

February 2005

FEDERAL
RESEARCH

NIH and EPA Need to
Improve Conflict of
Interest Reviews for
Research
Arrangements with
Private Sector Entities



G A O

Accountability * Integrity * Reliability



Highlights of [GAO-05-191](#), a report to congressional requesters

Why GAO Did This Study

An institute at the National Institutes of Health (NIH) and an office in the Environmental Protection Agency (EPA) entered into collaborative arrangements with the American Chemistry Council (ACC) to support research on the health effects of chemical exposures. NIH accepted a gift from ACC to help fund the research. EPA and ACC funded their proposals separately. The arrangements raised concerns about the potential for ACC to influence research that could affect the chemical industry. GAO determined the agencies' legal authorities to enter into the arrangements; the extent to which the agencies evaluated and managed potential conflicts of interest resulting from these arrangements; the extent to which the NIH institute complied with NIH's gift acceptance policy; and the extent to which NIH, EPA, and other agencies have similar arrangements.

What GAO Recommends

GAO recommends, among other things, that NIH and EPA develop formal policies for evaluating and managing conflicts of interest when entering into research arrangements with nongovernmental partners, particularly those representing a regulated industry, and that NIH revise its gift policy to require conflict of interest evaluations and documentation of decisions.

www.gao.gov/cgi-bin/getrpt?GAO-05-191.

To view the full product, including the scope and methodology, click on the link above. For more information, contact Anu Mittal at (202) 5123841 or Mittala@gao.gov.

FEDERAL RESEARCH

NIH and EPA Need to Improve Conflict of Interest Reviews for Research Arrangements with Private Sector Entities

What GAO Found

NIH's National Institute of Environmental Health Sciences (NIEHS) used the authorities granted to NIH's institutes and centers under sections of the Public Health Service Act to enter into its arrangement with ACC. Similarly, EPA's Office of Research and Development (ORD) relied on authorities granted to EPA under sections of the Clean Air Act, the Clean Water Act, and the Solid Waste Disposal Act to enter into its research arrangement. Nothing in these statutes appears to prohibit either agency from entering into research arrangements with nonprofit organizations such as ACC.

NIEHS and ORD did not formally evaluate the potential for conflicts of interest with ACC before they entered into the arrangements, but both agencies took steps to manage the potential as the arrangements were implemented. NIH and EPA had no specific policies requiring officials to evaluate or manage potential conflicts of interest when they entered into the ACC arrangements, nor do they currently have such policies. Although no formal evaluation occurred, agency officials managed the arrangements through their existing research management processes. Both agencies believe these actions helped mitigate the potential for undue influence by ACC and adequately protected the integrity of the scientific research conducted under the arrangements. Because the agencies' research management processes were not designed to address conflict of interest issues they are not a substitute for a formal evaluation of such conflicts. Without policies requiring a formal evaluation and management of conflicts, there is no assurance that similar arrangements will be appropriately evaluated and managed for such conflicts in the future.

NIEHS officials complied with portions of NIH's gift acceptance policy that guide the acknowledgement and administration of gifts. However, the policy's guidance on evaluating and managing potential conflicts is extremely broad, and it lacks clarity and consistency. As a result, the policy gives officials wide discretion in this area. In addition, the policy does not require the agency to document the basis for its decisions. Consequently, the policy does not provide sufficient assurance that potential conflicts of interest between NIH and donor organizations will be appropriately considered.

While some institutes and centers at NIH had arrangements somewhat similar to the ACC arrangements, GAO did not find any similar arrangements at other program offices at EPA or at the Food and Drug Administration and the Federal Aviation Administration—two other agencies with significant research budgets. None of the nine research arrangements GAO found at NIH institutes and centers involve organizations that represent industry in the same direct manner that ACC represents the chemical industry.

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Abbreviations

ACC	American Chemistry Council
EPA	Environmental Protection Agency
FAA	Federal Aviation Administration
FDA	Food and Drug Administration
NIEHS	National Institute of Environmental Health Sciences
NIH	National Institutes of Health
ORD	Office of Research and Development

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United States Government Accountability Office
Washington, D.C. 20548

February 25, 2005

The Honorable Bart Gordon
Ranking Minority Member
Committee on Science
House of Representatives

The Honorable Mark Udall
House of Representatives

The Honorable Eddie Bernice Johnson
House of Representatives

In fiscal year 2002, the federal government devoted an estimated \$45 billion to research, \$35 billion of which funded research conducted by universities, industry, nonprofit organizations and state and local governments.¹ Some agencies fund this extramural research through direct federal grants to or contracts with researchers, which are generally considered an effective way to encourage federal and nonfederal research partnerships. Other agencies collaborate with governmental and nongovernmental organizations to solicit and/or fund extramural research proposals, and in some cases have the authority to accept money from their partners to support the research.² These collaborative arrangements have taken the form of cooperative agreements or memorandums of understanding with external research partners. The American Chemistry Council (ACC)—a nonprofit organization that represents the chemical industry—has entered into two such research arrangements; one with the National Institute of Environmental Health Sciences (NIEHS) in the National Institutes of Health (NIH), and the other with the Office of Research and Development (ORD) in the Environmental Protection Agency (EPA). Since ACC represents chemical companies that are regulated by the federal government, these arrangements have raised concerns that ACC or

¹*Federal Funds for Research and Development: Fiscal Years 2000, 2001, and 2002.* Because it is being used for background purposes only, we did not assess the reliability of the National Science Foundation data in this report.

²Congress has provided some agencies, such as NIH, with the authority to accept gifts—including money—while other agencies, such as EPA, do not have this authority.

its members could potentially influence, or appear to influence, the scientific results that may be used to make future regulatory decisions.³

In 2001, ACC entered into an arrangement with NIEHS to solicit and fund research on the effects of environmental chemicals on human reproduction and development. Under the arrangement, NIEHS, which has authority to accept gifts from external organizations, accepted funds from ACC to support the research.⁴ In 2003, ACC entered into a similar arrangement with ORD to solicit and fund research; under this arrangement the first solicitation for research proposals focused on novel approaches to analyzing existing data on human exposure to chemicals.⁵ In the absence of authority allowing EPA to accept gifts, ORD and ACC solicited proposals jointly but funded selected research proposals separately. A goal of both research arrangements is to provide scientific tools or knowledge that will ultimately help improve the effectiveness of human health and ecological risk assessments.

In the context of these two arrangements, you asked us to determine the (1) legal authority NIEHS and ORD used to enter into the arrangements with ACC; (2) extent to which NIEHS and ORD evaluated and managed the possibility that conflicts of interest could result from their arrangements with ACC; (3) extent to which NIEHS complied with NIH's gift acceptance policy when accepting ACC's funds; and (4) extent to which similar research arrangements exist within other offices and programs of NIH and EPA, as well as other regulatory agencies.

To identify the legal authority each agency used to enter into collaborative research arrangements with ACC, we reviewed the authorities cited in each agency's arrangement, as well as the related legislative histories and policies at NIH and EPA. We also interviewed program and legal staff at the

³Although NIH is not a regulatory agency the scientific knowledge that results from NIH-sponsored research may be used by regulatory agencies, such as EPA, when making decisions about potential risks chemicals pose to public health and the environment. It is in this context that the ACC-NIEHS arrangement has raised concerns.

