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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, litigation, and regulation. I'm Lynn Bergeson.

Recently, we published a three-part article in Bloomberg BNA entitled "New Chemicals under TSCA: Stalled Commercialization." This week, I sat down with Charlie Auer, our Senior Regulatory and Policy Advisor, and Dr. Richard Engler, our Director of Chemistry, to talk about the article.

Our thesis in the article is very simple. The U.S. Environmental Protection Agency's (EPA) interpretation of our brand new industrial chemical law known as the Frank R. Lautenberg Chemical Safety for the 21st Century Act, signed into law in June 2016, needs to change. We believe that Congress never intended fundamentally to overhaul the new chemical review process and to require that EPA regulate north of 80 percent of all new chemicals. Ironically, however, that's exactly what the new law is being interpreted to do, in contrast to the old law that regulated approximately 10 to 15 percent of new chemicals. Our article explains the new law, contrasts it with the old law, and critically reviews the numbers coming from EPA's review of new chemicals, taken directly from EPA's database. We did this to prove our point, and we think we did a good job of doing so. Our discussion that you're about to hear offers some suggestions to fix the problem to move EPA in the direction of what we believe Congress intended: to effectuate an efficient chemical review process. Charlie Auer and Rich Engler are the perfect guests for this discussion. Charlie ran the Office of Pollution Prevention and Toxics (OPPT) for years at EPA before joining our staff. He knows more about EPA's inner workings in this area than anyone. Rich reviewed about 10,000 new chemical notifications during his 17 years at EPA before joining our staff, and he's been working closely with EPA and clients to address these issues. So here is my discussion with Charlie Auer and Rich Engler about the new Toxic Substances Control Act and the effect it has had on chemical innovation.

Good morning, gentlemen.

Gentlemen: Good morning.

LLB: So happy to be here today with you to talk about one of our favorite subjects: the Toxic Substances Control Act, and in particular, new chemical regulation by EPA. The reason we're talking about this is in September 2018, B&C prepared a three-part article on the commercialization of new chemicals and what changes in the law did to that process. There are both challenges and opportunities, but at the end of the day, we see there are many issues to dig into that we do in our article and we're going to talk about some of them here today.

Why don't we begin with the difference between old TSCA -- the law that existed before 2016 -- and new TSCA. Rich, maybe you can help our listeners understand what the process was like before the law was amended and how it has changed. Because as I understand it, under the old law, new chemical innovators were able to submit an application, pop it into the Agency, 90 days later, if EPA didn't say anything, you basically were good to go.

Richard E. Engler (REE): That's correct. A premanufacture notice (PMN) would be submitted to EPA. EPA would have 90 days to review it. If EPA took no action, you could immediately proceed to commercialization. Now, under the new law, EPA must review and must make a determination either that the substance is not likely or that there may be issues. And if EPA finds that there may be issues, EPA *must* take action, whereas before, EPA was not required to do anything. EPA had an opportunity to review, and if they did nothing, as you said, you could proceed to commercialization. That's no longer an option. EPA has to do something.

LLB: Charlie, what's wrong with that? One of the reasons TSCA -- the domestic industrial chemical law -- was subject to pretty extensive amendment in 2016 was that there was a public perception that EPA did not adequately control existing chemical substances and might not adequately investigate the potential toxicities of so-called new chemicals. What's wrong with EPA making a determination?

Charles M. Auer (CMA): I think that EPA moving to a scheme where it was required to take determinations was seen by some stakeholders as one of the issues with old TSCA. Although EPA in almost every case made decisions and took appropriate actions, there was not a record necessarily created to document that, and some stakeholders believe that you needed a more affirmative process where EPA was required to take a decision and then follow that with appropriate actions, and only after those steps were concluded could a company go into commercialization. At the same time, while new chemicals were seen as an issue by some stakeholders, I think in general the bigger issues were seen to involve concerns with existing chemicals. The *Corrosion Proof* [*Corrosion Proof Fittings v. EPA*, 947 F.2d 1201 (5th Cir. 1991)] decision regarding EPA's attempt to regulate asbestos, for example, pointed out the tremendous difficulties in old TSCA Section 6 and the ability to regulate existing chemicals. There was also a lot of concern about the failure by EPA to generate sufficient test data through use of Section 4. Those were the issues that, in my view, were the main drivers for TSCA amendment. However, as it played through, there were some surprising changes in Section 5.

