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Toxic Substances Control Act Reform: What's Happening, and What's Next?

Summary

Betting on Toxic Substances Control Act (TSCA) reform before the 2016 presidential election is anything but a sure thing. While most remain optimistic, with each passing day, the window of opportunity is narrowed. One possibility is that some version of reform will be passed, requiring the U.S. Environmental Protection Agency (EPA) to grapple with the demands of implementation. Another possibility is that TSCA reform is not enacted, and life as we know it goes on. Either scenario poses challenges, opportunities, and risks for EPA, the industrial chemical community, their downstream customers, and all of those impacted by chemical regulation. On November 19, 2015, the Environmental Law Institute convened a panel of TSCA practitioners and experts to discuss these issues. Below we present a transcript of the discussion, which has been edited for style, clarity, and space considerations.

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Lynn Bergeson: Welcome to our panel discussion on reform of the Toxic Substances Control Act (TSCA) of 1976.[1] We are going to talk about the current state of play in TSCA reform, share some thoughts on how the U.S. Environmental Protection Agency (EPA) may go about implementing reforms, and discuss what the challenges and opportunities are for stakeholders in the TSCA debate.

All of our panelists formerly served in leadership positions with EPA. Dr. Lynn R. Goldman is currently Dean of the Milken Institute School of Public Health at The George Washington University. During the William Clinton Administration, Dean Goldman served as Assistant Administrator of what was then called the Office of Pesticide Prevention and Toxic Substances (now named the Office of Chemical Safety and Pollution Prevention). Jim Aidala succeeded Dean Goldman in that position. Larry Culleen served in various leadership positions in the Office of Pollution Prevention and Toxics, and the Office of Pesticide Programs. Perhaps most pertinent for purposes of this discussion was Larry's service to EPA as Chief of the New Chemicals branch, the office responsible for implementing the part of TSCA that deals with new chemical notifications and notifications for products of biotechnology.

Larry will give a brief overview of TSCA and say a few words about some of the key concerns that have been driving TSCA reform for many years. Jim will bring us up to date on the current state of TSCA reform legislative activities and identify why we believe current legislative initiatives would address some of the deficits that Larry will have identified in his remarks. Then, Dean Goldman will discuss implementation challenges and opportunities by walking us through different scenarios, all based on the assumption that the U.S. Senate version, or something close to it, becomes law. Then we will look at day one, year one, year five, and year 10 from a TSCA implementation perspective. We hope that will give a clearer sense of both the challenges and the opportunities facing not only EPA, but all of us as stakeholders in the debate.

Lawrence Culleen: TSCA has a number of titles. We're going to focus today on Title I, which was the portion enacted in 1976. It's important to recognize that the law is now 40 years old and has many of the vestiges of those times. But at the time of its enactment, TSCA was very much characterized as what we would now call a pollution prevention statute.

There are certain core chemicals management provisions. The idea of the statute was that it would fill gaps in other legislation that were media-specific. For example, the Clean Water Act (CWA)[2] didn't specifically address chemical substances and other sources by which they could be discharged to various media or to which humans could be exposed. So, TSCA was enacted to allow the Agency to have the authority to deal with those potential risks. The

1. 15 U.S.C. §§2601-2692, ELR Stat. TSCA §§2-412.

2. 33 U.S.C. §§1251-1387, ELR Stat. FWPCA §§101-607.

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instrumentation under the law is that the Agency is given authority over "chemical substances."

As to chemical substances, it's very broadly defined. I like to tell clients that the statute essentially covers anything that's not naturally occurring, including modified living organisms or pieces of modified living organisms. Excluded from the statute's coverage are foods, drugs, cosmetics, pesticides—things that in the U.S. Congress' view were covered adequately at the time under other federal laws. TSCA's general scope is to provide EPA the authority to require the generation of data, to review new chemical substances before they come onto the market, and to regulate existing chemical substances for which EPA might identify risks.

Section 4 deals with testing. The Agency has the authority to require the generation of data by manufacturers and processors of chemicals, but it has to do this through a rulemaking process and the process requires the Agency to make certain findings with respect to either risk or exposure. Over the course of time, litigation has further articulated the parameters of EPA's authority.

Section 5 of the statute gives EPA the authority to review any new chemical substance that is imported or manufactured in the states. The procedures require that entities that are responsible for those substances submit a notice to EPA. The notices must include all the data that the entities have in their possession or control, but they are not required to generate new data for purposes of the Agency's review. EPA has only 90 days to complete its review, with some possible extensions. At the end of that review period, if EPA has failed to act, the substance becomes one that the sponsor (producer) can commercialize without restriction.

Once the substance enters the marketplace, it's listed on a document EPA maintains called the "Inventory" of chemical substances. EPA created the Inventory around 1980, and any substance that was in commerce at the time was included. New substances are those that are not on that list. After undergoing the new chemical review processes, a substance can be added. Substances that are on the Inventory, those that are in commerce, are eligible for regulation by EPA if the Agency in reviewing such a substance reaches a determination that the substance will present an unreasonable risk to human health or the environment.

This activity is also done through a rulemaking process. The rulemaking process can require a hearing if one is requested. There are specific findings that the Agency has to make in this context that go above and beyond the general reasonableness standard. The Agency has to identify alternatives that could exist, weigh the cost and benefits of the rulemaking activity and of the substance that would be regulated, and select from among the alternatives the least burdensome requirement. This requirement was a nod at the time to Congress' concern that the law might discourage innovation in the United States, discourage the chemical industry and practices related to that sector of the economy. The goal was to regulate and control risk, but to do so in a way that was the least burdensome.

This presented an encumbrance for the Agency. A significant piece of litigation was the *Corrosion Proof Fittings* case,[3] which related to asbestos in a rulemaking in which the Agency engaged for several years. The ligation overturned the Agency's rulemaking. EPA has subsequently not pursued asbestos with the vigor that it had at the time. That litigation has become the poster child for the inadequacies of the law. Until recently, the Agency has not talked about regulating pursuant to §6 in any specific manner.

Section 8 is the information-gathering section of the law. I won't run through the different provisions, but suffice it to say that the Agency can call in information that may be in existence. Under this provision, EPA expects to receive notice immediately if there's new information of which the Agency is unaware concerning significant risks. There are related authorities, including updating information with regard to chemicals that are in commerce.

