forward and say, "Oh, no. We're doing that thing that you say is an unreasonable risk." And that -- so I don't know if companies would do that.

LLB: It would be hard. It would be hard.

REE: It would be a challenge. It's certainly not a model that EPA has followed.

LLB: Right.

REE: EPA is following -- with its first 30 -- they're following a much more in-depth information gathering, a much more in-depth review of toxicity information, exposure information, use information, and pulling together a much more in-depth review under Section 6, and now has started to propose risk management rules based on those risk evaluation rules.

LLB: So let's kind of summarize where we're at. There are some thousands and thousands of existing chemicals listed on the Inventory. They pretty much get a free pass, except for a handful of them that are now being reviewed under the new law. And at some point in time, all existing chemicals that are thought to be high priority will be reviewed. So active high-priority substances will be reviewed, but not anytime soon. Let's face it.

REE: There are tens of thousands of substances for EPA to review under Section 6. And it's taking them years, right? It's supposed to be three to five years, but it's been longer than that.

LLB: Sure. It's been six since Lautenberg was signed into law.

REE: Right. And they started on the First 10, so it's going to be a long time.

LLB: Yeah, right. So that is what it is. And EPA under the law *must* review new chemicals as a predicate to their importation or manufacture for commercial purposes in the United States. So that's the reality. Although EPA *could* -- Congress really never intended for existing chemical substances that may be very, very similar to new chemical substances in terms of

any property or hazard that they might reflect to be regulated similarly. That's just not the way the program works.

REE: Yes. Congress really did separate the two universes. Section 6 is the prioritization process. Section 5 is submit the notice. EPA, as you state, must review and take action on the notice before the substance can proceed to market.

LLB: So like it or not, new chemicals are reviewed and regulated, whereas existing chemicals are not. So that's -- not now anyway. They will be, but the existing chemical substances are not *now* being reviewed. So hence that is the bias. New, you're reviewed and regulated; existing, you're not and won't be any time soon. So what does that mean commercially? What message does that send to both chemical innovators that are trying to issue or create and have approved new, innovative, greener, sustainable chemicals and chemistries for whatever purpose and driven by whatever market incentives there are, versus continuing to rely upon unregulated existing chemical substances that may or may not pose enhanced risks.

REE: Yes, I wouldn't say -- I mean, we use the term unregulated, but we're really just talking about unrestricted, right? They're all regulated under TSCA. There are just not specific restrictions. I think we need to take a step back and talk about the effect of orders and SNURs. So when EPA -- and EPA is restricting in some way or another, something like 85 to 90% of new chemicals on which EPA is making a determination. So when EPA, I mean, some PMNs are declared invalid, some are withdrawn. But when EPA reviews and makes a determination, EPA is restricting in some way 85 to 90%, which is to me, a really surprising percentage. What it looks like to my eye is if EPA identifies a hazard, then EPA is imposing some restriction to protect workers, general population, or the environment from that hazard.

LLB: Right.

REE: They say, you may not be exposed to this much, and you may not release more than this much to the environment. Which seems sort of intuitive, like, that's the way it should be, but the TSCA Section 5 requires that EPA look at reasonably foreseen conditions of use. They have to look at the totality of the substance and how it could be reasonably foreseen to be used or conditions of use, releases, exposures. And then based on that, impose a restriction, whatever that might be, worker protection or releases to the environment.

So EPA's current behavior of issuing an order or SNUR any time it identifies a hazard, we can talk about whether or not that fits within the law, but that's leading to this very high percentage of regulation. That regulation is, to varying degrees, is a market impediment. If you are used to using substances without SNURs, without orders in your supply chain, you may not have the infrastructure to document compliance. I mean, it's not just the restriction. It's documenting that you're complying with the restriction that -- in fact, that's, from what we have heard, the documentation by the customer or the folks downstream in the supply chain, *that's* the barrier. So the folks downstream are saying, "Now we gotta keep all these records that I'm not releasing to water? I don't release my stuff to water. Now I have to keep all these records."

LLB: Is it? I mean, I get that. The records are kind of a pain in the neck, but is it just as simple as saying to the customer, the purchaser and user of the chemical substance, we are not releasing this chemical to water, or must you prove a negative?

