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Energy and Commerce Committee

Subcommittee on the Environment

Chemicals in Commerce: Legislative Proposal to Modernize America's Chemical Safety Law, Strengthen Critical Supply Chains, and Grow Domestic Manufacturing.

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Summary of Written Testimony of Dimitri Karakitsos

In 2016, President Obama signed into law The Frank R. Lautenberg Chemical Safety for the 21st Century Act (Lautenberg Chemical Safety Act or LCSA) after it passed with overwhelming support in the House and Senate and from a wide range of industry, labor, environmental and other stakeholders. The law was designed to update the Toxic Substances Control Act (TSCA) of 1976 which was intended to protect human health and the environment by regulating new and existing chemicals.

Due to implementation challenges, including a court decision in 1991, the original TSCA failed to regulate existing chemicals on the TSCA inventory in any meaningful way, leading to a state patchwork of regulations that not only left people in one state with different protections and regulations than another, but also created burdens to interstate commerce.

The bipartisan, multiyear process to update the law saw many iterations, but the goals were relatively consistent. First, to fix the existing chemicals program that had failed to operate effectively following the 1991 court ruling overturning EPA's asbestos ban; second, to maintain a new chemicals program that was protective while allowing American industry to lead global innovation; and third, to create a unified national approach to chemical regulations.

Notably, the LCSA included an updated fees provision that was important to provide the Agency with additional resources to address its increased workload; at the same time, Congress chose to sunset the fees provision after 10 years. This was an intentional decision designed to create an impetus to look back at a decade of implementation and see if the law was working as intended, or if any clarifications or updates would be needed to make the law function better.

While the LCSA has already resulted in some greater protections to human health and the environment, its implementation has also faced some challenges, in some instances failing to match the intent of Congress. The most obvious of the implementation challenges has been the new chemicals program. It has not been implemented in any way consistent with the expectations of Congress and has, since the 2016 enactment, routinely missed deadlines and hindered innovation. Additionally, implementation has at times failed to adhere to the scientific requirements of the law, and provisions like the citizens' petitions have proven to be out of line with the rest of the statute in their current form.

Overall, it is a positive and necessary step consistent with the 2016 compromise for the Members of the Environment Subcommittee and full Energy and Commerce Committee to take a thoughtful look at the LCSA's implementation over the last nine years. The legislation we are discussing today is not a wholesale rewrite of the law, but a more targeted draft to ensure the law actually works better while aligning with the major goals of the LCSA. The Legislative branch should be looking back and examining how the law has actually operated in almost the decade since its enactment, and ensuring the next decade of TSCA implementation is more predictable and better protective of human health, the environment, innovation, and American manufacturing.

Testimony of Dimitri Karakitsos

Chairman Guthrie, Chairman Palmer, Ranking Member Pallone, Ranking Member Tonko, and Members of the Environment Subcommittee, thank you for the opportunity to testify today. My name is Dimitri Karakitsos, and I am a Partner at Holland and Knight here in Washington, DC. I want to begin by making clear that I am not here today representing the firm or any of its clients; I am here in a personal capacity based on my prior experience working as a Congressional staffer on the 2016 Lautenberg Chemical Safety Act (LCSA) amendments to the Toxic Substances Control Act (TSCA).

Serving as the lead Senate Environment and Public Works Committee Republican staffer on chemical policy, I worked on many different iterations of bipartisan TSCA reform bills, from the 2013 introduction of the Chemical Safety Improvement Act to the final LCSA that was signed into law. At that time, there was a shared view that the original law from 1976 was badly outdated, failed to adequately protect human health and the environment, and had resulted in an unworkable patchwork of state regulations that was impeding interstate commerce.

Working with this Subcommittee directly, we were able to pass one of the first major environmental law rewrites in decades with overwhelming bipartisan support. The overarching goals of reform were to fix the existing chemicals program that had failed to effectively operate since the 1991 overturning of EPA's asbestos ban, maintain a new chemicals program that allows American industry to lead global innovation while protecting human health and the environment, and create a unified national approach to chemical regulations – all while requiring EPA to use the best available science and weight of the scientific evidence. The law also included an updated fees

provision that was important to provide the Agency with greater resources to take on its additional responsibilities, while deliberately sunsetting that authority after 10 years. The sunsetting of the fees authority was designed to provide Congress with a forcing mechanism to look back at a decade of implementation and see if the law was working as envisioned, or if any updates were needed to make it function better.

The legislative process this Committee is undertaking, in my view, is well aligned with Congressional intent from 2016 to review how the law was functioning as part of the fees reauthorization process. I applaud the work of this Subcommittee in taking a thoughtful look at what has and has not been working well and where fixes are necessary – not to relitigate or undo the entire 2016 compromise, but to make the law operate better.

Since the LCSA was signed into law, I have had the opportunity to work with EPA career and political officials in four separate administrations as they navigate its implementation. Despite the Agency's best efforts throughout the last decade, there are a few glaring parts of the law that I do not believe are operating as Congress intended when it passed the Lautenberg Chemical Safety Act, and now Congress has the opportunity to address these issues while reauthorizing the fees through legislation.