Two additional provisions are worth mentioning specifically because of the efforts being made by Congress to amend, revise, or update the provisions. Section 14 deals with confidential business information (CBI).[4] The law, as it currently reads, entitles submitters of data or other information to claim that certain elements of that information should be deemed confidential for commercial reasons. The Agency has, until recently, been very deferential to those claims. There's a general perception these provisions can be abused if not strictly monitored by EPA.

Section 18 deals with preemption. We won't dwell on this, but it's worth saying that the current law actually has a preemption provision, something I think that members of Congress were unaware of until it became an issue. I cannot find any trace of anybody talking about the issue for the preceding 30 years of TSCA's existence, but it has become a central issue. This is in part because of the growth of activity among the states seeking to regulate chemical substances in the absence of EPA's efforts to do so successfully.

So, this is a short list of the key complaints with regard to the current law: A long-standing complaint is that the Agency appears to have the burden of proof under TSCA when seeking to regulate chemical substances. There has been a desire on the part of some advocates, for quite some time, to require the proponents, if you will, of a chemical substance to have to carry that burden. The instrumentation for how that would be achieved has been at the core of the debate over the years; taking shape in different forms of potential amendments to the regulatory standard for taking action under TSCA.

The issue that I discussed in the context of rulemaking with regard to least burdensome regulatory methods under §6 has also been a core issue. Historically, rulemakings for all government agencies, EPA in particular, have been difficult to perfect. Candidly, EPA's efforts to gather data have been slow under the testing provisions, as well as the infor-

3. Corrosion Proof Fittings v. EPA, 947 F.2d 1201, 22 ELR 20304 (5th Cir. 1991).

4. For more information on submitter claims of CBI and EPA review of those claims, visit http://www.epa.gov/tsca-cbi/about-confidential-business-information-cbi-claims-and-their-reviews-under-tsca.

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mation call-in provisions of §8. Concerns that I mentioned before about confidentiality inform the debate as well. Both of the bills we'll discuss today attempt to address this list of issues in one particular way or another.

Lynn Bergeson: I have a question from our audience: What administrative initiatives are under way at EPA that to some extent have abated the urgency of TSCA reform? (The question presumes that that is true; I'm not sure it is.)

Lawrence Culleen: There are a number of things in which EPA is engaged that the assistant administrator would point to as being successes and indicative of the Agency's effort to reinvigorate TSCA. Specific substances have been identified and placed on something called a work plan, which is a winnowing of a long list of chemicals that had been identified as presenting some potential level of risk or known exposures to human health or the environment that the Agency wanted to identify, select from among, and then focus on for potential refinement of risk assessments and for potential regulatory actions. So, the Agency has been very active in what they would call the work plan chemical review process. It's somewhat like the Canadian effort to prioritize and review chemical substances that was undertaken in recent years, so some of the criteria for selection and narrowing of those lists are very similar in that regard.[5]

Also in recent years, the Agency has been much more diligent about monitoring claims with respect to confidentiality. The Agency undertook a broad review of existing confidentiality claims, particularly in the context of data that had been submitted to the Agency previously and claimed to be confidential. At different points in time, the Agency has been considerably more aggressive in some of its statements on CBI, at least its interpretation of the law, than had been articulated previously. I believe that nearly a thousand previously-asserted confidentiality claims have been relinquished for chemical substances that are in commerce. Those are probably the two key areas that are both visible and about which the Agency has been vocal.

James Aidala: There's no such thing as a small amendment, and these are not small amendments that are being proposed and it's certainly not clear how the legislative pathway will get to yes. We all hope it does, but there's no guarantee here for a lot of different reasons. The whole point is that in order to fix the big problem, you've got to get through debates that are seemingly non-germane—except that it's the Senate, so everything is germane.

Lynn Goldman: I think the answer to the audience member question depends on what you think are the factors that are compelling people to want to change the law. I believe there are several factors that cannot be addressed from within EPA. One of those is an increasing engagement by retailers and others doing their own chemical regulations and making decisions that they don't want to have certain chemicals in products on the shelves. EPA internally can't address that without a stronger law that would increase the private-sector confidence in EPA's safety determinations.

We also have a major issue with the evolution of the system in Europe and how that has been moving forward, and at least a perception that despite some efforts administratively by EPA, we have a system that doesn't provide the same level of protection. I think that that is of concern to many of us, not just environmentalists, but also industry. That kind of perception isn't a good perception to have about our industry, and I think it has inspired congressional action to move something forward. Congress has waited almost 40 years to do this because it's not easy to do it. Congress wouldn't be doing it if an administrative fix was possible, in my view.

Lynn Bergeson: There seems to be a consensus that these administrative issues are moving forward. They have been widely regarded as successful in moving the needle, but not sufficient to address all of the issues that have been asserted with TSCA over the years.

Lynn Goldman: The third factor, which I'm sure Jim will talk about some more, is that some of the states' specific activity to control specific chemicals has brought industry to the table, because of the difficulty in predicting which state is going to take action on which chemical, and the very rifle-shot nature of some of those actions. When a state bans lead in children's jewelry, for example, that's a good thing, but its effect in addressing the lead exposure problem is fairly small and a little arbitrary. What are the states actually accomplishing? You can see one example after another where a single use of a single chemical is targeted. There's a need to inquire into the basis for saying that is the priority when there are so many other ways that people are exposed to lead. So, that also requires stronger federal legislation.

James Aidala: Right. Those problems are not going to go away unless there is new legislation, because you're going to see that ability to do that and do more niche things as opposed to a broader approach. It may have a better payoff in terms of protecting our environment. Lynn and I and a few other former reformers—these are two other senior EPA officials, Republican and Democrat—we put out a paper five years ago for the American Bar Association Sec-

5. Canada regulates industrial chemicals under the authority of the Canadian Environmental Protection Act (CEPA). In 2006, the Canadian government launched the Chemicals Management Plan whereby existing chemicals, those 23,000 or so chemicals listed on the Domestic Substances List (DSL), were determined to be priority or non-priority chemicals based on health and ecological criteria. The classification determined what level of additional scrutiny was directed at the chemical and according to what schedule.