REE: You have to have documentation. If you don't release it to water, you have to have the documentation of where it does go. So you have to have waste manifests, or you have to have

some documentation that shows that was not released to water. So it's not proving the negative as much as have something to show what you *did* do. But it's still -- you got to have the piece of paper, and you have to be able to show it to the EPA inspector when the EPA inspector shows up. And the downstream folks are understandably reluctant. They're like, "Well, I don't know that I could pull that together if an inspector showed up on my door tomorrow. I don't know that I could pull that together and have a complete set of records to document what we're doing. And I don't want the enforcement risk. I don't want to be at risk of hundreds of thousands of dollars of fines, because I couldn't find a couple of pieces of paper."

LLB: So is that disincentive to using that newer, greener, possibly more sustainable chemical sufficiently robust to incentivize that user to continue to use an unregulated or an unrestricted chemical substance?

REE: We've certainly heard that from clients. The market for the substance with the SNUR is much more limited than the market for a substance without a SNUR. Part of it is the recordkeeping. Part of it is just the scarlet letter of the SNUR. If you look at the SNUR regulations, it talks about when EPA can issue a SNUR. It has to be highly hazardous. It has -- they have to meet certain criteria.

LLB: Right.

REE: And so there's this historic -- and it may be unwarranted, but there's certainly this historic perception that SNUR substances are more hazardous than substances without a SNUR, regardless of whether they were new or existing. There's just like, "Oh, my God. There's a substance with a SNUR. It must be terrible. I don't want that in my supply chain." And we've heard stories about people that -- they put supply chain restrictions. They say, "Do not purchase any substance with a SNUR." Whether that's for the hazard or for the recordkeeping reasons, they restrict their purchasers from bringing anything in with a SNUR. So if you have a newer substance that's greener, by whatever metric, you could be frozen out of some markets. But there's certainly a disincentive for some of your customers.

LLB: If EPA were part of this discussion, they might say, "With all due respect, we're following the law and doing our job. Shouldn't *industry* be doing a better job of educating people with regard to what a significant new use restriction means? It means this chemical has been reviewed according to the highest standards of EPA regulation. And as a result, it's being permitted into commerce for use, which means it's passed our high standards of commercial use and import. So it's not a *bad* thing. It's a *good* thing." But again, that nomenclature and history of SNUR restrictions is entirely negative.

REE: Yes. The industry certainly is battling against the history of the perception of SNURs. That is part of the problem. And we do work with our clients to educate supply chains about SNUR compliance, and this is what the SNUR says, this is what the SNUR says you *may* do, this is what the SNUR says you may *not* do. Here's how you can document compliance with the SNUR. We're absolutely doing that with our clients and with our clients' customers and trying to do more in that supply chain communication.

Some of our clients are reluctant to give legal advice to their customers. And that's certainly a tension there. But we are doing more with clients to develop explainers to ease that. And EPA has certainly said to us. Lynn, we've been in meetings together. It's like, "When is industry going to get over SNURs?" And to a certain extent, the reality is there will be more orders and SNURs under Lautenberg. I don't think there's any debate about that. I think there's still a debate about when is it necessary, when is it when is it really -- is it really true

that if EPA identifies a hazard, there must be a restriction? Or is there some judgment that EPA can bring to the decision to consider the totality of the conditions of use, the substance, where the market is, and let some of these things go forward without restriction, whether there are other factors that lead EPA to conclude that there won't be an unreasonable risk or that, using the pollution prevention paradigm, the reduced risk decision making, being able to say, "Oh, look. This new chemical is actually quite a bit better. We actually want this in the market to display something that's there that EPA hasn't yet gotten to for an existing chemicals review but has some concerns about. This new chemical can displace that. Let's use the market and the pull, because there's certainly a lot of pull in the market right now for greener chemicals, use that market demand with this newer chemical, which may still have a hazard, but it's better than what's on the market. EPA used to do that. That started to fade away before Lautenberg, and now it's entirely gone, as far as I can tell.

LLB: Right. Well, it's always been voluntary, right?

REE: It's always been voluntary.

LLB: Which telegraphs a message. If it were mandatory, you must be greener, and demonstrate how, that might be a bit more influential. But let's drill down a little bit into that reasonably foreseen aspect because I know there are some borders around what is reasonably foreseen or foreseeable, right? But whose imagination controls what is reasonably foreseeable with regard to the utility or use or application of a new chemical? Is it the EPA reviewers? Is it the manufacturers? Is it the innovators? Who dictates what is reasonably foreseeable with regard to the use of a new chemical substance?