⁴NIEHS used its gift acceptance statute, 42 U.S.C. § 238(a), to accept the ACC funds as a conditional gift. In a separate effort, our Office of General Counsel is preparing a legal opinion to address whether the gift acceptance statute authorizes NIEHS to accept donations with the specific conditions attached by the agreement between NIEHS and ACC.

⁵For purposes of this report we will refer to the memorandums of understanding that NIEHS and ORD signed with ACC as well as documents to implement the memorandums, such as the announcement of funding availability, as research arrangements.

agencies. To ascertain the extent to which NIEHS and ORD evaluated and managed the potential that conflicts of interest could result from their research arrangements with ACC, we reviewed agency policy and documents relevant to the ACC arrangements and interviewed senior officials. To determine the extent to which NIEHS complied with the NIH gift acceptance policy, we reviewed the policy and related documentation and interviewed senior NIEHS officials and NIH legal advisors. To determine the prevalence of similar research arrangements, we interviewed officials within NIH and EPA. In addition, we contacted officials at the Food and Drug Administration (FDA) and the Federal Aviation Administration (FAA), both of which, like EPA, are regulatory agencies that have significant extramural research budgets. We interviewed officials responsible for 96 percent or more of each agency's extramural research dollars and reviewed research arrangements that have been signed since January 1999. We conducted our review from March 2004 through February 2005 in accordance with generally accepted government auditing standards. The details of our scope and methods can be found in appendix I.

Results in Brief

NIEHS used the authorities granted to NIH's institutes and centers under sections of the Public Health Service Act to enter into its arrangement with ACC. Similarly ORD relied on authorities granted to EPA under sections of the Clean Air Act, the Clean Water Act, and the Solid Waste Disposal Act to enter into its research arrangement with ACC. These statutes, among other things, provide broad authority to both agencies to collaborate with external organizations in support of research. For example, the Public Health Service Act, as amended, authorizes NIH and its institutes and centers to cooperate in, assist, and promote the coordination of research on the causes, diagnosis, treatment, control, and prevention of physical and mental diseases. Similarly, the Clean Air Act, as amended; the Clean Water Act, as amended; and the Solid Waste Disposal Act, as amended, authorize EPA to promote the coordination and acceleration of research on the causes, effects, extent, prevention, reduction, and elimination of pollution. Nothing in these statutes appears to prohibit either agency from entering into research arrangements with nonprofit organizations such as ACC.

NIEHS and ORD did not formally evaluate the potential for conflicts of interest with ACC before they entered into the arrangements, but both agencies took several steps to manage the potential for conflicts of interest that could occur as the arrangements were implemented. Neither NIH nor EPA had formal policies that required officials to evaluate or manage

potential conflicts of interest when they entered into the collaborative research arrangements, nor do they currently have such policies. As a result, no formal evaluation occurred. In the absence of formal policies to manage potential conflicts of interest, officials at both agencies relied on their existing research management processes to implement these research arrangements. According to these officials, the agencies' existing research management processes helped mitigate the potential for undue influence by ACC and helped protect the integrity of the scientific research to be carried out under these arrangements. For example, agency officials told us that NIEHS and ORD established the scientific topics that would be the focus of the research through routine agency planning processes before they entered into the ACC arrangements. These processes involved significant input from a range of stakeholders, and the agency-established research priorities did not change after the arrangements with ACC were implemented. Similarly, the opportunity to apply for funding under the research arrangements was widely announced within the research community, and the funding of research proposals was competitively awarded only after the proposals had been independently peer reviewed for their scientific merit. Furthermore, ORD officials told us that they took additional steps that they believe helped manage the potential for conflicts of interest. For example, ORD sought public input on the terms and conditions of its research arrangement with ACC. The processes that the agencies used to mitigate potential conflicts of interest were appropriate for managing and implementing the research arrangements with ACC but cannot substitute for a formal conflict of interest evaluation. This is because these processes were not designed to specifically address conflict of interest issues. Formal policies requiring the evaluation and management of conflicts of interest would help the agencies ensure that potential conflicts in future research arrangements will be appropriately addressed. Therefore, we are recommending that NIH and EPA establish formal policies for evaluating potential conflicts of interest when entering into research arrangements with nongovernmental partners (particularly those that represent regulated industry), and for managing these conflicts as the agencies implement these arrangements.

NIEHS officials complied with sections of NIH's gift acceptance policy for acknowledging and administering gifts, but the policy's guidance on evaluating and managing potential conflicts of interest is so broad that it allows officials to satisfy its requirements with a wide array of actions. As a result, the policy does not provide sufficient assurance that potential conflicts of interest between NIH and donor organizations will be appropriately considered before a gift is accepted. Specifically, the policy is

inconsistent on whether and how to evaluate potential conflicts of interest. As a result, agency officials have wide discretion in deciding how to comply with the policy. In addition, the policy does not require the agency to document any conflict-of-interest evaluations or the basis for deciding whether to accept or reject a gift. For example, the NIEHS official who decided to accept the ACC gift stated that he was concerned that accepting funds from ACC might create an apparent conflict of interest. However, he believed that his informal and undocumented consultations with other NIH officials and two representatives from external organizations satisfied the NIH policy. Other senior NIEHS officials also told us they had concerns about accepting funds from ACC. However, in referring the arrangement to the NIH Legal Advisor's Office for review, these officials said they did not specifically request a determination of whether the gift would constitute a conflict of interest because the policy did not require them to do so. Consequently, the NIH counsel conducted a more general legal review. Since NIEHS entered into the ACC arrangement, NIH has revised its gift acceptance policy. However, these revisions have not eliminated the inconsistency nor do they require agency officials to document the basis for their decisions. We are recommending that NIH further revise its gift acceptance policy to clarify how officials are to evaluate gifts for potential conflicts of interest, particularly from organizations that represent regulated industry, and require the officials to document the basis for their decisions, including what, if any, steps are needed to manage potential conflicts of interest.

While some institutes and centers at NIH had arrangements somewhat similar to the ACC arrangements, we did not find any similar arrangements at the regulatory agencies we reviewed: EPA, FDA, and FAA. We found nine signed research arrangements at NIH institutes and centers that share some, but not all, of the characteristics of the ACC arrangements. For example, all nine are formal arrangements with nonprofit organizations to jointly sponsor extramural research. However, none of the arrangements involve organizations that represent a regulated industry in the same direct manner that ACC represents the chemical industry, although several of the nonprofit partners have at least some corporate sponsorship. For example, the Juvenile Diabetes Research Foundation has a research arrangement with the National Institute of Neurological Disorders and Stroke to support extramural research into the neurobiology of diabetic complications. One of the corporate sponsors of the Juvenile Diabetes Research Foundation is an airline company, not an entity with any material connection to the outcome of the research.

In commenting on a draft of this report, EPA did not indicate whether it agreed or disagreed with our recommendation but provided technical comments that we have incorporated as appropriate. NIH agreed to implement our recommendations and also provided technical comments that we have incorporated as appropriate. EPA's comments are provided in appendix II, and NIH's comments are provided in appendix III.