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tion of Environment, Energy, and Resource entitled *Practical Advice for TSCA Reform: An Insider Perspective*.[6] You can evaluate how we did when you hear about the bills Congress is doing or not doing. It's not just concerns about the current program, but also what happens when you have a new law—practical advice about not only how to reform it or change it, but also what's going to happen. When reform catches up to the statute, how do you implement it? What's going to happen after the first few months, years, and many days afterwards? Here's a quick list of what we had in that paper.

Food Quality Protection Act (FQPA)[7] *as a template*: Specifically, safety standard, risk assessment concerns to our population, and focus of special exposure or high exposure. That was one of the things we had to enjoy, the thrill of having the FQPA be engineered and developed and enacted.

Organizational capacity: What EPA is able to do given their staff and resources, what the statute allows and doesn't allow, and how much of a burden. As a decisionmaker, the Agency has to make decisions on how to best allocate its resources.

The numbers game: Part of the energy behind TSCA reform is that there are 86,000 chemicals and EPA has only required testing for a few hundred. An important component of any reform is how you determine out of that 86,000 number what chemicals should be tested. How do you decide, how do you sort that out? Sorting is a nontrivial issue, building on those things that have been successful.

Section 5 premanufacture notice (PMN)[8] *reviews*: Widely considered to be fairly successful compared to other sections of the provision that we talked about. That's because for a lot of reasons anything we're talking about here has a long history, a 40-year history about how we got there. But structured activity relationship, ways of evaluating chemical safety. The Inventory itself is an achievement. It doesn't sound like much, just having a list of what's out there. But that's a nontrivial achievement.

Global issues: Because of other activities in other places, there were lots of activities that we had in order to fill some of the vacuum by what's going on in the international forums. The best approach is to keep it flexible. You never know what's going to happen. You don't want to lock down a bunch of weird science stuff in a law because of that pesky science problem of changing. One of the biggest problems of pollution is detection technology because we find things we didn't know. We find things we need to worry about now that we didn't think of when this law was enacted. You have to be adaptive.

Next, I want to touch on the status of legislation. The late Sen. Frank Lautenberg (D-NJ) took a passionate interest in chemical issues throughout his entire time in Congress. A bill in the Senate is named after him and was intended to be his big legacy. He worked tirelessly on it and held numerous hearings. That bill was approved by the Senate committee and reported to the full Senate.[9] Most importantly, there are 60 co-sponsors, a magic number, a large bipartisan representation. That's a good indication of broad consensus behind the bill. In the U.S. House of Representatives, even more interestingly, this bill actually made it to the House floor and was approved by a vote of 398 to 1.[10] That's a pretty impressive vote for this Republican-dominated partisan House, indicating a broad consensus.

Where does it stand now? The Senate bill is 177 pages long and almost all the provisions are very detailed. That can be good and bad. The House bill is shorter and a more targeted solution to some of the critical issues. Critical issues include how you sort through the 86,000 chemicals to determine what really needs to be tested. How the bills might handle that issue is very important.

New chemical review: I said it was widely considered by many as the most successful part of the current program, but that doesn't mean that you can't use other things. There have been critics and we're trying to address some of the criticisms of that program over the years.

Safety standards: Not trivial. You want to say absolutely no harm. You want to say there are benefits that can be considered. You want to say the current law in reasonable risk is usually seen to be a cost-benefit kind of standard. Is that appropriate when you're talking about chemical exposure? What is the safety standard? What happens if you exceed the safety standard? Should you go to jail? You should stop using it. You have to control it. You have to try and get rid of it. What does trying to get rid of it entail? That's part of the issue, one of the kinks.

Information-gathering: The Inventory itself is an achievement, but does it need any fixes right now? If nothing else, a lot of chemicals on the Inventory aren't made anymore.

CBI: What happens when EPA has information but they're not able to release it to the public? Why should they be required to release to the public? Under what conditions?

Preemption of state law: For 35-plus years, it was not an issue, but now it's *the* issue for many in the current debate.

Deadlines and resources: Limitations on resources are an obvious problem, but so are deadlines. Deadlines are good and bad in legislation, partly because they help you get money internally in EPA when you can say to the Administrator, we don't want to miss that deadline. On the other

6. James V. Aidala Jr. et al., ABA Section of Environment, Energy, and Resources, Special Committee on TSCA Reform, Practical Advice for TSCA Reform: An Insider Perspective (Aug. 2010), *available at* http://www.lawbc.com/uploads/docs/White_Paper_%2800062353%29.pdf.
7. Food Quality Protection Act , Pub. L. No. 104-170, 110 Stat. 1489 (1996).
8. A PMN is required under TSCA §5 to be submitted by anyone intending to manufacture or import a new chemical substance for a nonexempt commercial purpose and must be submitted at least 90 days in advance. For more information, visit https://www.epa.gov/reviewing-new-chemicals-under-toxic-substances-control-act-tsca/filing-premanufacture-notice-epa.
9. Frank R. Lautenberg Chemical Safety for the 21st Century Act, S. 697, S. Rep. No. 114-67 (2015); approved by the Senate Environment and Public Works Committee (bill and report available at https://www.congress.gov/bill/114th-congress/senate-bill/697).
10. TSCA Modernization Act of 2015, H.R. 2576, H. Rep. No. 114-167 (bill and report available at https://www.congress.gov/bill/114th-congress/house-bill/2576).

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hand, too many deadlines and too few resources mean you have to triage. How do you decide which one to do first?

On chemical testing, both versions of the legislation have some greater authority. They have what's called order authority. You don't have to write a rule because, as Larry said in connection with the asbestos rulemaking litigation, writing a rule turned out to be the functional death knell of getting a lot done under that part of the program. So, you have order authority, we'll let them more readily get to call in and get data from manufacturers. The House bill includes broader authority about maintaining some of the troubling elements of the current law. Some of us speculate it may hinder that ease of getting a lot of data in.

Now, I'm not trying to evaluate the bill. I'm doing a broad brush on the differences between the House and Senate versions. The Senate bill includes more clearly, significantly increased authority that feathers out to the preemption issue. Companies can ask for their product to be reviewed. If that happens, then in the Senate bill, there are certain provisions where the preemption effect takes effect once EPA is starting to review the chemical.

Lynn Bergeson: Wasn't that amended? I think there was an amendment to that provision.

James Aidala: There's preemption, but it's not clear how that's going to come out. That's one of the controversies now. The House bill says there's no preemption until EPA is done with the final risk assessment, risk conclusion. That's been one of the bigger sources of House/Senate differences. What is the Senate going to do? We expect a compromise, but officially nothing has been released.