LLB: Let's dig into that, because as we know, those of us who practice in the TSCA area were well aware of largely consumer concerns with the perception that existing chemicals -- those chemicals that are identified by EPA as in existence and have been for many years -- were underregulated and that EPA lacked appropriate authority to regulate risk posed by existing chemicals. From my perch as a TSCA counsel, I always thought the Section 5 program that dealt with new chemicals worked pretty darn efficiently.

As Rich, you noted, a new chemical PMN (premanufacture notification) went in, EPA would spend time rigorously reviewing it, and after 90 days, if no problem was discerned,

you were pretty much good to go. When we looked at the revisions to new TSCA in the Frank R. Lautenberg Chemical Safety for the 21st Century Act back in June 2016, I think we all let out an audible gasp at the depth and extent of changes to the new chemical program.

Was there an extensive critique of new chemicals leading up to TSCA reform, or did this come as kind of a shock to everybody? Rich?

REE: What I expected was for the Lautenberg Act to essentially systematize the new chemicals review. It insisted that EPA would review every PMN, so it's no longer "if EPA does nothing." EPA is forced to take action, but I didn't expect a change in EPA's *thinking* about individual PMNs. I agree. I thought the PMN process was very efficient, very effective. Among the many, many thousands of PMNs that I reviewed, I never felt that a PMN went forward without adequate protection. If staff identified an issue with a PMN, that would get addressed in the PMN process and EPA would impose a [significant new use rule] (SNUR) or consent order, depending on what the issues were. I thought that it was both efficient and protective to health and the environment.

The fact that the system seemed to be memorialized in the law made sense to me, and some of the details -- potentially exposed and susceptible subpopulations -- those were considerations. Reasonably foreseen uses -- those were considerations. I think what changed was the interpretation of some of these terms. Rather than the language in the law, I think what really changed on June 16 was the way EPA was interpreting its obligation and interpreting some of those legal terms.

LLB: Could one of you help me understand what a new chemical is? Under the law now, as I understand it, there are some 85,000 - 86,000 chemicals listed on the TSCA Inventory, which is the list of chemicals that are presumptively thought to be existing because they're on this list. What is not on the list, and what makes it a new chemical? Charlie?

CMA: Under the law, EPA was charged with creating this inventory of substances in commerce that's known as the TSCA Inventory, and any chemical not listed on that Inventory that a company wished to commercialize was required to go through the premanufacture notification -- the PMN process -- as a new chemical. Under old TSCA, EPA reviewed those notices and took decisions as appropriate. Under new TSCA, there's a bit more of a rigorous requirement to make determinations and take required actions. But in general, the processes are very similar under both old and new TSCA. Once a new chemical has passed through that process and a company decides that it wishes to manufacture or import the substance, they notify EPA, and the chemical is added to this listing of chemicals in commerce in the United States.

REE: An important distinction I think we need to recognize is that there are many, many, many more chemicals in commerce in the United States for other purposes. There are pharmaceuticals, there are cosmetic ingredients, there are food ingredients. Those are all regulated elsewhere. TSCA focuses on the uses that are not regulated by other statutes. Even though there may be hundreds of thousands of substances in commerce, only about 85,000 are in commerce for uses that are regulated by TSCA. Some people have the notion that just because a CAS [Chemical Abstracts Service] number exists that means that substance is in commerce and therefore it's on the Inventory, but that's not the case. We need to remind listeners that this list of existing chemicals is made of substances that have been manufactured or imported for specific TSCA uses.

LLB: Understood. Charlie, let's talk about the references in the article to chemical innovation in the 21st century. We here at B&C represent a fair number of new chemical innovators. Chemical innovation, however, is very different than it was 40 years ago, when old TSCA was first enacted. Can you help our listeners understand what some of these differences are and why they matter for purposes of this new program?