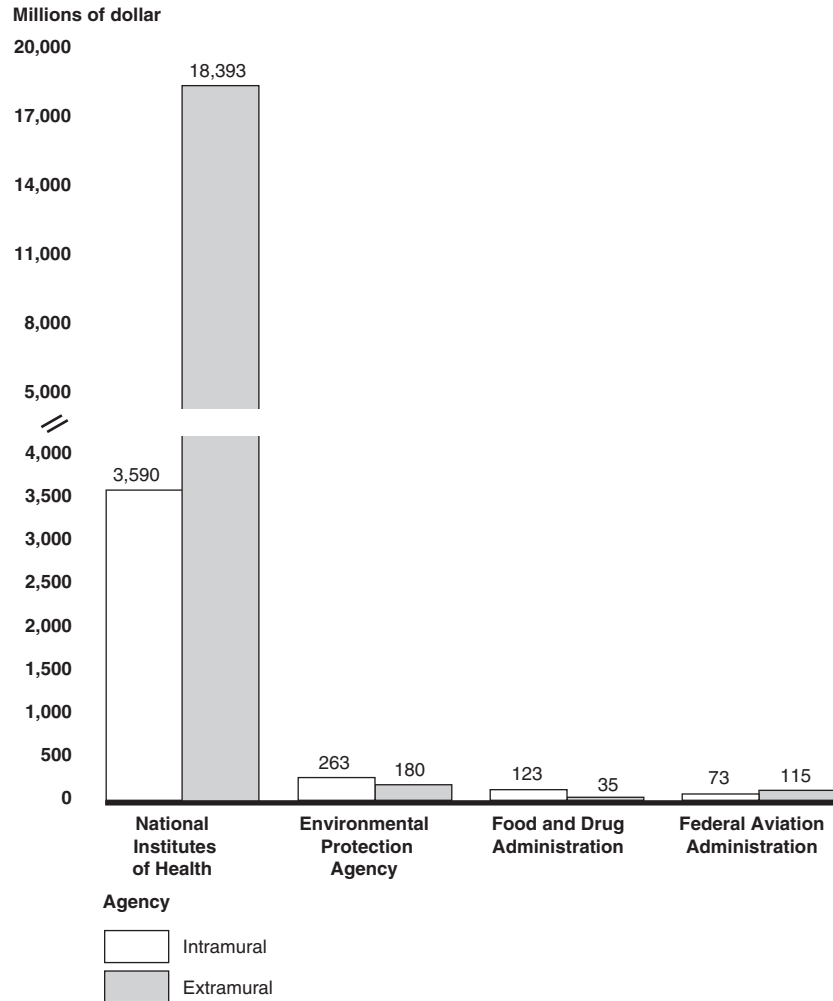
Background

Many federal agencies fund research to serve their goals and objectives. For example, NIH, the largest source of federal support for nondefense research, is the federal focal point for medical and behavioral research to help extend healthy life and reduce illness and disability. Each of the 27 institutes and centers that constitute NIH has an explicit mission focused on a particular disease, organ system, stage of development, or a cross-cutting mission, such as developing research tools. Other agencies, such as EPA, FDA, and FAA, support research, in part, to further scientific understanding that may in the future better inform their regulatory decisions. Nineteen offices within EPA conduct and/or support research to help carry out the regulatory aspect of the agency's mission to protect human health and the environment and to implement environmental laws.⁶ Similarly, FDA relies on research to help identify and assess risks and to serve as the basis for regulatory decisions about such issues as human and veterinary drugs, medical devices, and the nation's food supply. Finally, FAA, which enforces regulations and standards for the manufacture, operation, and maintenance of aircraft, conducts research to help ensure a safe and efficient system of air navigation and air traffic control.

Federal research can be conducted by scientists in government laboratories—called intramural research—or by scientists at universities, in industry, or at nonprofit organizations—called extramural research. In fiscal year 2002, NIH, EPA, FDA, and FAA devoted a total of about \$23 billion to intramural and extramural research. (See fig. 1.) Together, these four agencies accounted for about 50 percent of the federal funds devoted to research.

⁶EPA consists of nine programmatic offices and 10 regional offices that collectively develop and implement the agency's programs.

Figure 1: Four Agencies' Funding Devoted to Intramural and Extramural Research, Fiscal Year 2002



Source: GAO's analysis of NIH, EPA, FDA, and FAA data.

Federal laws have created an environment conducive to a full range of joint ventures between government and industry, or between industry and universities, as well as among companies. Specifically, through collaboration, federal and nonfederal partners attempt to share the costs, risks, facilities, and expertise needed for research and to promote the movement of ideas and technologies between the public and private sectors. This cooperation between federal and private sector researchers

may take many forms. Through informal cooperation, for example, federal agencies and industry may coordinate and share research agendas to prevent duplication of effort, or agency and private sector scientists may consult one another. Through formal cooperation, federal and nonfederal partners use written agreements, such as contracts or memorandums of understanding, to define the roles and responsibilities of each party. However, each type of arrangement differs in the extent of federal involvement in the research conducted under the agreement. Generally, work conducted under contracts is directed and overseen by federal agencies that do not participate in the work. In contrast, memorandums of understanding allow great flexibility in terms of participation by federal agencies and may also allow for sharing of resources or the funding of research by nonfederal partners.

Congress may provide federal agencies the authority to accept gifts from external sources. For example, under the Public Health Service Act, certain agencies, such as NIH, may accept funds or nonmonetary gifts to support their research efforts or other agency functions. Under the act, donors may stipulate how agencies may use their gifts, for example, to only support research on a specific disease or condition, or they may allow the agency to use the gift for the benefit of any effort without stipulations. An agency's statutory authority to accept donations is called its "gift acceptance authority."

In 2001 and 2003, NIEHS and ORD, respectively, entered into research arrangements with ACC to solicit and fund extramural research proposals. These arrangements specified how research proposals would be solicited, reviewed, funded, and overseen. Specifically, under the NIEHS-ACC arrangement, ACC and NIEHS agreed to support a 3-year research program to study the effects on reproduction and development of exposure to chemicals in the environment. ACC provided a gift of \$1.05 million to NIEHS to fund this research, and NIEHS contributed \$3.75 million to the project. Using the combined funds, NIEHS awarded a total of 17 research proposals from among the 52 it received. The program ended in 2004. Under the ORD-ACC arrangement, ACC and ORD agreed to support and fund research, with the first solicitation for research proposals focusing on novel approaches to analyzing existing human exposure data. In response to this first announcement of funding availability, issued in July 2003, 36 research proposals were submitted. ORD funded four research proposals, for a total of about \$1.7 million, and ACC funded two proposals, for a total of about \$1 million. ORD and ACC separately funded the research proposals that each had selected under this arrangement because EPA does

not have the authority to accept contributions from outside sources. Researchers could specify whether they wanted their proposals considered for funding solely by ORD or by either ORD or ACC.⁷

ACC is a nonprofit trade organization representing most major U.S. chemical companies.⁸ It represents the chemical industry on public policy issues, coordinates the industry's research and testing programs, and leads the industry's initiative to improve participating companies' environmental, health, and safety performance. In 1999, ACC launched a \$100 million research initiative to study the potential impacts of chemicals on human health and the environment and to help improve screening and testing methods. A primary goal of the initiative is to focus on projects or programs that might take advantage of work planned or conducted by EPA, NIEHS, and other laboratories to stimulate collaboration and/or to prevent unnecessary duplication.

Individuals or organizations can have conflicts of interest that arise from their business or financial relationships. Typically, federal conflict-of-interest laws and regulations govern the actions of individual federal employees, including their financial interests in, and business or other relationships with, nonfederal organizations. Conflict-of-interest concerns about individual federal employees typically arise when employees receive compensation from outside organizations; such arrangements often require prior approval from the federal employer. When a federal agency enters into a relationship with, or accepts a gift from, a regulated company or industry, concerns may arise about the agency's ability to fulfill its responsibilities impartially.

