

December 3, 2012

The Honorable Ralph M. Hall  
U.S. House of Representatives  
2405 Rayburn House Office Building  
Washington, DC 20515-4304

The Honorable Eddie Bernice Johnson  
U.S. House of Representatives  
2468 Rayburn House Office Building  
Washington, DC 20515-4330

Dear Chairman Hall and Ranking Member Johnson:

We are writing to oppose H.R. 6564, the "EPA Science Advisory Board Reform Act of 2012." This bill would amend the Environmental Research, Development, and Demonstration Authorization Act of 1978 to establish new conflict-of-interest requirements for U.S. Environmental Protection Agency (EPA) peer review panels and to implement a mandated composition of the panels with regard to research funding. The U.S. is known worldwide for the outstanding scientific research that we produce, which is in no small measure due to our high ethical standards for peer review as well as the incorporation of peer review into scientific and regulatory policy. As public health scientists, we oppose H.R. 6564 largely because it would undermine peer review in the U.S. with regard to science advice to EPA, and establishes a precedent for weakening peer review for other agencies as well. It also would have the consequence of potentially excluding knowledgeable experts from panels because of receipt of EPA research funding.

Our first concern with the bill is that it would nearly ban, from all EPA advisory committees and their associated panels and working groups, scientists who have any funding from the EPA. Such a ban is unprecedented, unwise, and not warranted given practices that already exist to assure that scientists do not provide conflicted advice about their own research. Moreover, the underlying idea that scientists who obtain funding from EPA for any project have conflicts about all EPA matters is baseless and reflects a misunderstanding of who we are as scientists and our role in society. Similarly, Congress should not attempt to impose a standard of peer review on EPA that would deprive the agency of scientists who have specific expertise on areas where there are questions. Given the complexity of the questions that EPA is taking to its science advisory boards, it needs to have the best advice possible, not the advice of non-experts. The current practice, well established by organizations like the National Academy of Sciences and the National Institutes of Health and used by most federal agencies, including EPA, is that

scientists be recused from any decisions that either directly or indirectly may influence the outcome of funding decisions or from peer reviewing their own research as well as research performed by their own collaborators.

Second, the bill seems to aim to open the door for more involvement on EPA advisory committees by scientists from industry who actually do have potential conflicts of interest. The bill contains a set of disclosure requirements that could allow individuals from industry who have conflicts of interest to serve, while academic scientists with grants cannot serve. We acknowledge that industry scientists bring relevant expertise and experience, but it has been the practice by scientific bodies in the U.S. to seek to assure that scientific advice is independent of financial interests. While exceptions can, and have, been made, such restrictions based on conflict of interest have increased the credibility of these efforts to the public.

Third, the bill is overly prescriptive of which questions EPA brings to its Science Advisory Board (SAB). Peer review is expensive, and creates delays in the agency's work. A requirement that all risk and hazard assessments are brought forward to the SAB must certainly reflect a lack of awareness of the large numbers of such assessments that are completed by EPA every year. Many of these require peer review; however, relatively few require an extensive review such as that given by the SAB which inevitably will delay the process. Consider the negative impact of delay on a community worried about risk to family members and having their property values plummet while awaiting the results of the SAB review; or on an industry waiting for a required SAB review of an EPA risk assessment finding that the industry's inadvertent pollutant release did not impose undue risk on the community. Nor would scientists serving on the SAB find it fulfilling to review a myriad of minor agency assessments. This provision imposes burdens without adding value scientifically and should be dropped. The bill also attempts to legislate the manner in which EPA brings forth public comment to the SAB. There is no evidence that any parties--industry, independent scientists or advocacy groups--have had difficulty bringing their comments to the SAB. Nor is there evidence that SAB members fail to read and to listen to those comments. Even harder to understand is the proposal that the SAB would be required to respond to each and every public comment. Such a requirement not only is unnecessary but also would harm the process of peer review by creating a burden for reviewers that very few independent scientists would be willing to take on. This provision misunderstands the role of the SAB and other peer review processes in making recommendations to EPA, which typically provide guidance but not detailed protocols. In short, H.R. 6564 would harm EPA's ability to draw on independent experts.