REE: Well, the statute gives that authority to the Administrator, which means all the way down the management chain. But really, it's in the eye of the reviewer, the specific EPA reviewer who sometimes, sometimes we hear -- well, let me take a step back. In I think it was about 2017, EPA was starting to wrestle with the term and put out some guidance, made some public statements saying "reasonably foreseen" means the intended, known, and reasonably foreseen, but not merely hypothetical. So there was nominally a limit, but that's not what we saw in PMN reviews.

LLB: And that was only guidance, right? That was never embedded in a law or a regulation.

REE: Those were public statements made by management. There was no -- that was just what the upper management within OPPT and [Office of Chemical Safety and Pollution Prevention] OCSPP was stating at the time. And it was written in their not likely determination document, so not likely to present unreasonable risk -- when EPA concludes that a substance is not likely to present an unreasonable risk, it writes a determination document. And in the footnote, it quoted that "reasonably foreseen" means this, this, and this.

That language is now gone, which I thought is very interesting. It appears that that's no longer, there's no longer a limit, or at least management's not citing a limit to what's reasonably foreseen, which, frankly, I think better matches what we've seen in terms of the implementation.

LLB: Well, in terms of the practice.

REE: The practice was well, somebody might do that. But we don't know in the future, like if somebody might do this, that, or the other thing. And so there has to be an order. And then if

that thing happens, then you have to come back and ask permission, which strikes me much more like a pesticide registration.

LLB: Very much so. Everything is use specific.

REE: Right. You get -- You're allowed to do what you asked for. And if you want something else, you have to come back in and ask permission again.

LLB: Right.

REE: And that *seems* like the way it's been operating, with a little bit more flexibility, because they'll be specific, like, there might be a surface water concentration limit. Well, you can use this anywhere as long as you don't exceed the surface water concentration limit. So there's a little bit more flexibility there. But it's still somebody might at some point someday exceed the surface water concentration limit. So we need to have one, even if it's a rather, a moderately or low moderate toxicity for aquatic. And EPA doesn't predict -- even with its most conservative models, EPA doesn't predict an exceedance. They still say, "Yeah, but somebody might someday exceed that, so we need to put the restriction in place."

LLB: But doesn't that tend to read out of the statute the term "reasonable"?

REE: Well, that's the debate, right. If EPA, rather than reviewing what is reasonably foreseen, EPA saying, "Well, we haven't looked at it yet, so we have to prohibit anything that we haven't looked at." And I think that's a failure to do that reasonably foreseen exercise. What *is* reasonably foreseeable to happen? And we do need to remind listeners that Congress specifically said that misuse is written out of the definition of what is reasonably foreseen. So that does -- it's not just like, well, somebody may do this horrible thing. It's well, okay, but is that horrible thing a misuse of a chemical?

LLB: It certainly wasn't an intended use of a substance, and an intentional misuse is not -- seems to me you could make the equation that an intentional misuse is, by definition, not reasonable.

REE: That's basically what Congress said. It was foreseeable, but not reasonable.

LLB: But not reasonable. And so I think the tension that we have seen -- and this exists also in the context of FIFRA [Federal Insecticide, Fungicide, and Rodenticide Act] applications. Intentional misuse of a pesticide is beyond the scope of the registration decision.

But that said, you start thinking creatively about what is reasonable and what might someone do if not being guided by an intentional misuse situation. EPA's job is to prohibit any type of hazard that might evolve or ultimately mature into a risk, given this chemical. And if some reviewer is thinking, well, this could happen. It's reasonable. What is reasonable to one reviewer and what is unreasonable to an innovator or a PMN submitter, I think therein lies the tension.

REE: Yes. This is -- and we've been talking about this now for over six years -- is what does this term mean? How should it be implemented? We've been advocating for, promoting an opportunity to discuss meaningfully, have a broad stakeholder discussion about the meaning of that term. And we've certainly talked about it on the TSCA at Five, TSCA at Six. These terms have come up. Even the very first one, you asked the committee, would anybody support --

LLB: A FACA [Federal Advisory Committee Act].