⁷Researchers who wanted their proposals considered for funding solely from ACC were advised to send their proposals directly to ACC for review and evaluation. ORD did not review or evaluate any such proposals.

⁸ACC was formerly known as the Chemical Manufacturers Association.

NIEHS and ORD Used Broad Legal Authority to Support Their Arrangements with ACC

The statutory provisions that NIEHS and ORD relied upon to enter into their arrangements with ACC grant the agencies broad authority to collaborate with external organizations in support of research. Nothing in these statutes appears to prohibit either agency from entering into research arrangements with nonprofit organizations such as ACC.

NIEHS used the authorities granted to NIH's institutes and centers under sections of the Public Health Service Act, as amended, to enter into its arrangement with ACC (sections 301 and 405). The act authorizes NIH and its institutes and centers to cooperate, assist, and promote the coordination of research into the causes, diagnosis, treatment, control, and prevention of physical and mental diseases. In its research arrangement with ACC, NIEHS cited sections of the act as the authority it relied on to enter into the arrangement. These sections enumerate the general powers and duties of the Secretary of Health and Human Services and the directors of the institutes and centers in broad terms, including the authority to encourage and support studies through grants, contracts, and cooperative agreements.

Similarly, ORD relied on broad authorities granted to EPA under sections of the Clean Air Act, as amended; the Clean Water Act, as amended; and the Solid Waste Disposal Act, as amended, to enter into its research arrangement with ACC (sections 103, 104, and 8001, respectively). These sections authorize EPA to promote the coordination and acceleration of research relating to the causes, effects, extent, prevention, reduction, and elimination of pollution in the air and water, and from solid waste. These sections authorize the EPA Administrator and other EPA officials to cooperate with appropriate public and private agencies, institutions, organizations, and industry to conduct research and studies.

NIEHS and ORD Did Not Formally Evaluate, but Took Steps to Manage, the Potential for Conflicts of Interest in Their Arrangements with ACC

NIEHS and ORD did not formally evaluate the possibility that organizational conflicts of interest could result from their research arrangements with ACC because neither agency had policies requiring such evaluations. However, officials at both agencies took steps to manage potential conflicts that might arise during implementation of the arrangements.

NIEHS and ORD Did Not Formally Evaluate Potential Conflicts of Interest that Could Result from Research Arrangements with ACC

In 2001 and 2003, when they entered into arrangements with ACC, neither NIH nor EPA had specific policies requiring officials to formally evaluate potential conflicts of interest that could result from entering into such collaborative arrangements. As a result, neither NIEHS nor ORD conducted such evaluations. During negotiations with ACC on their research arrangements, NIEHS and ORD officials recognized the potential for organizational conflicts of interest, or at least the appearance of such conflicts. However, in light of the lack of policies on this issue, neither agency formally evaluated the potential for conflicts before finalizing their arrangements with ACC. Instead, officials told us, they informally evaluated the potential for conflicts of interest and intended to manage potential conflicts that might arise during implementation. To date, neither agency has developed any such policy guidance.

NIEHS and ORD Relied on Existing Research Management Processes to Help Mitigate Potential Conflicts of Interest

In implementing their arrangements with ACC, NIEHS and ORD used their general research management processes to help manage potential conflicts of interest. These processes are designed to help ensure the integrity of scientific research undertaken by these agencies. According to agency officials, these processes helped guard against undue influence of ACC by limiting ACC's participation in the selection, review, and oversight of agency-funded research conducted under the arrangements. For example:

- *Developing research topics.* Research priorities at both NIEHS and ORD were identified through routine agency planning processes that involved significant input from a range of stakeholders before the arrangements with ACC were finalized. In addition, NIEHS included research topics suggested by the National Research Council, a congressionally chartered scientific advisory body. Both NIEHS and ORD then worked with ACC to select the specific scientific topics that would become the focus of the research conducted under the arrangements. According to NIEHS and ORD officials, their arrangements with ACC did not change or influence the agencies' research priorities. Because the research conducted under these arrangements supported the agencies' existing research agendas, officials believe that the ACC arrangements helped them effectively leverage federal research dollars.

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- *Advisory council consultation.* Both agencies have advisory panels that they routinely consult on matters related to the conduct and support of research, among other things.⁹ These consultations include public sessions that allow interested individuals, in addition to the panel members, to provide comments on the topics discussed. NIEHS obtained approval from its National Advisory Environmental Health Sciences Council before entering into the arrangement with ACC. ORD did not specifically consult its Board of Scientific Counselors regarding the agency's arrangement with ACC, but did seek input from the Board regarding the research priorities covered by the arrangement. Both advisory bodies were established under the Federal Advisory Committee Act and must comply with the requirements of the act as well as related regulations.
 - *Publicly announcing the availability of funds.* Both NIEHS and ORD, in 2001 and 2003, respectively, announced the opportunity to apply for grant funds available under the arrangements with ACC throughout the scientific community. Both agencies announced the availability of funding on their Web sites and included detailed information on the research programs and how to apply for funds. Both agencies also posted announcements in publications that are commonly used to advertise the availability of federal funding. Specifically, NIEHS published an announcement in the NIH Guide to Grants and Contracts, and ORD published its announcement in the Catalog of Federal Domestic Assistance. In addition, both agencies sent announcements to relevant scientific and professional organizations and to interested scientists who had signed up for electronic notice of funding opportunities. ORD also published a notice in the *Federal Register*. By widely announcing the availability of funds, the agencies hoped to ensure the participation of many qualified researchers and to avoid the appearance of preferential treatment for specific researchers. Moreover, widely publicizing the availability of funds would help ensure the openness of the agencies' research processes. However, the agencies differed in the clarity of their instructions regarding how information would be shared with ACC. For example, in the portion of the announcement labeled "special requirements," NIEHS's announcement stated that applicants "should," among other things, submit a letter allowing NIEHS to share their proposals with ACC. According to NIEHS

⁹These advisory panels are comprised of experts in scientific disciplines and other relevant fields.

this wording was not intended to be interpreted as a requirement but instead was intended to be a request. We believe that the language could have confused potential applicants about whether sharing information with ACC was required and could have dissuaded some qualified applicants from submitting proposals. In contrast, under the ORD-ACC arrangement, researchers were clearly advised that they could elect to have their proposals considered for funding by either ORD or ACC or solely by ORD. Applicants who did not want to share their proposals with ACC could elect to have their applications reviewed and considered solely by ORD.