First, the original TSCA required manufacturers to submit a notice to EPA 90 days prior to beginning manufacture of a new chemical substance to give EPA an opportunity to review the safety of the chemical within those 90 days and to take action as may be necessary to reduce any unreasonable risks. In the course of negotiating the 2016 amendments, Congress worked closely

with the EPA to codify what the Agency described in technical assistance as the new chemicals practices as they existed at the time, reaffirming the 90-day review period and for the first time actually allowing EPA to approve new chemicals in less than the statutory 90-day timeframe. There was not a significant push to overhaul the new chemicals program, and a number of environmental groups supported versions of legislation that left Section 5 untouched. At the time there was confidence that the Obama Administration was reviewing new submittals thoroughly enough under the original law to prevent dangerous chemicals from going to market unchecked, and because changes were being made to ensure a more robust and functioning existing chemicals program, there was bipartisan agreement that major operational changes to the new chemicals program weren't necessary. The primary fear at the time was that the way the original TSCA was drafted could allow a future Administration to do no safety review, simply let the 90-day clock expire, and add countless new chemicals to the existing chemical inventory whether they were safe for use or not. Forcing EPA to make a determination of "not likely to present an unreasonable risk" within 90 days in order for a chemical substance to go to market was not intended to be a significantly higher bar or designed to exhaustively analyze any and all risks, and it certainly was not intended to drastically upend the program. The understanding relayed to Congress by the Obama-EPA was that in practice they were already making a similar determination that a new chemical could go to market by allowing the 90-day clock to expire after a safety review, and the language in the law would simply memorialize that. Of course, that is not how the new chemicals program has operated in the nearly ten years since the updates were passed, and unfortunately, we have seen significant hurdles to innovation as a result with a vast majority of chemicals taking significantly longer than 90 days for review.

Requiring EPA to use the best available science and weight of scientific evidence was also a pillar of the compromise, and here, too, is an area where I think implementation has not met the goals of the 2016 law. At times, the Agency has relied on hazard values not at all consistent with real world scenarios or the weight of scientific evidence, which has led to some extremely conservative regulatory proposals out of line with international regulators in Europe and beyond. In some instances, EPA has gone against its own longstanding scientific guidance and its own scientific advisors, which at times gives the appearance it is not adhering to these important requirements under the law.

Finally, Section 21, the Citizens' Petitions section of the law, has eaten up valuable EPA resources while providing little to no benefit to human health or the environment. It is clear this section needs additional updating to bring it better in line with the changes previously made to Section 6 (the existing chemicals section of TSCA) and to ensure EPA decisions are based on adequate scientific information. In trying to limit the changes in non-core sections of TSCA at the time the LCSA negotiations were occurring, Congress left this section largely untouched. Unfortunately, because it had not conformed to the new changes in Section 6, the original Section 21 language was drafted in a way that could allow EPA to skip the prioritization and risk evaluation phase of the existing chemicals process and move directly to regulate a chemical substance, even when it lacked the scientific and other information needed to do so in a manner consistent with what the law requires for existing chemical rules. I believe this was an oversight, and we have seen overreaching petitions to force regulations on things like tobacco and greenhouse gas emissions which TSCA was not designed or intended to address. Making changes to Section 21 is not about limiting citizens' abilities to seek an appropriate remedy from the EPA; it is about making sure

that any EPA regulatory decision is adequately justified by a thorough scientific review. While to date EPA has denied most TSCA petitions or has found ways to scale back or not to proceed immediately to regulations for others, the Agency has spent an unreasonable amount of time and resources on review, response, and litigation related to petitions that are ill-suited to TSCA and the remedy being requested by the petitioners. EPA's time would clearly be better spent on other existing chemicals work, particularly since EPA generally cannot collect TSCA fees for work it carries out under Section 21.

In closing, both the House and Senate spent years developing and negotiating different bills and policies that ultimately led to the landmark bipartisan compromise that was the Lautenberg Chemical Safety Act. It is my belief that the efforts of Chairman Palmer and this Subcommittee are in line with the intent of the 2016 bipartisan compromise to ensure that the law is sufficiently protective of not only human health and the environment but also innovation and our domestic manufacturing. Looking at one of the stated policy goals of original TSCA that Congress maintained in 2016 sums it up well:

> *"It is the policy of the United States that - … authority over chemical substances and mixtures should be exercised in such a manner as not to impede unduly or create unnecessary economic barriers to technological innovation while fulfilling the primary purpose of this Act to assure that such innovation and commerce in such chemical substances and mixtures do not present an unreasonable risk of injury to health or the environment."*

The fee expiration was designed to provide Congress with a forcing mechanism to look at 10 years of implementation, identify challenges and shortcomings, and address them responsibly in order to ensure the 2016 law operates successfully well into the future.

Thank you again for the opportunity to testify, I look forward to your questions and being a resource for the Committee as you work towards fee reauthorization.