Union of Concerned Scientists
Citizens and Scientists for Environmental Solutions

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Thank you for the opportunity to share my concerns regarding the proposed discussion draft of amendments to the Environmental Research, Development, and Demonstration Authorization Act of 1978 (ERDDA). I want to begin by clarifying that while I will refer to and have contributed to both *"Improving the Use of Science in Regulatory Decision-Making: Dealing with Conflict of Interest and Bias in Scientific Advisory Panels, and Improving Systematic Scientific Reviews." released late last year by the Keystone Center, and "Improving the Use of Science in Regulatory Policy"* published by the Bipartisan Policy Center in 2009, my testimony is my own and in no way should be construed as an official representation of either report.

The changes to ERDDA as described in the discussion draft will slow down the work of the EPA Scientific Advisory Board, remove long standing and widely accepted practices for dealing with conflicts of interest (COI), reduce the expertise of SAB members, and do nothing to increase the transparency of its workings or results. Over the last decade, a great deal of attention has been paid to the improvement of federal scientific advisory committees. There are recommendations in the Bipartisan Policy Center report (Boehlert 2009), Keystone report (Keystone 2012), at least ten GAO reports (especially GAO 2001, 2004, 2008, 2009), a study by the Institute of Medicine Board on Health Science Policy (IOM 2009), the EPA Office of the Inspector General (USEPA 2009), and in the 2010 OSTP scientific integrity memorandum (Holdren 2010). This testimony is comprised of a brief discussion of the EPA SAB, a critique of the draft legislation under discussion, and recommendations distilled from the aforementioned reports.

The FEDERAL ADVISORY COMMITTEE ACT AND EPA's SCIENTIFIC ADVISORY BOARD

The Federal Advisory Committee Act (FACA) of 1972 (PL 92-463) created a process for convening, operating, and terminating federal advisory committees that provide advice to the Executive Branch. In the act, Congress articulated broad requirements for balance, independence, and transparency. It is very important to note two distinct committee roles. The first is to advise the Government based on the exercise of their own individual best judgment on behalf of the Government i.e. to discuss and deliberate in a way that is free from conflicts of interest, providing independent advice. The second is to provide consensus among various identified interests or

stakeholders. This matters because the members of committees created to provide independent advice are appointed as "Special Government Employees" (SGEs) and are subject to most of the Government's ethics rules (USOGE 2008). Members appointed as "Representatives" are not subject to this oversight and are expected to provide committees with the points of view of a recognizable group of persons. FACA instructs agency officials to ensure the committees will not be inappropriately influenced by any special interests and to appoint members accordingly.

Currently all the members of EPA's SAB are appointed as SGEs (USGSA 2013). Therefore all members of the SAB are subject to most of the Government's ethics rules. In a practical sense this means they must fill out an OGE form 450 as well as EPA Form 3110-48. Both of these forms ask for a variety of information about employment, consulting, honoraria and volunteer work, compensated expert testimony, research support, assets, liabilities, agreements or arrangements, gifts, travel reimbursements, and additional questions regarding other reasons for any impartiality, previous involvement and public statements on the issues under consideration.

While FACA is an excellent basis for the management of advisory committees it is important to note that decisions of the courts have created four loopholes in FACA that need to be closed. These are a contractor loophole that makes it easy for agencies to avoid FACA by hiring private contractors to organize and operate an advisory committee, the strict management loophole that makes it possible for agencies to let a regulated entity appoint committee members and share joint control of the agenda, the subcommittee loophole under which an agency can avoid transparency and balance requirements of FACA by assigning work to subcommittees, and finally, under the non-voting participant loophole, outsiders can take an active role in Government committees without the committee becoming subject to FACA so long as the outsiders do not vote on issues before the committee.

Although FACA somewhat lumps them together, COI and bias are two completely different concepts and both the information required of a potential panel member and how that information is applied to assessing bias and COI need to be quite different as well. COI applies to financial interests of an expert as well as to others with whom they share a common financial interests. Bias relates to intellectually or ideologically motivated points of view. COI should be eliminated. Bias should be managed by appointing members of a committee such that a balance of perspectives is achieved except for when a perspective is unreasonably far from the mainstream or the individual is totally unable or unwilling to consider other points of view. Then it might be wise to not appoint that particular expert. There are rarely bright lines. That is why it is important to collect sufficient information from potential candidates and offer opportunities for input from the public so that the designated federal officials together with agency ethics officers can make their best determinations regarding both COI and bias.