CMA: I would agree very much that a company's approach to new chemicals and innovation is very different compared to the approaches that existed 40 years ago. At this time, companies emphasize -- in addition to performance and cost, the traditional issues that might be important in innovation -- additional aspects, such as the need for reduced risks or greater interest in sustainability, a better energy profile. These are all examples of drivers that exist now in innovation.

At this point in time, most new chemicals are intended to achieve a particular and often discrete market need and frequently represent only an incremental improvement in performance or reduced toxicity, energy demands, and so forth. But the result is a very strong continuous improvement scheme with new chemicals moving into and then out of the market as further improvements are realized with other new chemicals. There are many drivers for this: tort and product liability, stewardship standards, the emergence of Green Chemistry concepts, and increasing societal and industry interest in providing reduced risk profiles and a better environmental footprint for their products.

When I first started reviewing PMNs in the late 1970s, these drivers were not evident. A classic example was submission of new chemicals on benzidine dyes. Benzidine is a known human carcinogen. Nonetheless, the industry regularly submitted such dyes during the early years of TSCA, until the companies came to recognize that the risks of these products were just not acceptable. The result of that was innovation in safer non-benzidine-based dyes. That's but one example. There are many others. There was great interest in the '70s and '80s in coatings that did not require solvents, and so the evolution of 100 percent solids polymer coatings was an important driver. Now there are so many other aspects that are emphasized in innovation.

LLB: It sounds like those drivers are really good.

REE: They're positive for the environment, they're positive for the economy.

LLB: Right. So what's the problem? If all of these drivers are incentivizing the development of new chemicals that are safer, less toxic, greener, and more efficient, I think that it really gets to the heart of the article. What exactly in new TSCA is causing that incentive to somehow work against new chemical innovation?

REE: One of the changes that we've seen in TSCA implementation is that, whereas before Lautenberg was passed, EPA would consider pollution prevention criteria in PMN reviews and think about how the substance in the PMN fit into the universe of existing chemicals. And could that substance provide pollution prevention benefits? Whether it was a less toxic substance, or it allowed low [volatile organic compound] (VOC) paints, or energy efficiency somewhere in the supply chain, and then EPA would consider that in its decision when deciding what action to take on the chemical. We haven't seen that under new TSCA. We've seen that fade away as a consideration, and we don't see support of that in the law.

LLB: If I recall correctly, Rich, the pollution prevention attributes of a substance under the old law was a voluntary field on the PMN form, So EPA's consideration of it was invited if asked but not required under the law.

REE: That's absolutely true. The optional pollution prevention information is exactly that, optional. That has not changed since Lautenberg. You still have the option to provide that information. What has changed is EPA no longer seems to consider it as part of its decision-making. That was one of the changes that I think has affected innovation and slowed the progress of innovative products into the market.

LLB: Charlie, perhaps you can help our listeners understand exactly what these new determinations are, because it sounds like under the old law, EPA in fact made determinations but perhaps not in as disciplined or transparent a way as what the new law requires. But what are these determinations, and how are -- is the process of making these determinations somehow slowing down the innovation process?

CMA: Sure. The first of the determinations is that a chemical presents an unreasonable risk. This determination is not made very frequently. It's relatively difficult with these substances at this point in the understanding. However, when EPA is able to make that determination, it's required to regulate the substance.

The second determination is a little more complicated; it has three parts. If EPA can find that there is insufficient hazard information, toxicity information, on the chemical, or that it may present an unreasonable risk, or that it has substantial production and exposure, EPA upon making that determination is required to regulate to the extent necessary to protect against the unreasonable risk.

The third of the determinations is a new one under the amended law. This is a determination that the chemical is not likely to present an unreasonable risk. When EPA is able to make that determination, the submitter may commence manufacture and EPA must publish a statement explaining its reasoning for the not likely determination. The result is that EPA now is required to take a decision and an appropriate action on every new chemical, and absent the decision, commercialization cannot go forward. In many ways, it's a very different scheme than existed before. The broad outlines are similar, but the details are different in important ways.

In its implementation of new TSCA, however, EPA has had to deal with some new terms, new concepts. Issues have crept in because of the way that EPA attempted to take its decisions and act, perhaps in a too precautionary way, which goes beyond what might be seen as the requirements under the law.