REE: A federal advisory committee to wrestle with all these new terms in the law? And it was like crickets. Nobody wanted to say, yes, that's a good idea. I think they've been frustrated enough in the past that they're like, "Oh, no, FACA. We don't want to do a FACA." Instead, now we have almost person-by-person different definitions of what is reasonably foreseen because it depends on what the individual or the small group at EPA decides on any particular case.

LLB: Right. Well, that absence of clarity, of more specificity, trying to just bound that concept of what is reasonably foreseeable, has consequences. What are the consequences that you see most often with regard to EPA review? People who submit PMNs can live with the consequences of EPA's review and live with the restrictions that are derivative of a PMN review, or they can push back. So let's talk first about what are the range of consequences, and then perhaps talk through what some of the pushback might include. And then if the order or SNUR ultimately comes out, what are the implications of that? And what are the consequences, and what is the recourse of that? But as you're going through the PMN review process, what is your typical fact pattern when you begin to suspect that EPA might be interpreting "reasonable" in a way that is far more generous than what we might, for example?

REE: These days, we advise clients -- we look at the totality, and we're like, "You are going to get an order for -- that includes these provisions." I mean, EPA has actually become fairly predictable in its precautionary stance. And so you look at the totality of the facts, at what's known about the hazard, about the substance, about analogs, EPA's models. You can use EPA's models to predict releases and exposures. You could even do measurements, workplace measurements. And you can bring forth a fact pattern that shows, as intended, there's no unreasonable risk.

And we can confidently work with a client to say, "Okay, with this set of facts, we can achieve a restriction, a consent order -- or an order -- take consent off the front of that for a minute -- you can achieve an order that allows you to do what you've stated here, but it's going to come with these restrictions for you and your customers, and those restrictions are going to trigger these recordkeeping requirements and export notification requirements and other paperwork. Call them paperwork because it -- it's not that it's never true, but generally, there's an understanding in the supply chain that if a substance has a particular set of hazards, you *must* protect your workers, you must limit releases to the environment, whatever's true for that substance.

And then the business has to decide, okay, we can live with that. Our customers are going to be able to live with that. Or not. If they think, "Well, then, if we get an order and a SNUR for this substance, it's dead in the market" then they may just decide not to submit a PMN. It may be quite a bit greener, but they're just like, "I don't want the public perception of this substance to be --"

LLB: Irrefutably prejudiced.

REE: "-- to be prejudiced by the existence of a SNUR. Because true or not, a SNUR is still perceived to be a mark of badness for a substance. So there's certainly some cases where clients have been like, "Yes, I'm not even going to bother. I'm going to stick with foreign markets. I'm going to stick with cosmetic market, or some non-TSCA use," even for these wonderful green chemicals. They just don't bother.

LLB: Yes, which is regrettable, obviously. So if the best possible PMN application is not able to persuade EPA that some new chemical, as green or greener and sustainable as it may be, *vis à vis* an analog existing chemical substance, and the submitter chooses to go forward and just endure the consequences of a perhaps diminished market, or whatever the consequence is. The bottom line is that the chemical review process as it stands now really doesn't allow many options. If you are wanting to commercialize a chemical and if 85% of the chemicals going through the process are subject to some form of restriction. That is what it is, right?

REE: Yes. Someone could submit a PMN, a very well-founded, well-documented PMN, could refuse to suspend, force EPA to take unilateral action. EPA would issue a unilateral order, presumably. And then you could challenge that unilateral order in court. You can't challenge a consent order. If you agree to a consent order, you can't then go and sue on that because you've agreed to it, which is partly why EPA likes consent orders.

LLB: Sure, because it eliminates the uncertainty of a judicial review.

REE: Right. But it's unusual that a company's willing to take the risk of a legal challenge of an order, so they pull together. They spend all the time and the effort, and they pull together a really good PMN. That's a lot of time and a lot of money. And they submit it to EPA and they wait however long they have to wait. EPA finally issues an order, and then they have to go to court. And then you have to endure the uncertainty and the expense of a court challenge. That's a pretty high burden. And so -- I'm not aware of any cases where someone's taken that action. It certainly hasn't been in the news or, as far as we can tell, in the courts.

So mostly your options are endure what's going on; withdraw, abandon the TSCA market, and innovate elsewhere; or political advocacy: Try to bring the powers that be or try to get the decision makers that put Lautenberg in place in the first place to say either, "Yes, this is exactly what was intended, or no, there were supposed to be some boundaries on what is reasonably foreseen. I think one of the markers for me that new chemicals are not being implemented as intended is test data don't really change the outcome.