Importantly, in the Senate bill there's a concept of a low priority. We're back to the 86,000 number. How do you triage that universe? Some things we don't have to worry about. There, you have to make a safety finding that the standard is met. Well, that's going to be difficult because a lot of that universe—the 86,000—are going to be substances where you don't have enough information to make that safety finding.

About the Inventory of 86,000 products and chemicals: Half of those are probably not active anymore, so we probably just got 40,000 chemicals reviewed in 10 seconds. That's a good start. About half (20,000 substances) of the remaining Inventory universe are probably things that can be readily exempted given their chemistry, or you can probably make a legitimate case that it's going to be "safe." So, the Inventory universe is reduced to at least 20,000. Probably, there are about 1,000 chemicals that you need to worry about, although that's a very loose number, maybe only a wild guess. So, what happens between 1,000 and 20,000? The universe in that low-priority category I personally worry about. They're dogging the program. Over time, in a five- or 10-year time frame, what is EPA going to do with that? There's an issue on the so-called designation of low priorities.

New chemicals: The House bill makes no changes at all to the provisions. In the Senate bill, there's some strengthening. For example, EPA estimates an affirmative finding right now. Under the current law, if EPA made no decision, it automatically can go on the Inventory. There are also more specific requirements for handling persistent, bioaccumulative, and toxic (PBT) chemicals. So, persistence, bioaccumulation, and toxicity are criteria. If you meet certain triggers on that, it requires EPA to take more action.

Section 6 regulatory controls: If you had to have a two-word amendment, if Congress allowed only two words to be changed, the "least burdensome" phrase in §6 regulatory controls would be it. Strike these two words. That is the biggest single thing over the many decades of the criticism on current law after the *Corrosion Proof Fittings* case that Larry mentioned. Both bills do that and that's very positive.

There's no economics that are supposed to be considered in doing the risk assessment, the science of the risk assessment. But then there are differences in what it may mean. There is some kind of exemption about if it does exceed the standard, what happens. For example, one section in the House proposal says things like it has to be cost-effective. Is that a definitional term? Is it going to cause trouble down the road? We don't know. But what's cost-effective versus more general terms such as "avoid significant adverse impact to the economy" or other phrasings that have been kicked around at this point over the many attempts to legislate this phrase?

Deadlines: Both bills have schedules for decisions. They have a positive value, but they can also be a straitjacket.

Information-gathering: This is §8. No changes proposed on the House side. There's the issue I mentioned earlier about what chemicals on the Inventory are still being produced, still active in manufacturing. The Inventory reset is what it's called when you determine which chemicals on the Inventory are still being produced. It helps with the sorting need. And then also there's an easier time to get information from processors. The point is to expose your data. This is probably going to lead to a lot more hazard information coming in. Risk assessments are going to be done pretty reliably. And according to previous established procedures on the hazard side, the exposure situation is going to be a whole different ballgame. I think one of the things not being talked about in the legislative deliberations so far is what to do about exposure data or lack thereof.

CBI: Both proposals are addressing it. The House bill doesn't make many changes. The Senate bill has a more significant revision. Making this data more public requires some kind of substantiation and time limitation. You don't get to just say something is CBI and keep it in the file forever. I worked on an oversight committee on the Hill before I worked for EPA. One of the things we used to talk about is that you could submit CBI and then time and the years passed. The *New York Times* had stories about a chemical that would be submitted as CBI, advertisements where a chemical will be submitted as CBI. As an adver-

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tisement, you're trying to make it public. So, how is that CBI? Currently, the hottest issue in CBI is molecular identity; it's considered super-sensitive information. What may happen to that when and after they release any of that kind of information? Some could argue that it would make the information derivable. That's very important.

State preemption: The key issue is when does preemption start? In the House bill, it starts after EPA has completed its assessments. The Senate bill says that it would start at some earlier time. Once EPA gets serious about analyzing the situation with that chemical, there's a time limit so they can't dally around forever. But there's a controversy about if and when any preemption should be triggered. This is the most controversial element of the current debate. It's what is holding up the Senate bill.

Lynn Bergeson: It's done. I think at this point the members of the Senate who were concerned about the preemption issue have gotten the amendments they wanted. I think it's done, but it was held up for a significant period of time, all wrapped around the issue of states wanting to be more involved.

James Aidala: Officially, there's been no public release on the next iteration of what the solution is. With regard to administration and fees—basically resources—there are deadlines and all kinds of terminologies are going to have to be sorted out. The bills require a lot of rulemaking to be done in the next two years. Doing one rule in two years is hard, let alone many. The heavy load of new rulemakings required, and the new terminology to grapple with, are going to be early implementation challenges. As for fees, there's less money generated by the House scheme, but a more significant contribution in the Senate scheme.

Audience Member: EPA's Office of Science and Technology Policy (OSTP) is engaged in a process to rethink the Coordinated Framework for the Regulation of Biotechnology,[11] and TSCA is the gap-filling statute in that zany system. Do you think that, with the politics going on the Hill now, it might get entangled with the potential rewrite or the questioning of the Coordinated Framework? OSTP just had a proposal requesting comments and over 130,000 people signed petitions or sent in letters.

Lynn Goldman: TSCA's scope of that biotech framework doesn't involve food in any way. The food issues are spread out among the U.S. Department of Agriculture (USDA), the Food and Drug Administration (FDA), and EPA in a way that's truly fascinating. Because of the boundaries that were placed around what a chemical is under TSCA, it can't be a food or a food additive or a pesticide. Those are regulated under other statutes. The part of biotech that is regulated under TSCA has not been very controversial. There is quite a bit of chemical production using biotechnology, but for whatever reason, people don't worry about their detergent enzymes coming from biotech the same way that they worry about their food origins.

James Aidala: There's nothing like the genetically modified organisms (GMO) debate in the other spaces, but it's there.

Audience Member: My question is about resources. Whatever bill passes, whatever form of the bill passes, EPA staff are going to have to do it. Can the panel comment on which version of funding is closer to which set of goals?

Lynn Goldman: I'll talk about that in the next section when we talk about what happens the day after.

James Aidala: The Administrator has discretion with the new law to get it done. It's not only industry fees that will help pay for it.