LLB: It's been 2.4 years since the law was amended, and in looking at the past two and a half years, TSCA implementation has often been likened to building an airplane while you're in the air. There was no transition period. EPA one day was working under the old law, and on June 22, 2016, it was operating under a new law. We lawyers find that very, very challenging, and I can imagine if, Rich, you were back at EPA reviewing new chemical substances, you were confronted with all kinds of logistical and operational challenges. One of the decisions EPA made immediately was to take everything that was in the innovation review pipeline and review pipeline at EPA and simply say, "You know what? We have to start all over again." The 90-day clock on every pending chemical substance began again.

REE: Notably, for things that had been suspended for a long time, for whatever reason.

LLB: When you say suspended, you mean what exactly?

REE: If for some reason during review, EPA asked for additional information or had some questions, EPA might reach out to the submitter and say, "We've identified this issue. We can proceed with a regulatory outcome, or you can try to develop more and provide us with more information develop some test data, or whatever, to help inform EPA's decision." And then the submitter might suspend the 90-day clock -- so just hit pause -- and then go back and develop whatever those data are. It might be toxicity testing; it might be some use scenarios, so that EPA can make a more informed decision about that particular PMN. PMNs can get suspended for long periods of time. There were a number of cases that were suspended four years -- that were in suspension four years on June 22. Even though they might have been submitted in 2014, their 90-day clock was reset, as you say, and EPA started the review all over again.

LLB: That must have caused a fair amount of confusion within the new chemical office at EPA. You had everything coming into the system. Everything in the system had to be re-examined under the new law. What did that mean in the real world? What happened?

REE: It meant that there were many, many cases that suddenly EPA had to review. Normally, there'd be a fairly steady rate of submission of PMNs. There was some variability throughout the year, but generally about a thousand cases a year come in, and it's pretty steady over the 52 weeks of the year. But now all these cases that we're in suspension had to go back in and get reviewed again, so not only were there new cases, but there were all these old cases that EPA had to re-review. That immediately put a tremendous burden on the PMN process, the review process, and all the teams that had to look at every PMN. They had the new stuff coming in, and they had the many, many old cases that they had to re-review, so they started in a deep hole.

CMA: It was not clear to me why EPA decided that it needed to restart the clock on all of these chemicals. We did not read the law as requiring this step, and EPA could have decided to handle old cases under old TSCA, perhaps for some limited time period. However, as Rich noted, because of EPA's decision to restart the clock, there was an immediate backlog created of several hundred cases, and the backlog only grew as the months progressed. This EPA decision contributed greatly to the problems that EPA and industry encountered at the outset. Now, over two years later, the delays have not been fully resolved.

LLB: Right. I recall in June 2016 receiving many phone calls from pretty irate, bewildered clients wondering where the heck their chemical review was. I think it's important for listeners to appreciate the domestic and really global chaos this new program invited. You had a relatively predictable chemical review process for 40 years, and now all of a sudden EPA had a brand new process that it had to implement as it was reviewing chemicals, which put a lot of chemical innovation in a state of suspended animation, with no clear pathway forward, as EPA struggled -- not in a bad way, but legitimately -- had to deal with the new program that Congress required that it implement. So, Rich, you recall at the time --

REE: Oh, there were cases that were on day 89 that had been dropped. EPA hadn't identified any issues under the old law. Day 89, they're ready, day 90, they want to commence on day 91, and the law gets signed and now, as you say, suspended animation. We don't know when EPA is going to restart the review. How long is that going to take? What decision are they going to make? It was quite chaotic for people that were in the process at the time. For people that were submitting new ones, it was also an unknown because we didn't know what

EPA was going to do, but for the folks that were in the process, and especially near the end of the process, it was very frustrating.

LLB: Indeed. This is especially so since Section 5, the new chemical program, was really never high on the list of congressional to-dos. I mean, a Section 5 do-over was not really what any of us anticipated, so to drop this bomb in the center of the TSCA program caused both domestic and international chaos in a way that none of us anticipated, and hence the impact was all the more dramatic.