- *Determining completeness and responsiveness.* Initially, NIEHS and ORD reviewed all submitted research proposals for compliance with administrative requirements. ACC did not participate in these reviews. At both agencies, research proposals judged incomplete were to receive no further consideration. NIEHS and ORD also had similar approaches for determining the responsiveness of the applications to the goals of the research program. At ORD, responsiveness was determined as part of the agency's completeness review and did not involve ACC. Similarly, at NIEHS, responsiveness was determined solely by agency officials. Although NIEHS's announcement stated that ACC would participate in the responsiveness review, NIEHS and ACC officials told us that ACC did not take part in this review.
- *Peer review of research proposals.* At both NIEHS and ORD, complete and responsive research proposals were independently peer reviewed for technical and scientific merit. According to officials, each agency followed its standard procedures for selecting experts to serve as peer reviewers and excluded representatives of ACC from serving as reviewers. At both agencies, only meritorious research proposals qualified for funding decisions. Both agencies also subjected these proposals to additional independent review. NIEHS's National Advisory Environmental Health Sciences Council reviewed qualified proposals, and ORD required other EPA staff to review research proposals that were judged "excellent" or "very good" to help ensure a balanced research portfolio responsive to the agency's existing research agenda.¹⁰

¹⁰Under the agreement, researchers could request that their proposals be considered for funding solely by ORD or by either ORD or ACC. Applicants who wanted their proposals considered for funding solely from ACC were advised to send their proposals directly to ACC for review and evaluation. ORD did not review or evaluate any such proposals.

ACC convened its own technical panels to review qualified research proposals to ensure the relevancy of the proposals to the industry's research needs and to ensure that the proposals balanced its research portfolio.

- *Making results available to the public.* NIEHS and ORD required—without input from ACC—the results of the research funded under the arrangements to be made public. For example, according to agency officials, NIEHS and ORD required researchers to discuss their preliminary findings in periodic public meetings, and, once their projects were completed, both agencies required researchers to submit their results for publication in peer-reviewed scientific journals.¹¹ In addition, NIEHS strongly encouraged researchers to present their results at professional conferences and workshops. Officials from both agencies agreed that publicizing the results of research conducted under the arrangements helped ensure that agency-sponsored research adhered to accepted analytic standards and was unbiased.

ORD Took Additional Steps that Officials Believe Helped Manage Potential Conflicts of Interest

In addition to the routine research management processes, discussed in the previous section, officials at ORD took further steps that they believe helped them manage the potential for conflicts of interest in their collaboration with ACC. Specifically:

- *Research arrangement developed with public input.* ORD publicly announced that it might collaborate with ACC and invited public comment on the terms and conditions of the proposed partnership. In addition, ORD invited public comment on the draft announcement of the opportunity to apply for funding. ORD officials told us that they believed an open and public process to define the terms of ORD's collaboration with ACC could help guard against real or perceived conflicts of interest.
- *Membership of review panels.* In addition to prohibiting ACC representatives from serving as expert reviewers, ORD did not allow employees of ACC member companies to serve on the peer review panels that evaluated research proposals for technical and scientific

¹¹In addition, ORD obtained agreement from ACC that results of ACC-funded research would also be discussed in periodic public meetings and published in peer-reviewed journals.

merit. ORD officials said this step helped minimize the perception that ACC or its members could play a role in evaluating the scientific merit of research proposals.

NIEHS Generally Complied with NIH's Gift Acceptance Policy, but the Policy Cannot Provide Assurance that Conflicts of Interest Are Evaluated and Managed

When accepting funds from ACC under the research arrangement, NIEHS officials complied with those sections of NIH's policy that guide the acknowledgement and administration of gifts. However, the policy's guidance on evaluating and managing potential conflicts is extremely broad, lacking clarity and consistency. Consequently, officials have wide discretion in deciding how to fulfill their responsibilities under the gift acceptance policy. Further, the policy does not require officials to document the basis of their decisions. As a result, the gift policy does not provide the public sufficient assurance that potential conflicts of interest between NIH and donor organizations will be appropriately considered.

Specifically, NIH's gift acceptance policy outlines several steps that officials must take to acknowledge and administer gifts. NIEHS officials generally complied with these policy sections when accepting the gift from ACC. For example, NIEHS officials acknowledged the acceptance of ACC's gift in a timely manner, deposited the funds in government accounts, and used the gift only for the purposes stipulated by ACC. As the policy also requires, NIEHS obtained ACC's written agreement that any remaining funds could be used to further NIH's goals without additional stipulation.

However, other policy sections are inconsistent or unclear about what actions officials must take to evaluate conflicts of interest when accepting gifts—thereby affording officials wide discretion in carrying out their responsibilities. For example, one part of the policy in effect at that time and in subsequent revisions requires the approving official to use two assessment tools to evaluate conflicts of interest before accepting a gift, but another part of the policy states that the use of these tools is recommended rather than required. The Director of NIEHS, who had authority to accept the gift, said he was acutely aware that accepting the ACC money could pose the potential for real or apparent conflicts of interest. In light of his concerns, he spoke informally with the Acting NIH Director, senior NIEHS officials, NIH legal advisers, and senior officials from two external groups. Through these discussions and using his professional judgment, the NIEHS Director determined that accepting the ACC funds would not present a conflict of interest for NIEHS. When he decided to accept the ACC gift, the Director said that he was unaware of the assessment tools recommended by NIH's policy. However, he believes

the steps he and other NIEHS officials took in accepting ACC's gift satisfied the gift acceptance policy regarding conflicts of interest. Given the lack of consistency in the policy sections that relate to conflicts of interest and the use of the assessment tools, it is difficult for us to determine whether the actions the director took complied with the NIH policy. Moreover, without documentation of his actions, we could not determine whether the steps he took were adequate to evaluate the potential for conflicts of interest.

Furthermore, the policy in effect at that time and in subsequent revisions does not provide clear guidance on what type of coordination should occur between NIH offices in evaluating the potential for conflicts of interest when accepting a gift. For example, several NIEHS staff were concerned that the proposed ACC gift could result in an apparent conflict of interest and, consistent with NIH's gift policy, forwarded the written agreement to the NIH Legal Advisor's Office for review. However, the gift policy does not require staff to identify their concerns when seeking legal advice. According to these officials, in referring the agreement to NIH attorneys for review, they did not specifically request a determination of whether the gift would constitute a conflict of interest. As a result, the NIH attorneys conducted a general legal review of the gift and the proposed research arrangement, focusing primarily on the agency's legal authority to enter into the arrangement. NIH legal staff told us that they could have provided assistance on conflict-of-interest issues had they been notified that the program staff had such concerns, or if in their view, the gift or written agreement had contained clauses that were obviously illegal or contrary to NIH policy. If the policy had been clearer about how conflict of interest concerns are to be communicated to NIH attorneys, we believe the legal staff would have conducted a conflict-of-interest review.

Finally, NIH's policy does not require officials to document how they have addressed conflict-of-interest concerns. Neither the NIEHS Director nor other senior NIH officials documented their consideration of potential conflicts of interest when accepting the ACC gift. The lack of documentation, coupled with the broad discretion resulting from the inconsistency and lack of clarity in the policy, allows officials to satisfy requirements with a wide array of actions, ranging from a formal evaluation to a highly informal one.

Research Arrangements Such as Those with the American Chemistry Council Are Not Widely Used

At NIH, we identified nine arrangements that were somewhat comparable to the ACC research arrangements, but we did not identify any similar arrangements at ORD, other EPA program offices, FDA, or FAA.¹² None of the nonprofit partners in the nine research arrangements we found at NIH represents industry in the same direct manner that ACC represents the chemical industry. However, some of the nonprofit partners have either general corporate sponsorship or corporate sponsorship for specific events. For example, sponsors of the Parkinson's Unity Walk in 2004 included pharmaceutical companies. The sponsors helped defray operating expenses to ensure that all proceeds from the walk supported Parkinson's research. Likewise, the Juvenile Diabetes Research Foundation received corporate sponsorship from an airline company, manufacturers of soft drinks and household products, and others, none of whom had any material connection to the outcome of the research. One nonprofit partner is a corporation's philanthropic foundation.