LLB: I was going to ask you about that.

REE: So the big driver of TSCA reform was getting more information about chemicals, existing and new chemicals. We need better data on all these things. Having data, having even extensive data, does not get you out of that adverse -- that restriction, right? It might change the *level* to which you are restricted. But if there's -- again, if there's any hazard, you don't -- there's no way to avoid a restriction. And that strikes me as an indicator that there's a disconnect between congressional intent and what EPA is doing.

LLB: Hazard is just one part of the equation, right? I mean, chemicals tend to be hazardous --

REE: To some degree or another.

LLB: -- because of their inherent chemical properties, right. It's not a value judgment. It's more a statement of fact. But that hazard is mitigated by the concept of exposure, which means if the intended conditions of use suggest that hazard plus exposure means there is limited risk, that equation can be easily altered once again by somebody else's presumption as to what a reasonable use might include, which might not be the use that was intended by the innovator, or even those that are likely to be using it. So it seems to provide an infinite variety of options that give the regulator an awful lot of discretion to impose restrictions in a way that perhaps Congress didn't intend and certainly the innovator didn't intend because of a well thought out

fact pattern regarding intended conditions of use, which wouldn't include some of the more outlandish, less reasonable, and in my view, almost fantastical conditions of use that we've addressed in the new chemical review process.

REE: Yes, opening the beer bottle with a chainsaw.

LLB: Well, talk about that a little bit, because that is a very visual optic that I think telegraphs some of the outlandish circumstances that we're referring to here.

REE: Yes. For me, it was the quintessential example of, well, yes, somebody might do this -- In this case, it's opening a beer bottle with a chainsaw. I think someone might use a chainsaw to open a beer bottle. Is that a reasonably foreseen condition of use for the chainsaw that then EPA would have to impose an order and a SNUR to say, "Thou shalt not open -- attempt to open a beer bottle with a chainsaw."

What reasonable person would do that? Is that reasonably foreseen? And it certainly happens, because you can go on YouTube and find videos of it. You can go, there's no question that it happens. And that, I think is, in my interaction with some of the assessors at EPA, they're like, "Yes, this might happen. Somebody could do this. Or this *has* happened. There are cases where workers -- where employers don't protect their workers." I can't debate that. I can't say that no one will -- that in no case will somebody ever try to open a beer bottle with a chainsaw, because I know it has happened.

LLB: No, but at some level, that is not the standard, because that is not reasonable.

REE: That's exactly right. The fact that it *has* happened or that it might happen cannot be the standard.

LLB: Right. Because if it is the standard, then nothing will escape regulation.

REE: And Congress would not have said that misuse is not a reasonably foreseen condition of use.

LLB: Or inserted the word reasonable.

REE: Absolutely.

LLB: Right, right. But these are the conversations that I know, Rich, you have pretty much every day, five days a week, on all the new chemical applications that are -- and I don't know how this debate will be resolved. We have urged in this part of our advocacy here at the firm the type of discussion with innovators, users, and others to get some boundaries around what could be an infinite set of circumstances that, absent better guidance, inevitably leads to everything being restricted at all times. And the consequence -- there are real consequences to that. If there's a disincentive to innovate, we've seen a precipitous drop-off in new chemical submissions. We've seen most chemical applications now being subject to a restriction of one form or another, which again in and of itself is not bad *per se*, but it would be wrong for EPA not to consider the consequences of that, because cumulatively or even individually, there are consequences, which could be we're just not going to go that route. We're going to stick with what we have. Users don't want the rulemaking, or recordkeeping requirements, or the uncertainty of how best to communicate SNUR restrictions down the value chain. So all of these things have consequences, and for the regulated community and all stakeholders to kind of take a blind eye to that strikes me as being just very unwise.

REE: And we have seen a substantial drop in the number of new chemical notices. We've had clients tell us about their restriction in research and development (R&D) spending. They're just not innovating, because you cannot get the return on your investment in the U.S. market. We certainly have clients that are taking their innovations and deploying them everywhere else in the world.

LLB: Except here.

