ENDOCRINE SOCIETY
Hormone Science to Health

May 5, 2015

U.S. Senator David Vitter
516 Hart Senate Office Building
Washington, DC 20510

U.S. Senator Tom Udall
531 Senate Office Building
Washington, DC 20510

Dear Senator Udall and Senator Vitter,

On behalf of the Endocrine Society I am writing to you regarding S. 697, the "Frank R. Lautenberg Chemical Safety for the 21st Century Act." We appreciate that the current Toxic Substance Control Act (TSCA) is an outdated law badly in need of substantial modification, and we acknowledge the bipartisan approach to reform TSCA in a thoughtful manner. After a careful review however, we are unable to support the legislation as currently constructed.

Founded in 1916, the Endocrine Society is the world's oldest, largest, and most active organization dedicated to the understanding of hormone systems and the clinical care of patients with endocrine diseases and disorders. The Society's membership of over 18,000 includes researchers who are making significant contributions to our understanding of the effects of exposures to manufactured chemicals that interfere with hormone systems – a new area of science investigating endocrine disrupting chemicals (EDCs). Below, we offer several recommendations to enhance the regulatory approach for chemicals, help federal agencies reduce harmful exposures to toxic chemicals and improve public health.

1. Incorporation of 21st Century Science in Assessments

The Endocrine Society has consistently argued that the current approach is inadequate to identify and characterize hazards associated with exposures to EDCs. Moreover "good laboratory practices (GLP)" should not be confused with "good science." GLP is a formulized record keeping system instituted in the 1970s in response to misconduct and fraud in contract toxicology labs. Its use is required in industry-funded studies to prevent such fraud from occurring again. Favoring GLP-compliant studies in risk assessment thus disproportionally favors data generated in contract labs and marginalizes or eliminates from consideration data generated in academic labs, including those of our members. We are concerned that, for example Sec. 3A subsection (e)(3)(B) incentivizes the use of "standardized test design and methods, consistent data evaluation procedures, and good laboratory practices" which essentially maintains the status quo approach for evaluating chemical hazards.

As written, S. 697 will maintain the inappropriately narrow set of guidelines under which studies are selected and weighted in risk assesements, and thus continue the practice of failing to consider the latest scientific studies from the world's top researchers into the mechanisms of EDC actions and impacts in humans. These studies are frequently published in elite scientific journals, have undergone rigorous peer-review, and have been corroborated through subsequent research by

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independent researchers. Moreover, the design of these studies has been evaluated by a very rigorous and competitive peer review system to qualify for public funding. To maximize the efficiency of the government's investment in biomedical research, these state-of-the-art scientific studies that form the basis for improving clinical care of endocrine diseases should also be used for chemical regulation in order to reduce the prevalence or severity of those same diseases.

Recommended Change: Sec. 3A subsection (e)(3)(B) should be modified, deleting the language "standardized test designs and methods" and "good laboratory practice." Furthermore, an additional clause should be added that includes the following statement: "Risk assessments should consider publicly-funded, peer-reviewed scientific information that incorporates the most sensitive endpoints relevant to human and environmental health."

2. Chemicals Should Not be Relegated to Lower Priority Status Based on Exposure Estimates

We appreciate that a key feature of the legislation is to ensure that EPA characterize a cadre of high-priority substances for potential regulatory action. It is therefore critical that criteria for prioritization are sufficiently inclusive to allow the EPA to appropriately evaluate all classes of chemicals for the potential to cause harm. We are concerned that S. 697, in multiple sections, uses "widespread" or "high" exposure e.g., as criteria for the identification of high-priority substances in Sec. 4A subsection (b)(3)(A).

The Endocrine Society asserts that for certain chemicals, such as EDCs, it cannot be assumed that there are thresholds below which EDC exposures are safe. Accumulated scientific evidence has established that hormones act at extremely low concentrations, during critical developmental windows, and with non-monotonic dose-response relationships. Regulatory policies should therefore be based on comprehensive data covering both low-level and high-level exposures, synthesizing basic science, clinical observation and epidemiological data. We applaud the acknowledgment in the legislation that certain populations, including pregnant women, infants, and children are particularly vulnerable to chemical exposures. Especially for vulnerable populations, the effects of very small amounts of EDCs must be taken into account systematically in regulatory decisions in order to ensure adequate protection. We recommend amending S. 697 to ensure that chemicals for which exposure estimates are low may still be considered for high-priority review status when exposures to vulnerable populations, including pregnant women, are shown to occur.

Recommended Change: Replace "exposure" with "hazard and/or exposure" in Sec. 3A subsection (h)(3), and replace "high hazard and widespread exposure" with "high hazard and/or widespread exposure" in Sec. 4A subsection (b)(3)(A). Additionally, add a new paragraph (4) "chemicals should be designated high priority if there is potential exposure to pregnant women, infants, or children."

3. Fees Collected by EPA Must be Adequate

Successful implementation of TSCA reform requires that the EPA has the necessary resources to identify, review, and conduct regulatory actions on high-profile chemicals. However, the magnitude of the problem facing EPA is immense. There are over 85,000 chemicals on the market in the United States; of these only a small fraction have been tested for safety. While we appreciate that S. 697 introduces user fees to help defray the costs of EPA action on high-profile chemicals, we are concerned that the user fees may be insufficient for carrying out the expanded duties demanded by the legislation. We note that S. 697 restricts fees collected to approximately 25 percent of EPA's budget, or no more than $18 million. By comparison, user fees imposed under the Prescription Drug User Fee Act cover nearly 65 percent of the drug approval process. In 2010 alone this totaled over $570 million in fees[1]. We therefore recommend that any caps imposed by TSCA reform legislation be increased to allow EPA to effectively conduct regulatory activities.

Recommended Change: Any caps imposed by TSCA reform legislation be increased to levels similar to those required under the Prescription Drug User Fee Act to allow EPA to effectively conduct regulatory activities.

In Conclusion

The Frank R. Lautenberg Chemical Safety for the 21st Century Act is an important bipartisan effort to reform TSCA and protect the health of our communities. However, we acknowledge and strongly support the efforts of individual states to craft evidence-based regulations to achieve effective protection from hazards associated with exposures to harmful chemicals. We note that several states have crafted responsible, evidence-based regulations to minimize risks from exposure to EDCs in the absence of federal leadership in this area. We ask that the ability to maintain strong laws and regulations across the system be maintained in future versions of the legislation.

We look forward to working with you to ensure that the final legislation appropriately protects individuals, including vulnerable populations, from harm due to exposure to chemicals such as EDCs. Thank you for advancing this important issue and considering our comments. If we can be of any assistance, please do not hesitate to reach out to Joseph Laakso, PhD., Associate Director of Science Policy at jlaakso@endocrine.org.

Sincerely,

Lisa N. Fish MD

Lisa Fish, MD
President, Endocrine Society

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1 http://www.fda.gov/AboutFDA/ReportsManualsForms/Reports/UserFeeReports/FinancialReports/PDUFA/ucm262847.htm Accessed April 13, 2015.