At NIH, we found a total of 11 institutes and centers—either singly or with other institutes and centers—that had entered into research arrangements with one or more nonprofit partners. Under the terms of four of the arrangements, NIH accepted gift funds from nonprofit partners to support the research described in the arrangements. In four other arrangements, when NIH institutes or centers lacked sufficient money to fund all the research proposals rated highly by peer review panels, they forwarded the research proposals to their nonprofit partner(s) for possible funding. (See table 1 for details on the NIH arrangements.)

¹²We also identified one agreement that is under negotiation at NIH, which if signed would share some characteristics of the ACC research agreement. Specific details on the terms and conditions of the agreement will not be available until it is signed.

Table 1: NIH Arrangements with Nonprofit Partners for Cosponsoring Research, 1999–2004

Purpose of arrangement	NIH partner	Nonprofit partner	Nonprofit partner's corporate or industry connection	Plan for funding research
"Progress for Patients" project on early phase clinical interventions in breast cancer	National Cancer Institute	Avon Products Foundation	Philanthropic arm of Avon Corporation	NIH accepted gift funds
Research on the neurobiology of diabetic complications	National Institute of Neurological Disorders and Stroke, National Institute of Diabetes and Digestive and Kidney Diseases	Juvenile Diabetes Research Foundation International	Sponsorship by Proctor & Gamble, Coca Cola, Delta Airlines, and others	NIH accepted gift funds
Support for infrastructure and research at Islet Cell Resource Centers	National Center for Research Resources	Juvenile Diabetes Research Foundation International	Sponsorship by Proctor & Gamble, Coca Cola, Delta Airlines, and others	NIH accepted gift funds
Research relevant to the cure, prevention, and treatment of Parkinson's disease and its complications	National Institute of Neurological Disorders and Stroke, National Institute of Deafness and Other Communication Disorders, NIEHS, National Institute of Mental Health	Parkinson's Unity Walk	2004 sponsors include Boehringer Ingelheim, MirapexPramipexoe Dihydrochloride Tablets, Pfizer, and others. Sponsors fund operating expenses for the walk	NIH accepted gift funds
		National Parkinson Foundation	Some corporate funding but no information available on who those corporate sponsors are	
		Parkinson Alliance	Corporate sponsorship varies with different fundraising events, includes sometimes Pfizer, Boehringer Ingelheim, Medtronic	
		Michael J. Fox Foundation for Parkinson's Research		
		Parkinson's Disease Foundation		
Support Muscular Dystrophy Cooperative Research Centers	National Institute of Neurological Disorders and Stroke, National Institute of Arthritis and Musculoskeletal and Skin Diseases, National Institute of Child Health and Human Development	Muscular Dystrophy Association	Extensive corporate sponsorship, including Albertsons, CITCO, Harley Davidson Motor Co., AmEx, Acosta Sales and Marketing	Partner provides separate funding directly to research centers

(Continued From Previous Page)

Purpose of arrangement	NIH partner	Nonprofit partner	Nonprofit partner's corporate or industry connection	Plan for funding research
Research on the effects of candidate drugs for neurodegeneration	National Institute of Neurological Disorders and Stroke	Families of Spinal Muscular Atrophy		Agency shares unfunded qualified research proposals with partner
Research on the neurological aspects of lysosomal storage disorders	National Institute of Neurological Disorders and Stroke	The Lysosomal Storage Disease Research Consortium		Agency shares unfunded qualified research proposals with partner
Research on treatment of hemophilia, von Willebrand disease, and other hereditary bleeding disorders	National Heart Lung and Blood Institute	National Hemophilia Foundation	Sponsorship from Wyeth, AHF, Baxter Healthcare, Bayer, Aventis Behring Company, and Novo Nordisk for its "it's time for a cure" campaign and "project red flag"	Agency shares unfunded qualified research proposals with partner
Research to better understand the role of religiousness and spirituality in the prevention, treatment, and recovery from alcoholism and alcohol-related diseases	National Institute on Alcohol Abuse and Alcoholism	Fetzer Institute		Agency shares unfunded qualified research proposals with partner

Source: GAO analysis of NIH data.

At EPA, none of the 16 program and regional offices we contacted identified any arrangements similar to the research arrangement between ORD and ACC. In addition, we did not identify any partnerships similar to the ACC research arrangement at FDA or at FAA. FDA officials we contacted said the agency had no research arrangements similar to the ACC arrangement with organizations that represent industry. Finally, FAA officials said that the agency had not entered into any research arrangements like the arrangements with ACC and generally did not use this type of collaborative arrangement to conduct extramural research.

Conclusions

Federally funded research advances scientific understanding and helps improve regulatory approaches to protecting human health and the environment. For both regulatory and nonregulatory agencies collaboration with external organizations is one mechanism to maximize the financial and intellectual resources available to federal agencies. However, collaboration, particularly with organizations that directly represent regulated industries, can raise concerns about conflicts of

interest that could call into question the quality and independence of federally funded research. As a result, it is imperative that federal agencies ensure, before they enter into collaborative research arrangements with nonfederal partners, that they fully consider the potential for conflicts of interest.

NIEHS and ORD relied on their general research management processes to minimize any potential conflicts of interest that might arise during implementation of their respective ACC arrangements. While these processes were appropriate for managing the arrangements, they were not specifically designed to address conflict-of-interest concerns and therefore cannot be considered adequate substitutes for formal conflict-of-interest evaluations. Consequently, without policies requiring officials at NIH and EPA to formally evaluate and manage potential conflicts of interest when they enter into collaborative arrangements such as those with ACC, neither agency can ensure that similar arrangements in the future will be systematically evaluated and managed for potential conflicts of interest.

When accepting the gift from ACC, NIEHS officials believed their actions satisfied the conditions of the NIH gift acceptance policy for conflict of interest. However, NIH's policy—both the wide discretion allowed in deciding on whether and how officials should evaluate conflicts of interest and the lack of required documentation—provides little assurance of systematic evaluation of gifts that may present potential conflicts of interest for the agency. To allay concerns about the potential for conflicts of interest that may result from accepting gifts, officials should clearly document both their evaluation of the potential for conflicts of interest and the basis for their decisions to accept or reject a gift.

Recommendations for Executive Action

The Director of NIH and the Administrator of EPA should develop formal policies for evaluating and managing potential conflicts of interest when entering into research arrangements with nongovernmental organizations, particularly those that represent regulated industry.

The Director of NIH should further revise the NIH gift acceptance policy to require NIH officials to evaluate gifts, particularly from organizations that represent regulated industry, for potential conflicts of interest and to document the basis for their decisions, including what, if any, steps are needed to manage potential conflicts.

Agency Comments and Our Evaluation

We provided EPA and NIH with a draft of this report for their review and comment. EPA neither agreed nor disagreed with our recommendation, but provided technical comments that we have incorporated as appropriate. (See app. II.) NIH concurred with our recommendations and stated it would take steps to implement them. In addition, NIH emphasized that it is not a regulatory agency and suggested changes to the report to clarify its role. We have added language to clarify NIH's relationship with the regulated industry. NIH also provided technical comments that we have incorporated as appropriate. NIH's comments and our response are included in appendix III.