CMA: It was quite surprising to encounter all of these issues. The House, in the version that it passed, did not even propose any change to Section 5, and the House and the Senate reconciled their differences, and the law comes out with changes that were kind of surprising in certain areas. I think that while measured change was expected, it was a complete surprise to me when, as discussed in the article, Congress decided that EPA should not consider the non-risk benefits or costs of new chemicals in taking risk management decisions on certain of the PMN cases.

CMA: When I ran the Toxics office, these non-risk issues were very important considerations. What were the performance attributes? What about lower exposures? What about the energy profile? Green Chemistry benefits? Pollution prevention benefits? These were all carefully weighed and considered in taking decisions. Now many of these things were no longer appropriate for EPA to consider because of this surprising change in the law.

REE: I'm not sure I agree that EPA is not permitted to consider many of those. I think a lot of those issues *are* risk issues. They can't consider cost, but there are other attributes -- reduced exposure, reduced toxicity -- those things are risk issues that EPA *should* be able to consider. I think EPA has *not* considered those. I think they've looked at each case in isolation, they've taken a very absolutist view of the hazards and the exposures, and if there's any -- EPA's interpretation was if there was any possibility of a condition of use where there might be an exceedance of a concern level, that EPA had to regulate, regardless of what was already in the market. The new chemicals bias that we'd seen before under old TSCA, which was something that people talked about, has gotten much worse, and new chemicals are facing regulatory burdens that I think weren't considered by most of the folks that were discussing TSCA reform prior to Lautenberg being enacted.

CMA: I think that's a good way of describing this change and its effect, because it was completely unexpected. Every other regulatory provision in TSCA allows, or requires, that costs and benefits be considered in taking an action, and all of a sudden, certain things could be considered, risk-based aspects could be considered. But the non-risk aspects were no longer valid for consideration. Big change.

LLB: I'd like to pick up on a point you made, Charlie, about new concepts and new terms in the law, and add another layer of both complexity and intrigue. The new law was signed on June 22, 2016. A few short months after that, we had a new administration ushered into the White House, Congress, and of course EPA. Did you detect any difference in the way the Obama Administration, which was in control when the new law was signed into law, and the ongoing interpretation of TSCA under the Trump Administration? I mean, none of us saw Section 5 changes coming to the extent that they were included in the new law. I for one didn't see the Trump Administration coming as the probable winner of the 2016 presidential election. But the fact that there was a change of administration at a critical time of implementing new terms, new conditions, and a newly enacted law strikes me as pretty impactful here. Do either of you wish to comment on that?

CMA: I think that EPA's initial implementation under the Obama Administration was very cautious, if not precautionary, and their insistence that there be no discernible hazard associated with a new chemical in order for it to enter commerce as not likely to present an unreasonable risk. I think that in many ways, there was a conflating of hazard and risk by EPA. As discussed in the article, EPA really, in my view, did not implement the law as written and render its judgments based on the risks, or the data insufficiencies, or whatever the new requirements were, and then take decisions accordingly, as required under the new law. Instead, it seemed like everything was seen to be a problem.

REE: Throughout the years, over the decades of old TSCA, the new chemicals program was largely apolitical. There really was not much change from administration to administration. I think that was true with new TSCA as well, after the new law was enacted. From my perch, I did not see a major change in how EPA was reviewing cases before and after January 2017. There wasn't like some switch flipped and suddenly nothing was getting reviewed, or things were going through smoothly. I think -- a lot of it was EPA wrestling with -- and they still wrestle with some of the interpretation of those terms, and we've written extensively about and commented on a number of those issues -- but it's only been recently that I think EPA is finally taking some comfort in a more moderate and more nuanced approach to what is reasonably foreseeable, how likely is "not likely" -- that are leading EPA to make some not likely determinations, even in cases where there is a discernible hazard.

LLB: Maybe you can help our listeners understand more precisely what some of those changes might be. I know the article talks about how chemical exposures in the workplace, for example, can reasonably be thought to pose risks under certain circumstances. But we also appreciate that the Occupational Safety and Health Act imposes certain workplace requirements on employers to protect their workers from foreseeable hazards in the workplace: gloves, and protective clothing, and supplied air respiratory protection, and so on and so forth. Maybe you can help give an example of how the interface between existing chemical controls in the workplace might somehow have been less recognized or underappreciated in a risk review of a new chemical, with respect to the imposition of new regulatory requirements under the TSCA program.

