Comments from Academics, Scientists and Clinicians on Nominations to the Science Advisory Committee on Chemicals (SACC)

EPA-HQ-OPPT-2016-0713 FRL-9956-17

Comments submitted to EPA-HQ-OPPT-2016-0713 and by email to Tamue Gibson, DFO, Office of Science Coordination and Policy (7201M), Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Washington, DC 20460–0001; telephone number: (202) 564–7642; email address: gibson.tamue@epa.gov.

These comments are submitted on behalf of the undersigned academics, scientists, and clinicians from universities and non-profit organizations located within the United States and other countries. We declare that we have no direct or indirect financial or fiduciary interest in the manufacture or sale of any chemical that would be the subject of the deliberations of this Committee.

In summary, our comments address the following main points:

- 1. Support for 11 of 29 individuals on EPA's proposed list;
- 2. EPA's proposed list does not include all relevant perspectives needed to ensure a robust SACC. EPA should include 1 or more members from NGOs and 1 or more members from directly impacted communities that represent the "public interest" as included in the Lautenberg Amendments to the Toxic Substances Control Act (TSCA);
- 3. EPA should strive to eliminate or minimize financial conflicts of interest (COI) from selected committee members. In the event that financial COI exists, EPA should collect information from each and every SACC member in an effort for complete transparency regarding any financial conflicts of interest (COI) that potentially bias members—such as those with a financial interest or who profit from decisions—toward undervaluing the scientific information related to health effects of industrial chemicals. Any and all existing financial COI should be made explicit and transparent to the public.

Background

We appreciate the opportunity to provide comments on the nomination of members for the Science Advisory Committee on Chemicals (SACC), pursuant to section 2625(o) of the Frank R. Lautenberg Chemical Safety for the 21st Century Act. This panel will "provide independent advice and expert consultation, at the request of the Administrator, with respect to the scientific and technical aspects of issues relating to the implementation of this title" and will include "representatives of such science, government, labor, public health, public interest, animal protection, industry, and other groups as the Administrator determines to be advisable, including representatives that have specific scientific expertise in the relationship of chemical exposures to women, children, and other potentially exposed or susceptible subpopulations."

When selecting members, in addition to scientific expertise, differing perspectives, and breadth of collective experience, EPA is considering:

- Background and experiences that would contribute to the diversity of scientific viewpoints on the
 committee, including professional experiences in government, labor, public health, public
 interest, animal protection, industry, and other groups, as the EPA Administrator determines to be
 advisable (e.g., geographical location; social and cultural backgrounds; and professional
 affiliations);
- Skills and experience working on committees and advisory panels including demonstrated ability to work constructively and effectively in a committee setting;
- Absence of financial conflicts of interest or the appearance of a loss of impartiality;
- Willingness to commit adequate time for the thorough review of materials provided to the committee; and
- Availability to participate in committee meetings.

On August 26, 2016 EPA published Federal Register Notice EPA-HQ-OPPT-2016-0474, inviting public nominations for the SACC. In response, University of California, San Francisco (UCSF) Program on Reproductive Health and the Environment (PRHE) submitted public comments nominating ten professionals affiliated with academia, government, and nonprofit organizations. Furthermore, UCSF PRHE also encouraged EPA to consider the following when considering nominations for SACC membership:

- The role of the SACC in supporting the mission of EPA in protecting human health and the environment. As such, EPA has a professional and legal duty to select committee members who will provide credible and independent scientific analysis and advice free from conflicts of interest or a strong bias toward the perspective of regulated industries that may have a vested interest in minimizing EPA's regulation of hazardous materials and products.
- The need for transparent and effective disclosure policies that are strictly enforced. These disclosure and conflict policies play an essential role in protecting EPA and committee work products and must be strictly enforced and routinely addressed to ensure the quality of SACC work products.
- The need for committee representation from directly impacted, susceptible, vulnerable, and/or highly exposed populations. We urge the Agency to not only seek "representatives that have specific scientific expertise in the relationship of chemical exposures to women, children, and other potentially exposed or susceptible subpopulations" (emphasis added), but to incorporate a broader and more inclusive definition to capture representation from individuals with diverse knowledge sources that represent unique perspectives to these critical issues. EPA has encouraged "citizen science" but then has then erected expertise barriers that essentially prevent those with expertise about impacted communities but perhaps without certain privileged credentials (i.e., holding a postgraduate degree) from taking part in critical discussions. There are many examples of successful implementation of such approaches, which have demonstrated that incorporating knowledge resources outside of traditional academics and science fields can greatly enrich the research and policy process.*

^{*} Anderson, B.E., Naujokas, M.F. and Suk, W.A., 2015. Interweaving knowledge resources to address complex environmental health challenges. *Environmental health perspectives*, 123(11):1095-1099.

Based on nominations received from Federal Register Notice EPA-HQ-OPPT-2016-0474, EPA has identified 29 candidates for further consideration for membership on the 14-member SACC, nine of whom are members of the existing EPA Chemical Safety Advisory Committee (CSAC).

Comment on Nominations

1. Support for 11 of 29 individuals on EPA's proposed list.

We are pleased to confirm our support for the following 11 candidates being considered for membership on the SACC. We believe these individuals are extremely well-qualified for the SACC duties and meet the criteria, with considerable experience and expertise that would contribute valuable service to the SACC in its mission to "provide advice and recommendations on the scientific basis for risk assessments, methodologies, and pollution prevention measures or approaches." We believe these individuals to be those who best meet the considerations listed above for SACC membership. We make no recommendation or comment on the remaining candidates other than to urge EPA to consider our comments below in regards to including individuals with domain expertise from directly impacted, susceptible, vulnerable, and/or highly exposed populations, such as environmental justice communities, and to minimize or at the very least strive for complete transparency of any potential financial conflicts of interest.

Nominees are listed below in alphabetical order.

Support for nomination #1: Dr. Henry A. Anderson
Support for nomination #2: Dr. Deborah Cory-Slechta
Support for nomination #3: Dr. Gary Ginsberg
Support for nomination #4: Dr. Melanie Marty
Support for nomination #5: Dr. Kenneth Portier
Support for nomination #6: Dr. Sheela Sathyanarayana
Support for nomination #7: Dr. Kristina Thayer†
Support for nomination #8: Dr. Leonardo Trasande
Support for nomination #9: Dr. Laura Vandenberg
Support for nomination #10: Dr. Christine Whittaker
Support for nomination #11: Dr. Tracey Woodruff

2. EPA's proposed list does not include all relevant perspectives needed to ensure a robust SACC. EPA should include 1 or more members from NGOs and 1 or more members from directly impacted communities that represent the "public interest" as required in the Lautenberg Amendments to the Toxic Substances Control Act (TSCA).

Notably missing is: 1) representation from nonprofit organizations that specifically work on public interest and environmental protection issues, such as the National Resources Defense Council (NRDC), Environmental Defense Fund (EDF), or EarthJustice; and 2) members from directly impacted communities.

In support of this, UCSF PRHE previously submitted comments to Federal Register Notice EPA-HQ-OPPT-2016-0474 that included two nominees representing nonprofit organizations—Dr. Veena Singla (NRDC) and Dr. Christopher Portier (EDF), neither or whom were ultimately included on the list of 29

[†]We are expressing support for Dr. Thayer as a nominee for membership on the SACC although it is our understanding that she has recently accepted a position at EPA, in which case she may no longer be eligible.

individuals for further consideration. We strongly urge EPA to expand their list of considered nominees to include representation from such organizations, which were specifically identified in the Lautenberg Amendments regarding the composition of the SACC. Furthermore, this would also expand the diversity and perspective of membership that would strengthen the SACC.