As agreed with your offices, unless you publicly announce its contents earlier, we plan no further distribution of this report for 30 days after the date of this letter. At that time, copies of this report will be sent to the congressional committees with jurisdiction over the Environmental Protection Agency and the National Institutes of Health; the Honorable Stephen L. Johnson, Acting Administrator of EPA; the Honorable Elias A. Zerhouni, Director of NIH; and the Honorable Joshua B. Bolten, Director of the Office of Management and Budget. This report will also be available at no charge on GAO's home page at <http://www.gao.gov>.

If you have any questions about this report, please contact me at (202) 512-3841. Key contributors to this report are listed in appendix IV.



Anu K. Mittal, Director
Natural Resources and Environment

Objectives, Scope, and Methodology

As requested by the Ranking Member of the Subcommittee on Environment, Technology and Standards, House Committee on Science, and the Ranking Member of the Subcommittee on Research, House Committee on Science, we determined the (1) legal authority the National Institutes of Health's (NIH) National Institute of Environmental Health Sciences (NIEHS) and the Environmental Protection Agency's (EPA) Office of Research and Development (ORD) used to enter into arrangements with the American Chemistry Council (ACC); (2) extent to which NIEHS and ORD evaluated and managed the possibility that conflicts of interest could result from their arrangements; (3) extent to which NIEHS complied with NIH's gift acceptance policy when accepting ACC's funds; and (4) extent to which similar research arrangements exist within other offices and programs within NIH and EPA, as well as other regulatory agencies.

To determine the legal authorities NIEHS and ORD relied on to enter the research arrangements with ACC to solicit and fund extramural research, we reviewed the statutes cited in agency documentation related to the arrangements. For NIH, these authorities included sections 301 and 405 of the Public Health Service (PHS) Act, as amended (42 U.S.C. §§ 241 and 284); and gift acceptance statutes contained in sections 231 and 405(b)(1)(H) of the PHS Act as amended (42 U.S.C. §§ 238, 284(b)(1)(H)). For ORD these authorities included section 103 of the Clean Air Act, as amended (42 U.S.C. § 7403), section 104 of the Clean Water Act, as amended (33 U.S.C. § 1254), and section 8001 of the Solid Waste Disposal Act, as amended (42 U.S.C. § 6981). We also reviewed the following related documentation on delegations of authority:

- Memorandum from the Assistant Secretary for Health to Public Health Service Agency Heads for "Delegation of Authority To Accept Gifts Under Title XXI of the PHS, Miscellaneous" (July 10, 1995), and
- NIH Manual Chapter 1130, Delegations of Authority, Program: General #5 Accept Gifts Under Section 231 of the PHS Act, Program: General #10 National Library of Medicine.

We also reviewed relevant legislative histories and Comptroller General decisions and interviewed attorneys at NIEHS and ORD about their reviews of the arrangements. Furthermore, we compared each agency's policies and both formal arrangements with the authorities cited above.

To determine what measures NIEHS and ORD took to evaluate and manage the potential that conflicts of interest could result from their arrangements

with ACC, we interviewed program officials on their perceptions of conflict of interest when the ACC arrangement was being considered, as well as on the actions they took to develop and implement the arrangements. We also interviewed budget and legal officials, as appropriate, at each agency on their involvement in reviewing and completing the arrangements. We reviewed the research arrangements with ACC, as well as other documentation related to the arrangements, including correspondence between agency officials and ACC, interagency memorandums, and documentation of agency legal and other reviews. We considered statutes on conflict of interest and ethics guidelines that might address the need for agencies to consider and manage real or apparent conflicts of interest (18 U.S.C. § 209, and the Ethics in Government Act of 1978, 5 U.S.C. app. 4). Finally, we interviewed ACC officials to obtain their views on conflicts of interest and on the role of ACC representatives in developing the announcement of funding availability, reviewing and funding research proposals, and administering the grants. We did not test the NIEHS or ORD internal controls governing the administration of grants awarded under the arrangements.

To determine whether NIEHS's acceptance of ACC funds as a gift complied with NIH policy for accepting gifts, we collected and analyzed NIH's policy for gift acceptance and we interviewed legal staff at NIEHS concerning their review of potential gifts and their assistance to program officials. We obtained and reviewed the research arrangement and related documentation on transferring and administering the gift funds. We interviewed program officials on their actions in accepting the funds and compared activities and documentation pertaining to NIEHS's acceptance of ACC's gift with the requirements and recommendations outlined in NIH's policy.

To determine the extent of similar research arrangements at other federal agencies, we identified officials responsible for 96 percent or more of the extramural research budgets at NIH, EPA, and two additional agencies. We then used a structured guide to determine what, if any, research arrangements the agencies had with external partners. In addition to NIEHS and ORD, we selected a nonprobability sample of two additional agencies on the basis of the magnitude of the research component of their

mission and congressional interest.¹ The two agencies selected were the Food and Drug Administration (FDA) and the Federal Aviation Administration (FAA) because each agency had a research component to its mission, a corresponding research budget, and a regulatory role. We determined that the selection was appropriate for our design and objectives and that the selection would generate valid and reliable evidence to support our work.

To determine the extent to which arrangements exist within these four agencies, we obtained the most current available data on extramural research budgets from institutes and centers in NIH, program and regional offices in EPA, and the programs and centers at FAA and FDA. To assess the reliability of these data, we used a structured guide to interview officials at each agency responsible for maintaining the databases containing the data provided. Specifically, we obtained descriptions of the databases, how data are entered into the databases, quality control checks on the data, testing conducted on the data, and officials' views on the accuracy and completeness of the data. We asked follow-up questions whenever necessary. FDA officials noted one limitation on the data that were provided. Specifically, when compiling data on research budgets, officials must sometimes subjectively interpret the term "research." The impact of such interpretation may cause the extramural research figures for FDA to be slightly overstated. After taking these steps, we determined that the data were sufficiently reliable for the purposes of this report.

We used these data to rank order the programs and centers and identify officials in each agency responsible for administering 96 percent or more of each agency's extramural research budget. In our interviews with these officials, we focused on arrangements established since January 1999—specifically, arrangements with characteristics similar to the ACC arrangements. We looked for and considered arrangements with nongovernmental, nonacademic partners to sponsor research extramural to both organizations. We did not collect information or report on the use of other types of agency research cooperation with external partners such as cooperative research and development agreements or informal consultations between agency and external scientists.

¹Results from nonprobability samples cannot be used to make inferences about a population because, in a nonprobability sample, some elements of the population being studied have no chance or an unknown chance of being selected as part of the sample.

At NIH, we used a structured guide to interview officials at the following institutes or centers, listed in order of greatest to least extramural research grant-dollar totals, in fiscal year 2002: National Cancer Institute; National Heart, Lung, and Blood Institute; National Institute of Allergy and Infectious Diseases; National Institute of General Medical Sciences; National Institute of Diabetes and Digestive and Kidney Diseases; National Institute of Neurological Disorders and Stroke; National Institute of Mental Health; National Center for Research Resources; National Institute of Child Health and Human Development; National Institute on Drug Abuse; National Institute on Aging; National Eye Institute; NIEHS; National Institute of Arthritis and Musculoskeletal and Skin Diseases; National Human Genome Research Institute; National Institute on Alcohol Abuse and Alcoholism; National Institute on Deafness and Other Communication Disorders; National Institute of Dental and Craniofacial Research; National Institute of Nursing Research; and National Institute of Biomedical Imaging and Bioengineering. Together, these institutes and centers accounted for 99 percent of NIH's total extramural research funds for fiscal year 2002.