The announcement of the legislation invokes two expert bodies whose advice you claim is incorporated into this legislation. Three expert processes, as well as testimony, have been invoked: the Bipartisan Policy Center (BPC) Report, the Keystone Center's Research Integrity Roundtable and a report from the EPA Science Advisory Board. One of us served as a member of the BPC Committee and in fact the report from the BPC served as the basis for the Keystone conclusions. Neither the BPC Report nor the Keystone Roundtable recommended that scientists with EPA funding be restricted or limited from serving on all of EPA's advisory

committees. Moreover both groups stated that while exceptions might be made to allowing scientists with financial conflicts of interest to serve on advisory boards, to quote from the Keystone document: "The goal of agencies should be to appoint only panelists who do not have conflicts of interest." Moreover both Keystone and the BPC concluded that "Waivers should be cautiously and carefully issued, and be the rare exception, not the norm."

Also the announcement references a meeting of the EPA Science Advisory Board to obtain public input to its operation. The following members of the public attended: William J. Adams, Rio Tinto; Eric Dubé, Steptoe & Johnson LLP; Howard Feldman, American Petroleum Institute; Bob Fensterheim, RegNet Environmental Services; David Fisher, American Chemistry Council; Larry Gephart, ExxonMobil Biomedical Sciences, Inc.; Brendan Mascarenhas, American Chemistry Council; and Kimberly Wise, American Petroleum Institute. Also in attendance were an agency representative (Kevin Bromberg, U.S. Small Business Administration) and a member of the press (Jenny Hopkinson, Inside EPA). The Science Advisory Board itself did not deliberate on these issues nor did it attempt to reach any conclusions. If anything, this report only serves to demonstrate that industry already has full access to EPA's SAB.

In closing, we are proud of the fact that, in the U.S., real progress has been made in health and the environment through the incorporation of independent science advice in policy making. This proposed legislation would only serve to reverse progress in bringing the best scientific advice and analysis to EPA. The consequence would be to deprive EPA of needed scientific advice on the most complex and pressing environmental health problems of our day.

Sincerely,

*Lyons Goldman, on behalf of* \_\_\_\_\_

**Georges C. Benjamin, M.D., FACP, FACEP (E)**  
Executive Director, American Public Health Association

**Patricia A. Buffler, , Ph.D., M.P.H., C.P.H.\***  
Professor of Epidemiology, University of California Berkeley.

**G. Thomas Chandler, Ph.D.\***  
Professor of Environmental Health and Marine Sciences, Dean, Arnold School of Public Health, and Vice Provost for Health Sciences, University of South Carolina

**David L. Eaton, Ph.D.\***  
Associate Vice Provost for Research, University of Washington

**Howard Frumkin, M.D., Dr.P.H.\***  
Dean, School of Public Health, University of Washington

**Lynn R. Goldman, M.D., M.P.H.\***

Professor of Environmental and Occupational Health and Dean, GW School of Public Health and Health Services

**Bernard D. Goldstein, M.D.\***

Professor and Dean Emeritus, University of Pittsburgh School of Public Health

**Richard J. Jackson, M.D., M.P.H.\***

Professor and Chair, Environmental Health Sciences, UCLA Fielding School of Public Health

**Philip J. Landrigan, M.D.\***

Professor and Chair of Preventive Medicine and Dean for Global Health, Mt. Sinai School of Medicine

**Gilbert S. Omenn, M.D., Ph.D.\***

Professor of Computational Medicine & Bioinformatics, Internal Medicine, Human Genetics, and Public Health and Director, Center for Computational Medicine & Bioinformatics, University of Michigan

**Martin Philbert, Ph.D.\***

Professor of Toxicology and Dean, School of Public Health

**Linda Rosenstock M.D., M.P.H.\***

Professor of Medicine, Health Policy and Management and Environmental Health Sciences and Dean Emeritus, UCLA Fielding School of Public Health

**Jonathan M. Samet, M.D., M.S.\***

Professor and Flora L. Thornton Chair, USC Department of Preventive Medicine and Director, Institute for Global Health

\*Institutional affiliations are provided for identification only.

Cc: House Science Committee Members