Furthermore, the UCSF PRHE prior comments recommended to EPA "(t)he need for committee representation from directly impacted, susceptible, vulnerable, and/or highly exposed populations" and urged the Agency to "incorporate a broader and more inclusive definition to capture representation from individuals with diverse knowledge sources that represent unique perspectives to these critical issues." We do not believe that any of EPA's proposed candidates meet these criteria. We would be happy to provide recommendations of such nominees if requested; one such nominee would be:

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We strongly recommend EPA consider expanding their nominees considered to include such representation to expand the diversity and perspective of committee membership.

3. EPA should also strive to eliminate or minimize financial conflicts of interest (COI) from selected committee members. In the event that financial COI exists, EPA should collect information from each and every SACC member in an effort for complete transparency regarding any financial conflicts of interest (COI) that potentially bias members—such as those with a financial interest or who profit from decisions—toward undervaluing the scientific information related to health effects of industrial chemicals. Any and all existing financial COI should be made explicit and transparent to the public.

We strongly recommend that EPA select members of the SACC who represent support for the protection of human health and the environment, consistent with the mission of the Agency. As such, we strongly believe that each selected committee member must be transparently vetted for any financial conflicts of interest that bias them in undervaluing the scientific evidence on health effects from exposure to hazardous chemicals, such as those working for or financially supported by industry.

By law, EPA committees must be composed in a way so as to ensure that industry bias is publicly disclosed, minimized, and eliminated if possible. The Federal Advisory Committee Act (FACA)[‡] requires federal agencies to ensure the advisory committee is "in the public interest" and is "fairly balanced in terms of points of view represented and the function to be performed," and does not contain members with inappropriate special interests. We encourage EPA to exclude financially conflicted members, so that committees are composed of individuals who are able to provide a fair and complete review of all relevant data or issues.

In other public health regulatory situations, it is customary to set a health benchmark or risk assessment based only on health and scientific considerations and then to consider costs, leads time or market considerations in the risk management or implementation phase. This risk management phase would be an appropriate avenue for industry consultation and advisement to the Administrator. In this manner, industry members are given the opportunity to directly provide advice on considerations that impact their

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[‡] The Federal Advisory Committee Act. 5 U.S.C. App. II

operations, but this separation would not allow for these economic considerations to intrude on the scientific risk assessment process.

We recognize, however, that the Lautenberg Amendments state that the composition of the SACC should be "...composed of representatives of such science, government, labor, public health, public interest, animal protection, industry, and other groups as the Administrator determines to be advisable." Thus, it could be deemed advisable that a member of industry with financial COI would be invited for SACC membership. In this event, we strongly recommend EPA strictly enforce its own disclosure and conflict policies. Effective disclosure policies play an essential role in protecting EPA and committee work products. If such interests are discovered later, it may seem that either the EPA or the individual was intentionally hiding this information from the public, thereby casting doubt on the SACC work products, and on EPA's ability to identify conflicts and enforce its own policies. Each SACC member should be screened up front for potential financial COI and these should be explicitly and publically identified to increase the transparency of the SACC and EPA's ability to identify conflicts and enforce its own policies. Declarations of financial conflicts of interest are a routine part of many scientific proceedings and conferences because of the importance of transparency. Other scientific committees (e.g., the National Academy of Sciences and Institute of Medicine) all require complete transparency of financial COI and similar guidelines should be adopted and consistently applied by EPA.

In summary, we encourage EPA to ensure SACC membership covers a wide breath of knowledge and experience from various relevant sectors who do not have a financial COI or whose financial COI is transparently and explicitly stated up-front. Our support for nominees includes scientists, researchers, and health professionals from academia, government, and nonprofit organizations, although we raise concerns with the lack of representation from public interest groups or members of affected communities.

Thank you for the opportunity to provide comments and nominations. Please let us know if we can provide any additional information or be of further help.

Respectfully,

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