REE: Except in the United States, under TSCA. They may deploy in the United States under other statutes, FFDCA [the Federal Food, Drug, and Cosmetic Act] in particular. But it's easier to get to market in Europe under REACH [the Registration, Evaluation, Authorization and Restriction of Chemicals regulations] than it is in the United States under TSCA. And I think that surprises a lot of people. And certainly some of our clients that are global are like, "Yes, we're doing this gangbusters in Europe, and it's going into all these consumer products, and there are all these wonderful benefits because this stuff is a lot greener. But, of course, to get to that level, they've developed a really good fact set of hazard data, because you have to have that to get to market in REACH. And you bring that hazard data to the United States, and you still end up with a restriction. And it's just the reality is that that right now PMNs are very likely to be restricted with an order and a SNUR.

LLB: Which is regrettable, given the extraordinary pressure, both commercial and social, to innovate chemicals that have fewer greenhouse gas emissions, can work at cold water temperatures --

REE: For laundry, yes.

LLB: -- are not as demanding for heat and other thermal con -- you name it.

REE: Oh, yes. And just the straight toxicity. There are cases of companies specifically designing hazard endpoints out of a molecule. They know the existing molecule has a particular hazard that's concerning, not that they've identified risk, but oh, we have this concern, so let's design that out. And they do the hard work, and they figure out what it's from, and they make that change, and they still get the function, but without the hazard. And that new molecule *still* is more heavily regulated than the existing one, that is known to be more hazardous, not just differential in risk, but here's a specific design to a lower hazard, and you still end up with that restriction. And it's disheartening for innovators, for green chemistry innovators. If you can't meet that magic threshold of low hazard to health and the environment, that you're going to be restricted.

LLB: What advice, Rich, do you give companies that come to you to say, "I've got a brand new pixie dust. I've got this fabulous new chemical substance that will make the world a better place. How can I prepare the PMN in a way that will not invite a restriction?" Or if, as I think what you're saying is, prepare yourself for restriction. It's a question of degree, not a question of whether there will be restriction.

REE: Yes. And one of the things we do when we're looking at a new chemical notice is what restrictions can we look for, anticipate, that allow maximum commercial flexibility while still protecting from the potential risk, basically protect against the hazards that EPA might identify. So in some cases we're looking for -- we've had some clients agree to production volume limits rather than restrictions elsewhere in the supply chain, because as long as the production volume is below a certain number, EPA didn't find an unreasonable risk. That is often commercially easier for the submitter to deal with because, if the order and SNUR are

written properly, no one else in the supply chain has to document that they did not manufacture or import over a threshold because they didn't manufacture or import. They still have export notice requirements. You can't -- there's no way to avoid that if there's an order or a SNUR. But something like that, a production volume restriction or some other restriction on manufacturing, or a threshold. So we've seen this with fragrances, that once you get a fragrance below a certain threshold in formulation, EPA will conclude that now it's low enough hazard that there doesn't need to be a restriction. And so that, again, limits the effect of the order and the SNUR on the upstream part of the supply chain that is probably more capable of doing the recordkeeping and being confident that it can do the recordkeeping and then less restrictive on the folks downstream that don't know how to *spell* SNUR.

LLB: One further question with regard to data. I know many of our clients are always trying to support their PMN applications with the best possible information and data. But if, to your point, some of those data might be overlooked or not relied upon because of worst-case assumptions that don't align with those data, what do you tell clients when they say, "Should I engage in these tests? Should I wait, do the data, submit it with the PMN with the hope of ensuring a better result?" Or -- what is your advice to clients that come to you to say data or no data?

REE: Yes, it depends a lot on the specifics of the case, because sometimes -- you definitely need a fact set to support no unreasonable risk as intended. Because if you don't have that, you can't go to market at all. So do we have sufficient facts with the information that they have with EPA's models and information on analogs? If we can support that, then the question is, okay, based on this information, this is what we think EPA is going to impose in terms of restrictions. Can you live with that?

And if you can't, here are the places we might be able to work at the margins. So we definitely have very robust conversations about what sort of testing might be needed and how can we fill those gaps while fulfilling EPA's mandate to minimize vertebrate testing. So how can we fill those data gaps without extensive *in vivo* testing? A lot of companies are like, "I just want to -- just tell me what testing to do, because I don't care how much it costs. I want to get this to market, and I want to get this market without restrictions. And we're like, "That's not going to help."

