ENDOCRINE SOCIETY
Hormone Science to Health

March 24, 2016

The Honorable James M. Inhofe
Chairman
Committee on Environment and Public Works
U.S. Senate
410 Dirksen Senate Office Building
Washington, DC 20510

The Honorable Frederick S. Upton
Chairman
Committee on Energy and Commerce
U.S. House of Representatives
2183 Rayburn House Office Building
Washington, DC 20515

The Honorable Barbara Boxer
Ranking Member
Committee on Environment and Public Works
U.S. Senate
456 Dirksen Senate Office Building
Washington, DC 20510

The Honorable Frank Pallone, Jr.
Ranking Member
Committee on Energy and Commerce
U.S. House of Representatives
237 Cannon House Office Building
Washington, DC 20515

Dear Chairman Inhofe, Chairman Upton, Ranking Member Boxer, and Ranking Member Pallone,

On behalf of the Endocrine Society, I am writing regarding the Toxic Substance Control Act (TSCA) Modernization Act of 2015 (H.R. 2576) and the Frank R. Lautenberg Chemical Safety for the 21st Century Act (S. 697). 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). The Endocrine Society endorsed and fully supports the recommendations sent by organizations dedicated to public health and safety sent February 12[1]. Our comments are meant to be complimentary to these letters, and our earlier comments on S.697[2].

We believe the current TSCA is an outdated law in need of substantial modification and we acknowledge the bipartisan approach to reform TSCA in a thoughtful manner. To achieve meaningful public health protections through TSCA modernization, it is critically important that the Committee reports accompanying the final legislation include the following:

[1] https://www.endocrine.org/~/media/endosociety/files/advocacy-and-outreach/society-letters/tsca-reform-signon-letters-sent-to-house-and-senate-leadership-committee-on-energy-and-commerce-and-committee-on-environment-and-public-works.pdf?la=en

[2] https://www.endocrine.org/~/media/endosociety/files/advocacy-and-outreach/society-letters/endocrine-society-comments-on-frank-r-lautenberg-chemical-safety-in-the-21st-century-act.pdf?la=en Accessed February 16, 2016.

2055 L Street NW
Suite 600
Washington, DC
20036

T. 202.971.3636
F. 202.736.9705

endocrine.org

- Language that states clearly that EPA needs a consistent approach and criteria that is applied in the same way to all studies in regulatory processes. This includes peer-reviewed academic literature.
- Language about Weight of Evidence (WOE) from the House report stating, "The term "weight of evidence" refers to a systematic review method that uses a pre-established protocol to comprehensively, objectively, transparently, and consistently, identify and evaluate each stream of evidence, including strengths, limitations, and relevance of each study and to integrate evidence as necessary and appropriate based upon strengths, limitations, and relevance."
- Additional language to WOE stating, "This requirement is intended to ensure that the Agency consider academic studies, or any other category of study, fully."
- Language providing direction to the agency that the default approach for evaluating risks from chemicals is that there are risks at low doses and that a dose at which there is no effect must be proven.

The Endocrine Society has consistently maintained that the current regulatory approach is inadequate for the identification and characterization of hazards associated with exposures to endocrine disrupting chemicals (EDCs). Currently federal agencies responsible for conducting risk assessments and protecting the public from harms due to exposure to EDCs may fail to consider the latest scientific studies from the world's top researchers into the mechanisms of EDC actions and impacts in humans. In addition, the processes federal agencies use to gather public input are particularly burdensome to academic scientists, whose expertise is imperative to ensure that assessments incorporate the latest peer-reviewed scientific studies.

Such studies are frequently published in recognized scientific journals that require conflict of interest disclosures, have undergone rigorous peer-review, and have been corroborated through subsequent research by independent groups. Moreover, the design of these studies has been evaluated by an additional rigorous and competitive peer review system to qualify for federal funding. To maximize the efficiency of the government's investment in biomedical research, we believe that 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.

