

**Testimony of Dr. Paul A. Locke**

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**Submitted to the House Energy and Commerce Subcommittee on Environment and the Economy**

**Hearing on TSCA Modernization Act**

**Tuesday, April 14, 2015, at 10:15 a.m.**

**Room 2322 of the Rayburn House Office Building**

Chairman Shimkus, Ranking Member Pallone, and members of the subcommittee:

Thank you for the opportunity to submit testimony on the TSCA Modernization Act and the important issues of toxic chemical evaluation, advancing scientific research and efficiency and implementing public health protections.

As Congress seeks to find consensus on reforming our outdated TSCA law, it will be helpful to keep in mind important areas where agreement can and has been reached in recent years. One area of consensus is the goal of advancing the science of regulatory toxicology by implementing the recommendations made to EPA by the US National Academy of Sciences (NAS) about how to improve its testing methodologies. In its report entitled “Toxicity Testing in the Twenty-first Century: A Vision and a Strategy,” the NAS advised EPA to move from a testing system based on animal models to one that is based on human biology, using cell lines and other methods that provide information about the pathways that lead to diseases caused or contributed to by chemical exposures.

Stakeholders in the issue of chemical regulation have long agreed that improving regulatory toxicology by advancing innovative testing methods, especially those that do not use animals, would be in the best interest for all involved. Industry has embraced the concept of non-animal testing, or in vitro testing, as a way to cut costs and learn about toxic cellular reactions. Animal testing can be very expensive and slow to produce usable data. Environmental and public health advocates have argued that advancing non-animal testing would provide useful data in a timely fashion that regulators could use to help make decisions that protect public health and welfare. Animal welfare advocates have also pushed for less reliance on animal tests as a way to improve and advance humane science.

Recent scientific advances offer to fundamentally change the way chemicals are tested for human health risks. These advances, which include in vitro testing, make it possible to rely less heavily on animal studies and instead focus on evaluating chemicals' effects on biological processes in cells and organs. Scientists can generate improved data to evaluate risks and expand the number of chemical assessments while taking less time and money and using fewer animal subjects. Several federal agencies — the Environmental Protection Agency, the Food and Drug Administration and the National Institutes of Health — embraced this approach and are working hard to further develop the science to make this vision a reality.

Existing chemical regulations place the burden of risk assessment on the EPA, and that is a heavy burden. More than 80,000 chemicals are registered for use in the United States and an estimated 2,000 new ones are introduced each year for use in everyday items such as foods, personal care products, prescription drugs, household cleaners, and lawn care products. TSCA has not been effective in generating chemical toxicity information for the vast majority of these chemicals. In March 2013, a Government Accountability Office report evaluated the EPA's efforts to strengthen its management of chemicals. The GAO found that the lack of data is one of the biggest impediments the EPA encounters in attempting to ensure chemical safety, even on substances prioritized for risk assessment.

It is encouraging that The TSCA Modernization Act contains at least some provisions that recognize the value of in vitro testing for regulatory decision-making. While these provisions could be stronger in this bill and other bills, the fact that they have been a common link shows that this is a fertile opportunity to build consensus. Strengthening the focus on in vitro, innovative science will increase the likelihood for consensus and put the bill on the path of employing the innovative toxicological methods that the NAS and others have recommended.

Congress has made clear its pursuit of advancing alternative methods of chemical testing as a means toward the development of better chemical safety data that is thorough, efficient and applicable to human exposure concerns. Last year, as part of the FY 2015 Interior, Environment and Related Agencies Appropriations bill (passed as part of the FY 2015 Omnibus Appropriations bill), Congress directed EPA to report on the modernization of risk assessment protocols and the incorporation of the recommendations from the National Academy of Sciences. In that directive, Congress requested that EPA report on (1) progress to date to research, develop, validate and translate innovative chemical testing methods that characterize toxicity pathways, (2) efforts to coordinate across federal agencies, and (3) future plans to continue to implement the toxicity testing vision and strategy in the NAS report. This report is expected to be submitted to Congress from EPA later this year.

A strong system of in vitro testing will help provide the necessary data for a risk assessment regime that is more efficient, accurate and effective in evaluating chemicals for toxicity and safety. It is a common sense approach that will offer all Americans a more risk-free environment. This is a real opportunity to build consensus that has been elusive as Congress has sought to modernize TSCA over the years. I hope that any legislation passed by Congress will include strong provisions that will build consensus and help build a model for a modern chemical safety testing that we can all believe in.