Audience Member: I want to go back, Jim, to one point you made that I think is a big point of contrast between the two bills. It has to do with the ability of companies to request EPA reviews of their chemicals. That is in both bills, not just in the Senate bill. The big difference is that in the House bill, it is unlimited. For any chemical, any company requesting EPA review, EPA must review and must review more quickly than for the chemicals that EPA selects itself. In the Senate bill, that is capped at 30%. EPA has discretion and has to develop criteria by which it selects those. The other really big difference is that in the House bill, the only fees that EPA can collect are to fund the assessments of industry-selected chemicals, not Agency-selected chemicals. In the Senate bill, those fees can go for both industry and EPA-selected chemicals.

James Aidala: There's a much longer list in the Senate bill on where funding can be imposed for which things. I was surprised to see the House have anything in their proposal about fees. With the 398-to-1 vote, you're giving more fees and more authority to EPA. Considering the political climate, it was an achievement just getting it that far. But you're right about everything you said. And that is an implementation concern about how you have the system swamp it. No matter how they come in and even if people just dump a lot of data on the system, what happens to it and to what end? That's underneath some of what you were just articulating.

Lynn Goldman: These are the things that are always an issue for EPA or any agency with the enactment of a new bill. The agency lawyers will need time to interpret what the definitions in the statute really mean. There are transition periods that are or are not built into bills. But whether

11. On July 2, 2016, OSTP, the Office of Management and Budget, the U.S. Trade Representative, and the Council on Environmental Quality jointly issued a memorandum, entitled Modernizing the Regulatory System for Biotechnology Products, that directs EPA, FDA, and USDA to update the Coordinated Framework.

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or not they are found in the new statute, they exist in a practical sense.

Deadlines: EPA will tell you any deadline is unrealistic. I'm not saying whether I agree with that or not, simply that it is what you will hear.

Fees: The TSCA program hasn't had this kind of a fee structure. Nineteen years ago, the same office had to develop a fee structure for the FQPA. There might be a few people around who still remember how to do that.

Time Lines: In thinking about what happens after the bill becomes a law, let's examine it on the very next day, the first year, the first five years, or the first 10 years. I'm simplifying matters for this discussion by assuming that the new law will be the Senate bill or something close to that, and I'm doing that because of what I'm aware of in terms of the political realities. As this bill is moving forward, I think that that's the most likely scenario. It's also possible that Congress will succeed in tying itself up in knots. But the very day after, there are so many things that EPA will immediately have to address. One obvious thing is that there are a lot of transactions occurring, and occurring very rapidly.

The Next Day

Currently, there is the 90-day review for a PMN. EPA is going to be in the middle of hundreds of 90-day reviews of PMNs, and there is no way in the middle of that kind of process that they're going to be able to just flip a switch and do the process in a completely different way. Hopefully, there are already people in their policy office thinking about this. They're planning because that very first PMN that comes out of the hopper is going to have to have different findings, especially if you have a law like the Senate bill that says there has to be a determination of safety.

Now, one of the interesting things in the politics around this is that EPA has been pretty clear, as they have discussed these bills, that they feel they already provide an affirmation of safety for a new chemical. But they are not currently required to make an affirmative declaration of safety. I heard things like that before the enactment of the FQPA, that no real change would be achieved. But afterward, the new legal requirements, and the ability for people to litigate over them, meant that a little more effort had to be made—more effort, a different kind of effort, and a different kind of document. I think that point is to be true in this case as well. A problem is that there are ongoing CBI submissions coming in every single day. At what point in time will the EPA begin to apply the new criteria and how will they manage this transition?

Year One

In Year One generally, there is a tremendous amount of policymaking that's going to have to be done very quickly. Some of this involves rulemaking and policy analyses to chart a course toward meeting deadlines. Some of this doesn't require rulemaking, but it does require that the Agency make clear statements to provide guidance to the regulated community and other stakeholders. Some of this involves science. There are new policies that have to do with a safety standard. How does that impact risk screening and risk assessment processes? How will they address special provisions like protection of subpopulations or special provisions for PBT chemicals?

Science policies: The Agency has gone on record for what it means by a PBT chemical, but it would certainly need to rearticulate that using current science. Also, there are provisions in the bill for promoting sustainable chemicals; the Agency will need to articulate what it means by that. There were such provisions in the FQPA having to do with safe pesticides, and the Agency was able to make an articulation of what a safe pesticide would be. Development of this kind of scientific guidance and interpretation will require engagement of the outside scientific community, including scientists who were associated with stakeholder interests in science or in academia and so forth. EPA may have to establish some new mechanisms to bring all of that to bear—which in turn will involve establishing administrative time lines and project planning processes. You've got these deadlines in the statute, but what are the time lines beneath the deadlines?

Budget and organizational capacity: I see the schedule and process for implementing the new fees as a very high priority because of the fact that the resources are going to help with everything else. Even though there are fees that will help the Agency build the capacity it will need (and I have to say that the amount of fees that are in the Senate bill will be very helpful), they won't necessarily cover everything that the Agency will need in order to do this. The fees won't kick in right away. Taxpayers will be paying for some of this. My experience with the Office of Management and Budget (OMB) is that they were not the ones to make it difficult to implement provisions requiring fees.

But establishment of fees takes time and so there's a chicken-and-egg problem where you need the capacity before you necessarily are going to see the resources coming to the Agency. It isn't just about money. It is also about having the right people on board. Those people who currently work in the chemicals program are not very oriented toward a number of aspects of this legislative fix. EPA will need a number of people who can help reorient the chemicals program toward doing the new assessments and determinations.

Prioritizations: Yes, EPA has been coming out with priority lists. But their current priority lists that are guiding administrative actions are probably very different than the priorities that will need to be established. First, their internally generated criteria, which, to be fair, have included stakeholder input, differ from the criteria in statutes. A priority list that's required by a statute and that is pushing statutorily mandated activities will require far more public engagement. Even though EPA has been very serious about public engagement, the lower stakes for administrative actions have resulted in a fairly low level of public attention and participation. Even if the criteria for prioritization were exactly the same, there will need to be a new stakeholder process to inform prioritization under the statute.

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Role of states: As for possible partnerships with states and other agencies, current TSCA includes no expectation of EPA working together with, sharing information, *or* co-enforcing TSCA with states. There is a state partnership group for the chemicals program, but it's nothing like the kinds of partnerships that other EPA programs have. That will need to be built, and it can probably be built on the existing partnerships. Because the new statute will more fully engage states, there's going to be a higher level of interest and there may be different people (e.g., state attorneys general) that want to play.