REE: EPA has long identified workers as a potentially exposed subpopulation. Under old TSCA, under new TSCA, workers were definitely a key subpopulation that EPA would review for unreasonable risk. What changed under new TSCA is that, if EPA identified hazards that a worker might be exposed to, EPA felt obligated to regulate to protect against those hazards. EPA would be issuing consent orders to require workers to wear impervious gloves in the workplace. As you say, [the Occupational Safety and Health Administration] (OSHA) already requires that if a worker is exposed to a hazard and dermal protection is necessary, that they must wear impervious gloves. We felt that the TSCA regulation was duplicative of an OSHA regulation and that that was going beyond the "extent necessary" language in Section 5 that EPA must regulate to the extent necessary to protect against the risk.

The question was, was it reasonably foreseeable that workers would not wear gloves? And we were challenged by OPPT management to show that appropriate gloves were commonly used. We rose to that challenge and found that it was very rare, in fact, that OSHA issued violations for workers not wearing appropriate gloves -- not wearing gloves, or not wearing appropriate gloves. Fewer than a half a percent of 12 million OSHA violations in the last 40 years related to inappropriate gloves. It's actually very common: In the vast majority of cases, workers *do* protect themselves. Their employers *do* provide appropriate protection, so it was *not* reasonably foreseeable, and I think that has changed EPA approach. That's part of what has changed EPA approach to making not likely determinations.

LLB: It sounds like what you are saying, Rich, is that EPA now might be more flexible in appreciating that those types of risks are not reasonably foreseeable when another federal law imposes restrictions to prevent that risk from occurring, and that fewer chemicals in the new chemical review process are being regulated for that purpose.

REE: That's exactly right.

LLB: Which is helping the commercialization of new chemicals proceed apace?

REE: Absolutely. When the only potential risk that EPA identifies is to workers -- they're not general population risks, they're not aquatic toxicity risks -- then EPA can review the safety data sheet (SDS) and make sure that the SDS appropriately reflects the hazards and has appropriate risk warnings, and that the appropriate PPE [personal protective equipment] are mentioned, and then EPA can allow those to proceed to market with a not likely determination, and the manufacturers can commence as soon as it is commercially convenient.

LLB: I think -- although not considered in the article, because there was a more recent change that we wrote about in our client communications -- it sounds like the Agency is making some affirmative adjustments to its new chemical review process, including the one that we wrote about just very recently. Charlie, did you want to talk a little bit about the Agency's more recent change?

CMA: There've been a couple of important changes of late. One concerned a case where EPA, despite identifying hazards, aquatic hazards, occupational hazards with the chemical, nonetheless determined that the chemical was not likely to present an unreasonable risk under the reasonably foreseen circumstances of use. This was a very important decision that EPA took because it's really the first instance where we've seen that EPA went beyond hazard and considered risk, as required in the law, in judging whether a chemical should be permitted to enter commerce as not likely to present an unreasonable risk.

The second, and more recent, example concerns several cases where EPA has determined that it could propose SNURs that would deal with certain uses in a way that would open the door to EPA being able to make a "not likely to present an unreasonable risk" determination on those new chemicals. This was a particularly important decision because of the way that EPA was very careful to establish that these uses were not ongoing and thus they would be subject to future regulation under the SNUR such that EPA could render a "not likely to present" determination.

We think there are many cases where some kind of an action may be required, but it doesn't have to involve a consent order in all cases, and the ability to go forward with SNURs, we think, is a very nice tool for EPA to acknowledge exists in its toolbox.

LLB: It sounds like there have been a number of important and helpful -- mid-course corrections, for lack of a better term -- or just embellishments on the Agency's interpretation of new TSCA that is helping develop a more predictable and perhaps more efficient chemical review process. Can we give any comfort to new chemical innovators in terms of temporally how long the process is taking these days?