PROVISIONS IN THE DISCUSSION DRAFT WOULD SLOW THE WORK OF EPA's SAB

The discussion draft would slow the work of EPA's SAB in three ways: broadening the scope of the committee, adding additional meetings, and requiring written responses to significant public comments. The draft would insert "risk or hazard assessment" at three places in ERDDA. This appears to expand the scope of the SAB's work to include every risk or hazard assessment proposed by the agency. This represents a large and unnecessary expansion of responsibilities. The board's current scope is already quite large and it is hard to see how this would do anything but overwhelm already limited resources and both add years to these assessments and make the board less effective and certainly slower overall. It is hard to see how this adds value when these risk and hazard assessments can, when necessary, be reviewed by other means.

The discussion draft would also require that prior to conducting major advisory activities, the Board hold a public information-gathering session to discuss the state of the science related to the advisory activity. Since the SAB meetings are open to the public with time set aside for public oral comments, the Board accepts written public comments, and will be discussing the state of the science many times, it is hard to see the value added by this provision. Instead it appears that this is another delay tactic that would take precious resources away from the work of the committee.

Finally, while the SAB has always encouraged, read and acted on public comments, including oral comments and discussion during the proceedings, they would now be required to respond in writing to significant comments offered by the public. This is a very large burden and distraction, making it necessary for the Board to offer endless opportunities for such input and taking limited resources away from the work of the committee to fix a problem that does not exist. It is generally accepted that the committees have been responsive to public comments without having to do so in writing (Beinecke et al 2012 and Benjamin et al 2012).

Such a slowdown leading to even longer delays in regulation harms both citizens and businesses (CSS 2011). The failure to release health and safety rules obviously leaves families, workers and consumers unprotected. But it also costs businesses money through the general toll of regulatory uncertainty, increased health costs from sick workers and lost billions as consumer anxieties rise when they are faced with tainted food and dangerous products.

CONFLICT OF INTEREST

Conflicts of interest threaten the integrity of science. Specifically, the objectivity of the members of an advisory committee and the public's trust in the advice rendered by that committee are damaged when a member of an advisory committee has a secondary interest that creates a risk of undue influence on decisions or actions affecting the matters in front of the committee. The scientific experts who advise the Government should reflect the best minds in America, possessing comprehensive, independent and up-to-date knowledge. Although other interests may inappropriately

influence advisory board member behavior, financial interests are easily identified and regulated.

Scientists are not immune to having their work and conclusions influenced by their financial prospects. Several recent meta-analyses found that scientists with conflicts of interest publish scientific findings that are more supportive of their interests, (or those of their funders) than other reports in the literature. Conflicted scientific conclusions have been found to be biased relative to the broader literature on the safety of various drugs, second-hand tobacco smoke, the health effects of soda consumption, and other topics. This is commonly known as the "funding effect," (Michaels 2008) and its prevalence and seriousness prompted the editors of thirteen major biomedical journals (including *NEJM* and *JAMA*) in 2001 to stop publishing studies done under contracts allowing sponsors to control the research findings (Davidoff et al. 2002). Similar restrictions on research information used in regulation have been proposed (Michaels and Wagner 2003). Experts on advisory committees with conflicts of interest can influence panel decisions in multiple ways, not only by voting but also by dominating the discussion and pressuring other panelists.

In 2009, the Institute of Medicine did an exhaustive report entitled *Conflicts of Interest in Medical Research, Education and Practice*. The IOM (IOM 2009) observed that

> "*concerns are growing that wide-ranging financial ties to industry may unduly influence professional judgments involving the primary interests and goals of medicine. Such conflicts of interest threaten the integrity of scientific investigations, the objectivity of professional education, the quality of patient care, and the public's trust in medicine.*"

The goal of conflict of interest policies should be to protect the integrity of the professional judgment and to preserve the public trust. Disclosure of individual and institutional financial relationships is a critical but limited first step. Disclosure does not resolve or eliminate conflicts. The designated federal officers must then evaluate and act upon the disclosed information.

The draft contains a series of disclosure requirements that would upend widely accepted practice for limiting COI.