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 H. Fish MD

Lisa Fish, MD
President, Endocrine Society

ENDOCRINE SOCIETY
Hormone Science to Health

March 24, 2016

The Honorable Mitch McConnell
Majority Leader
U.S. Senate
United States Capitol, S-230
Washington, D.C. 20510

The Honorable Paul Ryan
Speaker
U.S. House of Representatives
United States Capitol, H-232
Washington, D.C. 20515

The Honorable Harry Reid
Minority Leader
U.S. Senate
United States Capitol, S-221
Washington, D.C. 20510

The Honorable Nancy Pelosi
Minority Leader
U.S. House of Representatives
United States Capitol, H-204
Washington, D.C. 20515

Dear Majority Leader McConnell, Minority Leader Reid, Speaker Ryan, and Minority Leader Pelosi,

On behalf of the Endocrine Society, I am writing regarding the Toxic Substance Control Act (TSCA) Modernization Act of 2015 (H.R. 2576) and the Frank R. Lautenberg Chemical Safety for the 21st Century Act (S. 697). 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). The Endocrine Society endorsed and fully supports the recommendations sent by organizations dedicated to public health and safety sent February 12[1]. Our comments are meant to be complimentary to these letters, and our earlier comments on S.697[2].

We believe the current TSCA is an outdated law in need of substantial modification and we acknowledge the bipartisan approach to reform TSCA in a thoughtful manner. To achieve meaningful public health protections through TSCA modernization, it is critically important that the Committee reports accompanying the final legislation include the following:

[1] https://www.endocrine.org/~/media/endosociety/files/advocacy-and-outreach/society-letters/tsca-reform-signon-letters-sent-to-house-and-senate-leadership-committee-on-energy-and-commerce-and-committee-on-environment-and-public-works.pdf?la=en

[2] https://www.endocrine.org/~/media/endosociety/files/advocacy-and-outreach/society-letters/endocrine-society-comments-on-frank-r-lautenberg-chemical-safety-in-the-21st-century-act.pdf?la=en Accessed February 16, 2016.

2055 L Street NW
Suite 600
Washington, DC
20036

T. 202.971.3636
F. 202.736.9705

endocrine.org

- Language that states clearly that EPA needs a consistent approach and criteria that is applied in the same way to all studies in regulatory processes. This includes peer-reviewed academic literature.
- Language about Weight of Evidence (WOE) from the House report stating, "The term "weight of evidence" refers to a systematic review method that uses a pre-established protocol to comprehensively, objectively, transparently, and consistently, identify and evaluate each stream of evidence, including strengths, limitations, and relevance of each study and to integrate evidence as necessary and appropriate based upon strengths, limitations, and relevance."
- Additional language to WOE stating, "This requirement is intended to ensure that the Agency consider academic studies, or any other category of study, fully."
- Language providing direction to the agency that the default approach for evaluating risks from chemicals is that there are risks at low doses and that a dose at which there is no effect must be proven.

The Endocrine Society has consistently maintained that the current regulatory approach is inadequate for the identification and characterization of hazards associated with exposures to endocrine disrupting chemicals (EDCs). Currently federal agencies responsible for conducting risk assessments and protecting the public from harms due to exposure to EDCs may fail to consider the latest scientific studies from the world's top researchers into the mechanisms of EDC actions and impacts in humans. In addition, the processes federal agencies use to gather public input are particularly burdensome to academic scientists, whose expertise is imperative to ensure that assessments incorporate the latest peer-reviewed scientific studies.

Such studies are frequently published in recognized scientific journals that require conflict of interest disclosures, have undergone rigorous peer-review, and have been corroborated through subsequent research by independent groups. Moreover, the design of these studies has been evaluated by an additional rigorous and competitive peer review system to qualify for federal funding. To maximize the efficiency of the government's investment in biomedical research, we believe that 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.

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 H. Fish MD

Lisa Fish, MD
President, Endocrine Society