REE: Not yet. There are still many cases that are that are backed up, especially as EPA has developed these new interpretations. They've gone back to cases that are currently suspended, and looking at, for instance, work protection. If the only concerns that EPA had

identified were for worker protections, EPA is re-reviewing those and reviewing the SDSs, and then making "not likely" findings. That takes some time. The engineers and the health experts have to go back and re-review again. Remember, EPA has to document these findings, so not only do they have to do the scientific review, but they have to write it out, write it down, and say, this supports our "not likely" finding. That takes some additional effort, so EPA's still working through that backlog.

I do hope that in the next few months that PMNs will start being reviewed in a more timely way as new cases are coming in, and meet the new criteria that the Agency has set. We may start to see PMNs that are limited to worker issues. Those might be reviewed in the 90-day timeframe. Some other cases, I think, we'll continue to see if EPA feels like they need to regulate, those will still get hung up in the consent order or SNUR process. There'll still be some delays, but I do hope that the timeframe will improve.

LLB: It could go anywhere from 90 days -- when you're dealing with relatively predictable, well-managed worker-type issues -- to a year, a year and a half?

REE: If a client walked in the door today and said, "How long can I expect for a PMN?" I would say, plan on a year. I think that's a reasonably conservative assumption. It gives you some cushion if things go sideways during a PMN review and gives you time to get things back on track. If EPA needs more information, it gives you some time to develop that. I would say a year is a good guess for something that's not going to easily find a "not likely" outcome.

LLB: Agree, Charlie?

CMA: Unfortunately, I think that that is the case. I think the industry had the hope that under the new law it would proceed at about the same pace as under old TSCA. While I agree with Rich that the recent changes are very promising, EPA will have a number of challenges as it goes forward and attempts to implement those new policy approaches. This is looked at very carefully by chemical innovators. They need to consider whether they should attempt to go through the U.S. new chemicals process, or are they commercially better served by shifting production or use of the chemical offshore, so that they don't have to go through this type of process until they can get to the point of being more of a known quantity than is the case right now.

LLB: Regardless of who prevails in the midterm elections, do you see congressional hearings in our future in early 2019, with a view toward addressing any of these issues more fundamentally in the law, or just by way of government oversight to move things along more briskly? To give a greater sense of predictability and commercial certainty, while also discharging EPA's obligation to ensure new chemicals are safe when used as intended?

CMA: I'm kind of disappointed there hasn't been an oversight hearing to this point. The law is two years into its implementation, and I think it's important for the Congress to look back on its work and come to understand what's working and what's not working. I do think it will be very difficult to enter into another legislative process, but I think that kind of conversation among stakeholders would be very valuable in clarifying some of the policy and legal challenges, and hopefully developing a way forward that could allow for the goals and purposes of the new law to be achieved, while also ensuring that new chemical innovation can proceed apace.

REE: We discussed it at the TSCA at One, our first anniversary meeting. We questioned the panelists about a FACA [Federal Advisory Committee Act] committee, you know, that a federal advisory committee could be convened to discuss the meaning of some of these terms. Because in our view, the interpretation of the term was so fundamental to EPA's approach. There seemed to be zero meeting of the minds on what "reasonably foreseeable" might mean. I think to a person everyone on the panel said that they were not interested in a FACA. These are the things that exactly need to be discussed, whether it's in a hearing, a FACA committee. I worry that in the end, it's going to be decided by a judge, and then whatever the court case's interpretation will be, will be what we have to live with until -- until the next time the law is amended.

LLB: You're reading my mind, Rich, because we wanted to spend a little bit of time talking about litigation. Have any of these issues been litigated?

CMA: There've been a number of legal challenges that have been filed under various provisions of TSCA. Specifically in the new chemicals area, the NRDC, the Natural Resources Defense Council, filed a challenge against an EPA framework document that existed in an EPA draft for comment, and nonetheless the NRDC filed a legal challenge characterizing that as a final rule. That challenge -- I guess NRDC has requested that that challenge be dismissed. I guess they got some statements out of EPA clarifying certain points, but I think that that is just emblematic of the kinds of litigation likelihood that will confront this process as we go forward.

