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September 17, 2017

Comments on EPA's Requests for Nominations: Augmented Science Advisory Committee on Chemicals (Docket ID: EPA-HQ-OPPT-2016-0713)

Comments submitted online via Regulations.gov to EPA-HQ-OPPT-2016-0713

The following comments are being submitted by the University of California, San Francisco (UCSF) Program on Reproductive Health and the Environment (PRHE). 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 24 individuals total from EPA's previous and augmented lists;**
- 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 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- those with a financial interest or who profit from decisions) 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 COI that potentially bias members 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.¹

Based on nominations received from Federal Register Notice EPA-HQ-OPPT-2016-0474, EPA identified 29 candidates for further consideration for membership. UCSF PRHE, along with other academics, scientists and

¹ 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.

clinicians submitted comments on January 6, 2017 to docket EPA-HQ-OPPT-2016-0713 supporting 11 of the 29 individuals from EPA's proposed list.

We are pleased to see that EPA has augmented the original list to include additional candidates, some of whom represent public interest and environmental protection non-governmental organizations (NGOs). This is a critical perspective to have on the SACC as we previously commented, and members with industry affiliation should be balanced with public interest and environmental NGO members.

Comment on Nominations

1. Support for 24 individuals total from EPA's previous and augmented lists.

We are pleased to confirm our support for the following 24 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.

We continue to support 10 of the candidates who are still eligible from EPA's original list of 29 (listed in alphabetical order).

1. Dr. Henry A. Anderson
2. Dr. Deborah Cory-Slechta
3. Dr. Gary Ginsberg
4. Dr. Melanie Marty
5. Dr. Kenneth Portier
6. Dr. Sheela Sathyanarayana
7. Dr. Leonardo Trasande
8. Dr. Laura Vandenberg
9. Dr. Christine Whittaker
10. Dr. Tracey Woodruff

Additionally, we support the following 14 candidates from EPA's augmented list (listed in alphabetical order).

11. Dr. Scott Belcher
12. Dr. Weihsueh Chu
13. Dr. Johanna Congleton
14. Dr. Elaine Faustman
15. Dr. Ulrike Luderer
16. Dr. Maricel Maffini
17. Dr. Jennifer McPartland
18. Dr. Charles Plopper

19. Dr. Christopher Portier
20. Ms. Ruthann Rudel
21. Dr. Veena Singla
22. Dr. Gina Solomon
23. Dr. Robert Thomas Zoeller
24. Dr. Ami Zota

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 directly impacted communities that represent the "public interest" as required in the Lautenberg Amendments to the Toxic Substances Control Act (TSCA).

Though EPA's augmented list contains qualified candidates from NGOs, members from directly impacted communities are notably missing. UCSF PRHE previously submitted comments to Federal Register Notice EPA-HQ-OPPT-2016-0474 that 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 strive to eliminate or minimize financial conflicts of interest (COI- those with a financial interest or who profit from decisions) 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 COI that potentially bias members 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, 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)² 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

² The Federal Advisory Committee Act. 5 U.S.C. App. II

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.

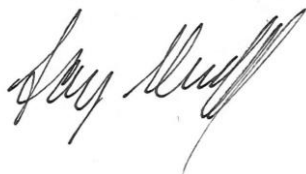
In other public health regulatory situations, it is customary to set a health benchmark or risk assessment based only on health and scientific considerations and then to consider costs, lead time or market considerations in the risk management or implementation phase. This risk management phase would 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 operations, but this structure would keep these economic considerations separate from 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 publicly identified to increase the transparency of the SACC. 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.

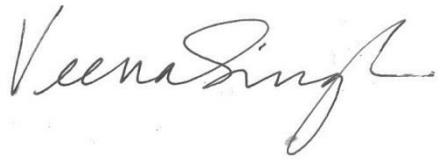
In summary, we encourage EPA to ensure SACC membership covers a wide breath of knowledge and experience from various relevant sectors who do not have a financial COI or whose financial COI is transparently and explicitly stated up-front. Our support for nominees includes scientists, researchers, and 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,

A handwritten signature in black ink, appearing to read "Tracey Woodruff". The signature is fluid and cursive, with a large, sweeping flourish at the end.

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