> "Persons with substantial and relevant expertise are not excluded from the Board due to affiliation with or representation of entities that may have a potential interest in the Board's advisory activities, so long as that interest is fully disclosed to the Administrator and the public;" (Discussion Draft)

This means that an individual who works for a company who has a chemical or product being reviewed by an advisory committee could still serve on the committee and even vote so long as they work on a slightly different chemical or product, have relevant expertise and the conflict is reported. This will not increase the public trust, protect

the integrity of the SAB, increase the objectivity of the panel's deliberations, nor reduce the influence of that company on the professional judgment of that individual. This is contrary to the current operations of the National Academies, IARC, and many other scientific bodies. I acknowledge that industry scientists bring relevant expertise and experience and I suggest that when a scientist has irreplaceable and necessary expertise, but is affiliated with or represents an entity that may have a potential interest in the Board's advisory activities, that the expert be invited to present to the committee but not to actually serve on the committee.

One notable and notorious example of how COI can influence outcomes is the EPA's consideration of hexavalent chromium – the chemical made famous in the Oscar-winning film *Erin Brockovich*. Full details of this complex story have been recently revealed in a series of articles and video created by the Center for Public Integrity and the NewsHour (Heath and Greene 2013, Heath 2013, and O'Brian 2013).

The discussion draft also contains a provision requiring that at least 10% of the membership of the Board be from State, local, or tribal governments. While there is no inherent reason why scientists from State, local or tribal governments could not have the needed technical expertise to serve on the SAB, this sounds like stakeholder representation that could be misconstrued to mean that these members of SAB would be appointed as "Representatives" and not as SGEs, thus losing the requirement that they are subject to most government ethics rules and hence able to serve without any investigation of conflicts of interest. SAB asks its members to advise the Government based on the exercise of their own individual best judgment on behalf of the Government i.e. to discuss and deliberate in a way that is free from conflicts of interest or to provide independent advice. GAO has written extensively that while some FACA committees at EPA legitimately include representatives of various stakeholders, members of SAB and other committees that consider scientific and technical issues should be appointed as SGEs (GAO 2001, 2004, 2008, 2009).

REDUCING THE EXPERTISE OF SAB SCIENTISTS

The questions brought to the SAB are complex. EPA needs to have scientists with the deepest and most direct expertise possible. The discussion draft would not allow experts to "participate in advisory activities that directly or indirectly involve review and evaluation of their own work" even if their work is one of hundreds of relevant studies. This would disqualify some of the most specialized experts and many committees would instead engage experts whose scientific work is either tangential or unrelated to the committee's deliberations. Currently most federal agencies recuse scientists from any decisions that either directly or indirectly influence the outcome of funding decisions or from participating in peer review of their own work and the work of their collaborators. This works well at the National Academies, the National Institutes of Health, the National Science Foundation, and a host of other federal agencies including EPA.

LINE-BY-LINE CRITIQUE OF THE DISCUSSION DRAFT

SEC.2. SCIENCE ADVISORY BOARD.
"(2)(A) the scientific and technical points of view represented on and functions to be performed by the Board are fairly balanced among the members of the Board"

- This language is redundant and unnecessary. The Federal Advisory Act (FACA) already says this.

"(2)(B) at least ten percent of the membership of the Board are from State, local, or tribal governments"

- This is a science advisory board. The Office of Government Ethics and the GAO state that when members are acting to advise the government they are not stakeholders. BPC and Keystone stress that members of scientific advisory boards are to be appointed as SGEs not stakeholders.
- It is not clear what problem this is intended to fix or how this would enhance the scientific credentials or expertise of the SAB.

"(2)(C) persons with substantial and relevant expertise are not excluded from the Board due to affiliation with or representation of entities that may have a potential interest in the Board's advisory activities, so long as that interest is fully disclosed to the Administrator and the public;

- Overturns generally accepted practice of reducing, removing or creating a waiver to manage conflicts of interest.
- This undermines the public's trust in the EPA and its SAB.

"(2)(E) Board members may not participate in advisory committees that directly or indirectly involve review and evaluate their own work".

- The National Academies, the National Institutes of Health and the National Science Foundation address this through recusal. It is not necessary to eliminate scientists with the closest expertise to the issue under deliberation form the panel entirely.
- The Research Integrity Roundtable (RIR) (Keystone 2012) states "Caution must be exercised to ensure that panel members are not engaged in evaluating their own work as a central part of a scientific review." Note the inclusion of "as a central part". As a participant in the RIR deliberations leading to this report, I took this to mean that if the work of an expert is one of some 50 or 70 articles being looked at, that could be dealt with through recusal rather than elimination of that expert from the pool of panel candidates.