As part of reprioritizing, a TSCA Inventory reset is important. That we don't yet really know what is the universe of chemicals in commerce in the United States is another chicken-and-egg problem, because EPA will have to start prioritizing before they've been able to reset the Inventory. I think that's where one would hope that there's some flexibility. EPA is going to need to do an iterative process of Inventory reprioritizing.

CBI: My daughter and other people in her generation have never seen photographic film. Yet, EPA is still protecting the identities of all the chemicals involved in the process of making that film and nearly all other CBI that has ever been submitted. Within the first year, there could be an enormous amount of release of CBI data for claims that have expired or should have timed out under the provisions of a new law. In the original law, it wasn't appreciated that you would need to sunset those claims at some point. Sunsetting the CBI claims is going to have a large impact in terms of release of a lot of significant information.

New chemicals: The first year, they'll have to very clearly establish the new process for new chemicals review. That has to be done very quickly.

The First Five Years

High-priority chemicals: For discussing the five-year framework, I'm thinking less about how things went with the FQPA and more about FIFRA '88.[12] That was a statute that reformed the pesticide law to require EPA to go back and reassess all of the "old" pesticides. In this case, it's not old pesticides; it's the so-called high-priority chemicals. But it's much the same focus. I think it's a focus that has come from the state actions on certain chemicals and the concerns of many of the public health and environmental groups that the pace and process for taking on a big chemical—like a formaldehyde or a phthalate—has been too ponderous. It has not been productive.

The bills, both of them, but especially the Senate one, include a number of processes and deadlines around doing these assessments. I would guess, just as with FIFRA '88, that at first the progress is not going to be as fast as people would have hoped. While there is a need to get started right away to make the deadlines, there's also a need to have in place a procedure for how you're going to do it. You can't just say it's high priority because you don't like the chemical. You need to have a process. I think by the end of the first five years there will not only be a procedure in place, but also a pretty good pace for decisions. However, over the first couple of years, the pace isn't going to look very impressive.

PBT chemicals: I expect the same will prove true with action on PBT chemicals. These decisions are likely to flow a lot more quickly because it's not going to be difficult for EPA to rely on their past experience with PBTs in the chemicals program.

Low-priority chemicals: There also are completely new processes that are needed for selecting chemicals nominated for low-priority review. I think it's likely that far more chemicals could be nominated than EPA will have the ability to review for this assessment. The current Senate bill includes a 30% limit for low-priority decisions, but the House bill does not, potentially overwhelming EPA with this effort. In any case, EPA will need to have objective criteria for selecting whose nominations they're going to take. They can't do that arbitrarily and shouldn't just take them in chronological order. They probably need to develop criteria that could be similar to the criteria that they would have, if you may, for the sustainable chemicals. Perhaps there is overlap between the sustainable chemicals and the chemicals that would first be reviewed as low priority.

Data call-in: There's some low-hanging fruit here in terms of the new data call-in provision. One thing that I think is a huge opportunity is all of the data that have already been presented to the European Union (EU) for REACH.[13] That data has been created; it exists. Currently, EPA doesn't have an easy way to request it. They've tried to work with the EU to be able to access it. Having that data would help EPA prioritize as well as take actions on existing chemicals.

Completing rulemaking for the Inventory reset and updating: The Inventory reset and update isn't going to happen without a rule. As much as OMB loves fees, OMB hates information collection. So, such a rule will be deemed major no matter what, and it will be reviewed extensively, possibly delaying its completion.

Toxicity testing: There are provisions in the bill to use new toxicologic testing methods that reduce or replace the use of animals. That will require a process as to how the Agency will research and validate these methods to be able to do the right thing by the animals. It certainly is required now, or it will be required if the bill goes into place.

The First 10 Years

By the end of 10 years, the process for testing and assessing chemicals will look different. This bill will push EPA not only toward tests that use fewer animals or don't use animals at all, but also toward using tests that are *in vitro*, higher throughout and faster. Hopefully, EPA and others will begin to understand how to actually use the data from those tests in the risk assessments. Despite transition

12. Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), 7 U.S.C. §§136-136y, ELR Stat. FIFRA §§2-35.

13. REACH is the European Regulation on Registration, Evaluation, Authorisation and Restriction of Chemicals. It entered into force in 2007, replacing the former legislative framework for chemicals in the EU. For more information, visit http://ec.europa.eu/growth/sectors/chemicals/reach/index_en.htm.

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problems and growing pains, over the first 10 years, EPA did complete ambitious deadlines under FIFRA '88 and FQPA. They were characterized as impossible deadlines, but EPA did complete them and I believe EPA will figure out a way to complete the new TSCA deadlines as well.

Even though not necessarily during the first two years, over 10 years, there will be thousands of decisions made by EPA, the states, industry, and others that will be better-informed because of all the data that TSCA reform will generate. I think we will see action on all the PBT chemicals as well as the new chemicals on the market so that people will have more assurance that they're safe. Hopefully, the sustainable chemicals program will successfully incentivize the development and marketing of greener chemicals.

Let me address a question from the audience: What is the impact on those of us in industry who are involved with nanotechnology and the production of new products generally? I think that there is an impact, there will be increased information that those companies will need to be presenting to EPA consequent to the new mandates, and that EPA will be looking more closely to determine safety using processes that will be more transparent. EPA will be required to be more explicit that a safety determination has been made; or, where there isn't one, that there's a significant new use rule that restricts the use until an assessment can be done.

On the other hand, for those in the nanotechnology area who are bringing forth technologies that fit the new sustainable chemicals category, that should be a boost if companies are trying to compete with chemicals on the market that are hazardous and that are going to hit the high-priority list. The process of regulating high-priority chemicals will create openings in the market for new materials. So, I think overall it's a good thing for the nanotechnology industry. Today, in some ways, the new chemicals are scrutinized more carefully than most of the existing chemicals, because there really isn't something like a PMN for new uses of existing chemicals.

James Aidala: What are two or three things that have been the least discussed but will make a difference, from our perspective as EPA-ers or just as practitioners in the arena? One of the things on my list is exposure data. Lack of exposure data is going to hinder this program. It's not just lack of experience. There's really going to be a big difference between the way other things are regulated in this space and how that is going to happen.