LLB: I note in the paper, there is considerable discussion about the fact that in the early days of TSCA implementation of the new law, approximately 90 percent of all new chemicals were being flagged and set for regulation. That number is now coming down. What's causing the differential between 90 percent of all new chemicals being regulated and a less robust number?

REE: I think it's largely in EPA's interpretation of the terms that we touched on. What is reasonably foreseeable? What is the extent necessary to protect health and the environment? And how likely is "not likely"? All those terms require some judgment upon EPA, and EPA is, I think, changing its approach.

CMA: Yes, as an old TSCA hand, I think that increased regulation is required in order to meet the requirements under new TSCA. But the real issue is: What is the balance that you strike in doing that? My view is that the Congress did not intend a wholesale rewrite of this law and changed it fundamentally from the approach that existed previously, and I view an approach that results in regulation of 90 percent of new chemicals as a pretty fundamental change.

I am appreciative and optimistic that EPA is taking on the meaning of these terms, such as "extent necessary" and "reasonably foreseen," and bringing what I view as a more pragmatic and practical interpretation, applied in the context of the law, to make the appropriate determinations and take the actions that in fact are needed under the new law.

REE: In the early days, EPA was regulating every substance that it identified as having some hazard other than low hazard. If that was Congress's intent, Congress would have said: use a hazard-based standard rather than a risk-based standard. EPA was clearly overinterpreting what was reasonably foreseeable, or what was likely, or what was the extent necessary. As we move away from that, we'll find some equilibrium, and it's not clear where that's going to be, but it'll probably be somewhere between the 90 percent we've seen in 2016 and the 15 percent that we saw before new TSCA was enacted.

LLB: At the end of the day, some judicial gloss might well be part of the mix.

REE: Indeed.

LLB: I think we want to get some closing thoughts from our speakers today. It sounds like Section 5 really started off on pretty shaky ground; that the Agency was struggling to implement it in a way that maintained the predictable and systematic review of new chemicals that had existed under the old law; that we see progress, better clarity, and certainly speed to market with some of the changes that have been implemented by this administration. But at the end of the day, are you both optimistic about the availability of new chemicals being briskly and efficiently placed on the market without a lot of regulatory pushback, or is this still very much a work in progress? Charlie?

CMA: I think things are certainly better than they were six months, or two years ago, and I am measuredly optimistic going into the future. Whether my optimism continues remains to be seen, however, and it's in large part due to the kinds of changes that may occur as future lawsuits get heard and resolved.

REE: I think that there are a couple of key things that will make the future brighter. Part of it is EPA's more measured approach. Part of it is, now that the fee rule is in place, EPA will begin to be able to staff up. One of the challenges that EPA has been facing for two and a half years is that they just have not had the resources that are necessary to implement new chemicals as written. It's a significant burden. There's more effort required on the part of EPA, and they haven't had the staff to do it. As they bring in staff from around the Agency to help cover the need, those folks don't have the experience with TSCA, and so they've had to come up to speed. You've got new folks who aren't aware of the law, or aren't aware of the policies, and the policies have been changing. Those challenges, I think, will lessen. The backlog will be diminished as EPA gets through the many cases that are pending right now.

I think a year from now, we'll have a more predictable PMN process, but I think it's still going to take at least a year to get back to a relatively predictable 90 days or less for "not likelies" and three to nine months for cases where some regulation is necessary. But it's still going to be a while, so there's still going to be a barrier to innovation.

LLB: I remain cautiously optimistic as well. I think the leadership at the Office of Chemical Safety and Pollution Prevention has worked very hard and made considerable progress in providing a legally defensible and scientifically predictable determination on a lot of new chemicals and building a framework that is predictable and well understood. We've made a lot of progress. With that, gentlemen, I think we will call it for now. Charlie, thank you so much for offering your thoughts. Rich, I thought it was an excellent discussion and really appreciate your contributions.

REE: Always a pleasure.

CMA: Thank you, Lynn. Thanks for the opportunity.

LLB: Thanks again to my colleagues Charles Auer and Rich Engler for sitting down to discuss our article. If you'd like to read the initial set of articles that prompted this discussion, you can find them at our website, www.lawbc.com. You will also find there many other interesting topics and points of information all about TSCA.

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