"(3)(D) require that upon nomination, nominees shall file a written report disclosing financial relationships and interests, including Environmental Protection Agency grants, contracts, cooperative agreements, or other financial assistance, that are relevant to the Board's advisory activities for the three-year period prior to the date of their nomination,

- This information is already required to be disclosed going back two years by both the Office of Government Ethics and the EPA on forms OGE form 450 as well as EPA Form 3110-48. Both BPC (Boehlert 2009) and RIR (Keystone 2012) support a two year look back "when considering whether a conflict of interest exists".

"(3)(D) continued: and relevant professional activities and public statements for the five-year period prior to the date of their nomination;

- This information is already required without a time limit designated. This information would be important in considering bias and hence a five year period seems short. RIR (Keystone 2012) suggests a CV which would include relevant professional activities, testimony and publications "that go as far back in time as is reasonably possible but in all cases, at least 5 years."
- Both RIR and BPC states the following regarding professional activities "going back five years. Members should also be asked to disclose, to the best of their ability, any relevant professional activities that occurred more than five years prior to their committee service."

"(3)(E) make such reports public, with the exception of dollar amounts, for each member of the Board upon such member's selection.

- RIR suggests "the agency should post…the CVs of proposed panelists and any waivers for COI on the agency's website and allow for public comment on the appropriateness of the panelists."

"(4)(b) (1)(A) and (B) and (2) (A) – three insertions of "risk or hazard assessment"

- Potentially broadens the scope and duties of EPA's SAB at a time when resources are being reduced leading to dilution and delay of efforts.

"(4)(d)(2) Prior to conducting major advisory activities, the Board shall hold a public information-gathering session to discuss the state of the science related to the advisory activity.

- Since the SAB meetings are open to the public with time set aside for public oral comments, the Board accepts written public comments, and will be discussing the state of the science many times, it is hard to see the value added by this provision. Instead it appears that this is another delay tactic that would take precious resources away from the work of the committee.

"(4)(d)(4) The administrator and the Board shell encourage public comments, including oral comments and discussion during the proceedings, that shall not be limited by an insufficient or arbitrary time restriction. Public comments shall be provided to the Board when received. The Board shall respond in writing to significant comments offered by members of the public."

RECOMMENDATIONS

EPA's Science Advisory Board has been the object of much attention from Congress through the GAO. Starting in 2001 GAO has released at least 10 products that to some degree make recommendations to improve advisory committees at the EPA. It is noteworthy that in 2009 a statement by John Stephenson notes the following:

> "EPA has been responsive to our 2001 recommendations for improving the balance and independence of committees convened by EPA's Science Advisory Board by developing policies and procedures that represent best practices. As a result, if these policies and procedures are implemented effectively, EPA can have an assurance that its Science Advisory Board panels are independent and balanced as a whole."

Certainly this is a good place to start. Both the BPC report and RIS have extensive recommendations. Here is a subset I believe are critical to further improvement.

1. All federal scientific advisory panels and subcommittees, including those put together or managed by contractors, should be subject to FACA and have all members appointed as SGEs.

2. The goal of agencies should be to appoint only panelists who do not have conflicts of interest. (Keystone 2012 and Boehlert 2009)

3. Waivers should be issued as a rare exception with the premise that over time panelists with waivers would be replaced by experts without any COI.

4. Panelists with waivers should not be allowed to serve as panel chairs or in any other leadership position.

5. The chair of the panel, or the convening authority's designated staff member should actively track and manage waivers and recusals and make sure recusals take place when necessary.

6. Panel chairs should remind panelists at every panel meeting of their ongoing duty to disclose any new or previously undisclosed information relevant to determining conflict of interest.

7. Agencies should select scientific advisory panel members based on their expertise, experience, and on their ability to contribute to the panels deliberations without COI or undue bias. (Keystone 2012)

8. Except when specifically prohibited by law, agencies should make all Conflict of Interest Waivers granted to committee members publicly available. (Holdren 2010)

9. All reports, recommendations, and products produced by SAB should be treated as solely the findings of the committee rather than of the US Government and thus are not subject to intra- or inter-agency revision. (Holdren 2010)

10. While still collecting all the necessary information on panelists and their immediate families over the number of years designated in Keystone, the OGE and GSA should work on ways to centralize reporting to minimize the burden on panel candidates.

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