You're not going to do at least 15 rulemakings in the first two years. You could say, Congress said you don't need OMB review on this thing; you're automatically getting a gazillion information collection request (ICR) hours to do the Inventory reset in the first *x* amount or whatever. Those are the kinds of practical implementation hurdles.

Another thing that has not been widely discussed is that the administration has not been officially at the table. They have been helping out under the guise of technical advice. But there was no administration bill. That's a problem because outsiders can say let's make the government do all the rulemakings in two years. The administration folks will say, excuse me, senator, congressman, staff, we can't do more than a couple in two years. Can you give us some guidance to triage that, whether it be in legislative text or report language?

Lynn Goldman: We've also had the experience of telling them those things and they put in the impossible deadlines anyway.

James Aidala: Staff said we're going to need at least eight, nine, 10 years to do it. We said politically you're not going to get more than three. We're not going to say this is an important emerging issue and it will take 10 years to solve it. We said, two years. Staff said, "No way, boss." So, we said three years. But we knew it was going to take longer than that.

Lynn Bergeson: It has been 19 years.

Lynn Goldman: I do think that it's different when there's an actual deadline that people can sue over. That matters to the Agency. It matters in budget discussions. The Agency resources, how they're managed in the Agency, it does matter.

Lawrence Culleen: Dr. George Gray, former Assistant Administrator of EPA's Office of Research and Development, and currently a professor in GW's Department of Environmental and Occupational Health and Director of the Center of Risk Science and Public Health, is in the audience and might like to comment on this. What I'm hearing the least talk about, but I have personally the greatest concern with, is the extent to which the Agency (particularly in the Senate bill) would be required right out of the blocks to start to define how the Agency will perform scientific assessments. I don't think that's something the Agency is inherently good at. Over the past few years under great scrutiny and pressure from Congress, EPA's Integrated Risk Information System (IRIS)[14] program has tried to redefine how you "do science" and how to be more inclusive and open and receptive to input. I don't see it getting any faster. It's difficult to articulate how you're going to both "do science" and have it under the microscope when you do it, and then have it potentially subject to judicial review. Although arguably, the IRIS program isn't subject to judicial review.

Audience Member (Dr. Gray): Yes, there is a discussion going on. You're exactly right.

James Aidala: When you write science into laws, it creates mischief because it's just hard to do. What we think is the

14. EPA's Integrated Risk Information System (IRIS) program is the assessment process for identifying and characterizing the health hazards of chemicals. For more information, visit http://www.epa.gov/iris.

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state of the art for risk assessment today could be very different in another five or 10 years. If it takes Congress 40 years to get around to changing it again, maybe we'll triple that rate and it will only be 13 years. But hold it: There's still going to be a lot of different science 13 years from now.

Lynn Goldman: My perspective on this is that the science will never be perfect, and that Congress should never tell the Agency exactly how to do it. In this round, there were people who were advising Congress that they should write in things like to benchmark dose models. My perspective is, how are you going to feel about that in 40 years when this law is still around? You don't want that.

But on the other hand, people are making decisions about these chemicals and risks every day. Most of the decisions are completely uninformed by science. The extent to which EPA can use the science it has to shed light on that, it's going to be better than the decisions that are being made. Are they going to be perfect? No. But I think that we're in a situation where these decisions are being made in quite an arbitrary fashion when you consider that, the retail industry is making them, the individual state legislatures are making them. They'll ban a chemical and then it might happen that, well, "we got this flame retardant chemical out of our furniture and now there's another one that we are concerned about." Too often these decisions are made in a vacuum. They don't know about the substitutes. There has been no real analysis.

That is just not the way to make these decisions. But I can't think of who would do a better job, including a lot of us academics who are very good at critiquing EPA and taking its decisionmaking apart. That's what we're good at doing. But we can't afford for these problems to go unaddressed forever while we are trying to develop a perfect scientific process.

Lynn Bergeson: Question from the audience: Can the panelists generally talk about what you envision coming out of the sustainable chemistry provisions of the bill and how they will impact and affect existing chemical programs such as the Safer Choice program?[15]

Lynn Goldman: I can give a start with the idea of the sustainable chemicals provisions. I think it's trying to build on EPA's existing efforts, like the Design for Environment efforts that Larry had some involvement in starting. These efforts were very creatively brought forward even though there was no statutory requirement. In a sense, it has been an effort by EPA to move the industry toward safer chemicals without regulations. In the bills, it is a regulatory approach to incentivize bringing these chemicals on the market. I can't help but think that that would be a stronger approach than the strictly voluntary measures EPA has used. In a sense, it will still be voluntary because industry won't be forced to try to designate chemicals as being sustainable.

Lawrence Culleen: I'm enthusiastic about the idea that the Agency would be able to find a vehicle to incentivize people to not only identify and generate safer substitutes, but also help them to get the substitutes through the regulatory processes. It has been a challenge, in my opinion, in the PMN program where you can currently put a checkmark in a block and write a page that says here's why my chemical is safer or better and improved. Currently, I think it befuddles the program, specifically how to accept the premise that something is a safer substitute and then say, "okay, you are free to go." Often, there's a layer of potentially well-deserved data requirements imposed where there are gaps. But to people in the regulated industry, it seems like, "wait a minute, I thought we're all here to try to get safer chemicals on the market." So, if encouraging substitution is a statutory creature, if it becomes something that the Agency has to do *and* is willing to do, it's a great idea.

James Aidala: Once you identify what is good and what is bad, however broadly phrased, you're starting to help provide those guideposts. So, does it obviate the need for retailers to individually assess everything and come up with their own hit list, let alone the states? It's not just that EPA needs to fill that gap in stages and phases. Talk about limited resources and everything else—states have better things to do in all these phases. That will be obtained once you have a decent program up and running.

Lynn Bergeson: As much as we hope TSCA reform legislation will be enacted, what if it isn't? Let's say TSCA reform does not happen this year, next year, or in the immediate future. EPA has completed some very good work under the TSCA Work Plan Chemicals Program. Larry mentioned some of the administrative changes intended to narrow CBI claims. EPA's use of its authority under the TSCA §5 significant new use rule is much more robust. EPA's assertion of jurisdiction over articles is much more robust. If TSCA is not reformed, are we on the right path to where we need to be, independent of legislative reform?

