Key Findings of the GAO Report "EPA's Science Advisory Board Panels: Improved Policies and Procedures Needed to Ensure Independence and Balance"

Prepared by Minority Staff Committee on Government Reform U.S. House of Representatives

At the request of Rep. Henry A. Waxman, the General Accounting Office conducted an investigation into potential conflicts of interest on EPA's Science Advisory Boards. These panels peer review scientific studies and methodologies used by the agency in formulating rules and regulations. The panels serve an important role in the agency, as they have broad influence over the scientific basis of regulations governing air and water quality, toxic chemicals, and a variety of other public health issues. Science Advisory Boards were established by EPA to provide independent and unbiased advice to the agency on complex scientific issues.

The GAO investigation was designed to determine (1) whether panelists serving on the Science Advisory Boards have potential conflicts of interest; (2) whether EPA's procedures to prevent conflicts of interest on Science Advisory Boards are adequate; and (3) whether the public is sufficiently informed about potential conflicts of interest on Science Advisory Boards.

GAO's investigation examined four Science Advisory Boards convened by EPA. One of the panels addressed the risk from 1,3-butadiene, a cancer-causing chemical. 1,3-butadiene is used in the manufacture of synthetic rubber, nylon, and paint, and is emitted by chemical plants and automobiles. The other three panels addressed draft EPA guidelines on assessing cancer risks from toxic chemicals.

GAO's Findings

The GAO report found serious deficiencies in EPA's procedures to prevent conflicts of interest and ensure balance on Science Advisory Boards. According to GAO, EPA fails to provide for adequate determinations of conflict of interest when panels are formed, does not obtain sufficient information to evaluate conflicts of interest, fails to obtain appropriate information on financial disclosure forms, fails to review disclosure forms in a timely fashion, and fails to adequately disclose potential conflicts of interest to the public.

As a result of these deficiencies, EPA Science Advisory Boards frequently contain numerous individuals with ties to affected industries or with other potential conflicts of interest. GAO found that four of the thirteen members of the 1,3-butadiene panel worked for chemical companies or industry-affiliated research organizations, including one panel member who worked for a company that manufactured 1,3-butadiene and another panel member who led an industryfunded study of 1,3-butadiene. Two other panelists owned stock in companies that manufacture or distribute 1,3-butadiene. In total, EPA staff indicated to GAO that they viewed six of thirteen panelists on the panel as representing the industry position on the risk from 1,3-butadiene.

Although GAO did not assess whether the panel's membership affected its deliberations, the 1,3-butadiene panel in fact recommended that the risks of exposure to 1,3-butadiene be significantly downgraded. This recommendation contradicted the findings of other scientific bodies. Based on studies that show high rates of leukemia in exposed workers, EPA senior staff scientists had recommended that 1,3-butadiene be classified as a "known" human carcinogen. The National Toxicology Program had also reached the same conclusion. The Science Advisory Board, however, recommended that 1,3-butadiene not be classified as a known human carcinogen.

In addition to the problems on the 1,3-butadiene panel, GAO found similar problems on the three other cancer risk assessment panels they reviewed. On one panel, seven of seventeen members worked for chemical companies or industry-affiliated research organizations. Confidential disclosure forms also revealed that five panelists received consulting or other fees from chemical manufacturers. On another panel, four of eleven members worked for chemical companies or industry-affiliated research organizations. Several others also received consulting or other fees from chemical manufacturers. And on a third panel, three of eleven members worked for chemical companies or industry-affiliated research organizations.

Specific findings of the GAO include the following:

• EPA policies do not provide for adequate determination of conflict of interest requirements at the time a panel is developed and chosen.

GAO found that EPA takes the position that conflict of interest rules do not apply to almost all issues reviewed by Science Advisory Boards. According to GAO, EPA takes the position that most issues reviewed by Science Advisory Boards are "broadly applicable" issues, not "particular matters" to which conflict of interest rules apply. According to GAO, "[b]ecause the staff office did not believe the 1,3-butadiene review was a particular matter at the time the panel was convened, it did not identify potential conflicts of interest that should have been examined." As a result, several panelists who worked for or owned stock in companies that manufacture or distribute 1,3-butadiene were allowed to serve on the panel without an adequate review of their potential conflicts of interest. Numerous other individuals with ties to the industry also served on this panel.

• EPA routinely fails to obtain sufficient information to evaluate conflicts of interest

and ensure an appropriate balance of viewpoints.

Panelists are required to provide EPA with confidential financial disclosure forms that provide details on potential conflicts of interest. However, GAO found that some panelists did not identify all income sources or otherwise provide complete information on the form. For example, some panelists excluded a primary employer entirely or identified a source of income as coming only from "various clients."

GAO also identified many limits to the financial disclosure forms. For example, the forms do not request information on the panelist's background in the subject matter under review (such as research conducted and previous public statements or positions). The forms also do not request information on the interests of the panelist's employers or clients in the matter. In the 1,3-butadiene case, relevant information not requested on the confidential disclosure included the fact that a panelist on the 1,3-butadiene peer review panel worked on a legal case for a manufacturer of this chemical and led a major industry-funded study of 1,3-butadiene, as well as the fact that other panelists on the panel were conducting research that was sponsored by organizations funded by the chemical industry.

In other cases, GAO found that even when information is provided on financial disclosure forms, EPA staff did not adequately determine if these presented conflict of interest problems. For example, one panelist who was reviewing EPA's draft cancer risk guidelines reported receiving fees from a tobacco company and a tobacco company research organization. But EPA staff made no effort to determine if these ties to the tobacco industry presented a conflict of interest or to determine how the ties affected the panelists scientific viewpoints.

• Financial disclosure forms are not reviewed in a timely fashion.

GAO found that many financial disclosure forms are reviewed too late, or not reviewed at all. In total, 47 financial disclosure forms were examined by GAO. Eleven of these were not reviewed until after the first panel meeting, and three were never reviewed at all.

• Public disclosure of potential conflicts of interest is inadequate.

In addition to the confidential disclosure forms, panelists are given an opportunity to make voluntary public disclosures at the beginning of meetings. GAO found that these disclosure sessions are inadequate. In many cases, disclosures are not recorded in meeting minutes. For example, in one case the recorder left the room during the disclosure period. In other cases there was no follow-up from EPA staff when public disclosures raised additional questions or were too vague to be of use.