LLB: Right. It might not happen.

REE: You can spend all these millions of dollars, and you're still going to end up with some restriction. It's only if the new substance is very far outside, like, we can't find any analogs. We have no idea what argument to make about hazard. Then it's like, okay, we're going to need some test data on this just to fill these most basic requirements because we have no idea how hazardous this might be because it's so novel. Then we'll come up with a test plan that looks probably more like something that you would do for REACH, where you're working up through tiers of testing, do some *in vitro* testing and use that to inform some low-level *in vivo* testing to show that, in a critter, that you're not seeing a really remarkable toxicity endpoint. It's like, no, this is moderate toxicity, presumably, or low toxicity for some endpoints and moderate for others. And then you have that fact set to again get to "use as intended." But right now, I do not see a path to unrestricted use in a PMN if it's not documentable as low hazard to health and the environment, acute and chronic.

LLB: Got it. And you're in a position to let PMN preparers know what that means.

REE: Oh, yes. That's an intimate part of the conversation where this is what we've got. I'm like, "Okay, here's what you can expect out of EPA if you submit that as a PMN, with the data that you have or with the data that you can develop.

LLB: Right. So in closing, Rich, what advice do you give to a chemical innovator, whether it's from a big company or just a brand new university knockoff? They have a new pixie dust. How do you prepare them in terms of expectations, both in terms of the level of pushback you might get, what type of restriction might you expect, and what timeframe are you looking at in terms of submitting the new chemical notification to actually having a commercial product ready to rock and roll?

REE: Yes, the latter thing is tough right now. EPA's review timelines are exceedingly long.

LLB: What's long?

REE: Years.

LLB: Really?

REE: I would -- if a client came in today and said, "How long?" I'd say no less than a year. Right. It's going to be at least a year for you to get an order, and maybe two. And then, because the way the order is written, you can't distribute more than one level of supply chain until the conforming SNUR has been published in final, and 75 days after that.

LLB: Wow.

REE: Yes. If you're looking at supply chain two deep, then it could easily be four years from when you submit, to 75 days after the SNUR is final. And that's a tough pill to swallow. And sometimes we can mitigate that, again, with these, sort of like, where does the restriction end? So that you *can* do that distribution. And we're certainly trying to be creative with that. And EPA has been --again, if we can make that argument, here are the facts that say, "Okay, EPA, after this point in the supply chain, whether it's concentration or, whatever it is, that restrictions are no longer needed." And EPA can bound the order and the SNUR, then that's where you can shorten that four years to maybe two. But it is a long slog right now, getting through EPA. And it's tough. And EPA knows they're in a tough hole, in a tough spot, and they're doing what they can. But they just -- the reality is it takes a long time.

LLB: Yes. Well, I know, Rich, nobody does it better. No one provides better science and regulatory counsel than you in navigating this very, very challenging pathway.

REE: Well, I would say our team. You've assembled really quite an extraordinary team here. And it's --

LLB: Which you lead, as Director of Chemistry.

REE: I'm happy to be part of it. I feel like we serve our clients well, even if we can't give them happy answers.

LLB: And maybe you can direct listeners to where they might look on our website for additional information on these difficult and scientifically challenging topics.

REE: We are frequently writing on TSCAblog®. So there's -- multiple times a week we're writing on TSCA issues. We also have TSCA Tutor®, so people that are new to TSCA and they need some training, TSCATutor.com provides on-demand, online training in manageable chunks. So you can sign up for one or many of the modules there. If you've got a particular technology that you're considering bringing to market, that's really a conversation we should have because the devil's in the details. The resources, the very generous resources that B&C puts out in terms of what's going on in TSCA and nuts and bolts are all available on lawbc.com.

LLB: Right. There's a number of TSCA pages that listeners might log onto to help in that regard.

Well, Rich, always a pleasure. You are so good and so expert in this space. And I know you're a very, very popular guy and very much in demand on these issues. You just are brilliant, and we are so grateful to get this information out to the public.

REE: I appreciate it. And again, it's great to be back on the podcast with you.

LLB: My thanks again to Dr. Rich Engler for speaking with me today about new chemicals, the bias in TSCA rules, and EPA's implementation of them, and what can be done to minimize the effects of this bias.

All Things Chemical is produced by Jackson Bierfeldt of Bierfeldt Audio LLC.