James Aidala: The answer is yes and no. EPA is doing better at doing risk assessments and will continue to get better at it. But if they can't overcome the "least burdensome" issue, you could try and put something out and see if the courts believe EPA has a better justification now. On the other hand, as noted in my summary on preemption and why I think it's always a tempest in a teapot, there are situations where the governor or the Administrator says, "I really think this is a problem, but court cases or some other thing limits me." That has, shall we say, a market impact. It's not a great scenario and it could help be improved by having a new law. But even with a revitalized program, you've got more pronouncements at EPA, more techniques by EPA under current law, and those things would be able

15. EPA's Safer Choice program helps consumers and businesses find products that perform well and are safer for human health and the environment. For more information, visit http://www.epa.gov/saferchoice.

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to have an impact. It can be leveraged, if you will, and that would be a positive thing.

Lynn Goldman: EPA has been on a good track. It started under Jim Gulliford, assistant administrator for EPA's Office of Prevention, Pesticides, and Toxic Substances in the last administration. Steve Owens, and now Jim Jones, assistant administrator for EPA's Office of Chemical Safety and Pollution Prevention, have accelerated those efforts. All three have shown an extraordinary amount of creativity in using a law that lacks several of the levers that are really needed. I hope those efforts will continue. One of the problems is that because those efforts are not mandated, they are very much dependent on the support of the administration. So, the fact that the White House has supported them, EPA's Administrators have supported them, they've had budgetary resources to do them, all of that could fall away in a new administration.

Under President Clinton, every year in the internal EPA budget process, questions were raised about why EPA needs a new chemicals program. This is because EPA doesn't even need to open the envelope for new chemicals to go onto the market. The current statute does not require any affirmative work by EPA. Why, they would ask, do we need the existing chemicals program? Section 6 doesn't work. And so forth. EPA's chemicals program has had to fight to hold onto its resources. What I would worry about is what happens in the transition to the next administration, no matter who wins the White House in the context of an Agency where most of the regulatory activities are driven by court-ordered deadlines, legal deadlines, very strict mandates—if you have to cut back, where can you do it?

Audience Member: With respect to prioritization, Jim mentioned the Canadian effort. Is there room under the bills for EPA to say in essence we're going to accept what Canada did? And so, whatever they characterize as low priority, we're going to regard that as low priority unless and until somebody makes a case for why one of those chemicals should be treated as high priority.

James Aidala: The Canadian system is one that many view as a good template. If you have to read a fundamental way of reforming current law and things, yes, I think you would see some of that. I do think the low-priority designation issue—I get worried about that sorting issue—that you're going to end up with a big limbo category. I believe it's a big problem. What happens to that? Do we use a suite of conservative models to say, well, what's the exposure and this and that? That starts getting into the history of the pesticide program, which, in my experience, is based on bias that way. But you ended up with characterizations of, oh, my goodness. I mean, literally one Friday at 4:00 a phone call came saying the risk cup is 800,000% full and we might have to take action next week. I said, oh, yeah. And so, by Monday morning, the risk cup was acceptable. I'm not making that up; true story. Things like that can happen without having clear guidance and a clear regimen of how to do the analysis.

Lynn Goldman: EPA cannot automatically accept the Canadian determinations. That just would not be possible. However, the United States and Canada have worked together closely under the North American Free Trade Agreement (NAFTA) and the Organization for Economic Cooperation and Development (OECD) and in other settings. They're very aware of the opportunities to share assessments and approaches. I do think that the Canadian example is one that shows that something like this Senate TSCA bill could work, could be workable, as opposed to a REACH-type activity, which is far more burdensome and complicated.

Audience Member: Chemicals in industrial and consumer products are made from some of the most highly traded global products, which means companies doing business in those markets have to engage regulatory programs in multiple jurisdictions simultaneously for the same chemical. Lynn has mentioned major changes in the EU. We've also seen a brand new program in China and Korea with their K-REACH. But what is your sense of how this TSCA reform, if it actually happens this year, how well it does or doesn't integrate with those other programs? Would it be easier or more difficult for companies to do multiple regulatory approvals with this suite of programs when TSCA reform goes into effect?

James Aidala: The lack of what's considered rigor or stringency in the current program makes it harder for the U.S. position to allow these situations to be accepted. So, with a stronger and more enhanced regimen, more data, more affirmative declaration to safety, here is our full scientific assessment—you're still going to have differences in other things, but it just helps you in those international settings. It is an irony if you go back 30 to 40 years because Europe was reacting to the fear that EPA was going to get way ahead of them based on chemical testing regimens and things. And then it languished, for a lot of reasons, that's a whole separate set of seminars. So, that would drive some of the system.

Larry Culleen: I'm not certain it has been a concept that's been successfully addressed in either bill. There were provisions (varying over time) with respect to acceptance of the PIC list and implementation of various treaties through TSCA legislation, but all of them, I believe, have fallen by the wayside. Similarly, information-sharing across the pond dropped out at the last minute in the most-current versions of each of the bills before they were put to vote. So, I suspect the problems are only going to continue. I don't think there's a lack of desire on the regulators' parts to make things easy, but you've got different statutes and and there are different standards and regulatory approaches for data sharing among data generators.

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There's certainly cross-country participation, but I don't think functionally it's going to get easier. Somebody has to comply with all of these different requirements.

Lynn Goldman: The OECD chemicals process to me is the best way forward toward that kind of harmonization. There are other things that are being tried. I know that the Transatlantic Trade and Investment Partnership is trying to make mutual acceptance automatic. I don't see the political reality behind that in terms of the idea that we will sign a trade agreement and then we'll just live under European laws. I don't think that's going to happen. In terms of harmonization with Europe, there's a willingness to do it on both sides, but it's a lot of effort. Frankly, the EU has to put a tremendous amount of effort into harmonizing among themselves. Once they've agreed among themselves, they sometimes are reluctant to harmonize with the United States or Canada or others. We need to be in the game earlier.

Lynn Bergeson: On that note, I think we will stop. I want to thank Dean Goldman, Jim Aidala, and Larry Culleen for their excellent contributions.[16]

16. For the powerpoint and video presentation of this seminar, please visit http://www.eli.org/events/tsca-reform-panel-summit-whats-happening-now-and-whats-next. Please also visit www.TSCAreform.org, for additional resources.