At EPA, we used a structured guide to interview program officials from the following offices and regions (shown in order of greatest to least funding available for extramural research fiscal year 2003):² ORD; Office of Water; Region 6; Region 9; Office of International Affairs; Region 3; Office of Solid Waste and Emergency Response; Region 4; Region 5; Region 1; Region 2; Region 7; Region 10; Region 8; Office of Prevention, Pesticides and Toxic Substances; and Office of Air and Radiation. Together, these offices accounted for 99 percent of the EPA's extramural research funds for fiscal year 2003.

At FDA, we interviewed the agency official responsible for getting approval for Memorandums of Agreement from the General Counsel's Office and Office of Grants Management and for ensuring that each agreement is published in the *Federal Register*. FDA does not accept funds from external partners under these agreements.

Finally, at FAA, we interviewed officials from the research and development offices at headquarters as well as the division manager of the Acquisition, Materiel, and Grants Division of the William J. Hughes

²EPA has 10 regional offices, each of which is responsible within its states and territories for the execution of the agency's programs.

Technical Center. Together, these offices accounted for 96 percent of the agency's fiscal year 2003 funds for extramural research.

To independently corroborate the information obtained from agency officials, to the extent possible, we collected documents on the agreements we identified at these agencies and reviewed agency Web sites maintained by the relevant centers and offices, as well as Web sites maintained by external sources, such as advocacy or trade groups.

We conducted our review from February 2004 through February 2005 in accordance with generally accepted government auditing standards.

Comments from the Environmental Protection Agency



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

JAN 26 2005

OFFICE OF
RESEARCH AND DEVELOPMENT

Ms. Anu K. Mittal
Director, Natural Resources and Environment
U.S. Government Accountability Office
Washington, DC 20548

Dear Ms. Mittal:

Thank you for the opportunity to comment on the Government Accountability Office (GAO) draft report entitled, *Federal Research: NIH and EPA Need to Improve Conflict of Interest Reviews for Research Agreements with Private Sector Entities* (GAO-05-191). We are especially pleased that GAO found that: (1) "...the actions the agencies took to manage potential conflicts of interest were appropriate;" and (2) "ORD officials took appropriate steps to minimize potential conflicts of interest as their research agreements with ACC [American Chemistry Council] were implemented." In light of these findings, we believe that GAO needs to substantially revise the title of the report to more accurately portray the results of its review. We, therefore, suggest a more accurate title to consider could be: "Federal Research: Agencies Took Reasonable Steps to Manage Potential Conflicts of Interest but Policies and Procedures Can be Improved." This revision would be consistent with the findings of the draft report.

Extramural Research Agreements

As discussed below, GAO's use of the term "research agreement" to describe EPA's legal relationship with organizations that EPA cooperates with to coordinate environmental research is not accurate. In addition, we have enclosed detailed comments on specific portions of the text of the draft report.

Extramural research agreements may take the form of contracts, grants, cooperative agreements, or Memoranda of Understanding (MOU), depending upon the nature of the transaction. Contracts allow federal agencies to purchase services and products for their direct use or benefit, including research that agencies use directly in the development of regulations. Agencies use grants and cooperative agreements to support research that has broader application in the scientific community as a whole. Once the scope of work for a grant is negotiated, federal involvement in grant-funded research is generally limited to that necessary to effectively oversee the use of federal funds. On the other hand, federal agencies are substantially involved in

**Appendix II
Comments from the Environmental
Protection Agency**

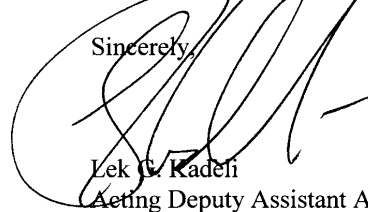
2

research carried out under cooperative agreements through ongoing collaboration on scientific matters, and data sharing and other joint activities, with more intense monitoring of the substantive aspects of the research. MOU specify the terms under which federal agencies will cooperate with non-federal organizations, but do **not** involve transfers of funds between the parties to the MOU, unless the federal agency has gift acceptance authority. The term, MOU, is accurate and avoids confusion with “research agreements,” which are used for grants or cooperative agreements.

The MOU that the Office of Research and Development (ORD) entered into with ACC is not unique. Since 1975, ORD has entered into MOUs under its broad authority to cooperate with federal and non-federal parties to encourage, coordinate, and accelerate environmental research.

We appreciate the opportunity to respond to this draft report. Should you have any questions or need additional information, I can be reached at 202-564-6620.

Sincerely,



Lek W. Kadei
Acting Deputy Assistant Administrator
for Management

Enclosure

Comments from the National Institutes of Health



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

National Institutes of Health
Bethesda, Maryland 20892
<http://www.nih.gov>

JAN 31 2005

Ms. Anu K. Mittal
Director, Natural Resources and Environment
U.S. Government Accountability Office
441 G Street, N.W.
Washington, D.C. 20548

Dear Ms. Mittal:

We appreciate the opportunity to review and comment on the draft report entitled *Federal Research: NIH and EPA Need to Improve Conflict of Interest Reviews For Research Agreements With Private Sector Entities (GAO-05-191)*. Enclosed are the comments of the National Institutes of Health. Since the report involves both the NIH and the Environmental Protection Agency, a regulatory agency, we feel it is important to emphasize that NIH is not a regulatory agency. A reader could infer, from the recommendations that contain references to "regulated industry," that there are industries regulated by NIH. We believe that the report should clearly indicate that NIH is not a regulatory agency and therefore could not enter into research agreements with or accept gifts from industries that it regulates.

Should you or your staff have any questions, please call Patricia Quast at 301-402-8264.

Sincerely,

A handwritten signature in black ink, appearing to read "Elias A. Zerhouni".

Elias A. Zerhouni, M.D.
Director

Enclosures

**Comments of the National Institutes of Health (NIH)
On the U. S. Government Accountability Office (GAO) Revised Draft Report
“Federal Research: NIH and EPA Need to Improve Conflict of Interest Reviews for
Research Agreements With Private Sector Entities”
GAO-05-191**

We appreciate the opportunity to review and comment on this revised draft report. The report acknowledges that NIH used the tools, then extant, to assess and manage potential conflicts of interest. It is important to note that the GAO evaluation team did not identify or conclude that conflicts of interest existed in the collaborative research effort described in the report. Nonetheless, we know that improvements can be made to our policies and procedures for evaluating the potential for conflicts of interest. Therefore, we concur with the two recommendations and plan to take actions to implement them.

Despite our concurrence with the recommendations, we believe that the report contains erroneous comparisons and unsupported statements that could lead the reader to make incorrect conclusions about the public health role and mission of the NIH. For example:

- The body of the report, and both recommendations, discuss relations between governmental agencies and “regulated industry.” The way this is written, a reader of this report could infer that there are industries regulated by the NIH. We believe that it is important to clarify--throughout the report--that NIH, unlike the Environmental Protection Agency (and the other Federal agencies used in the report for comparison purposes), is not a regulatory agency. By definition, therefore, NIH could not enter into research agreements or accept gifts from industries it regulates.
- The revised version of this draft report added a sentence on page 13 that states, in part, that “...certain aspects of NIEHS’ announcement **could** [emphasis added] have deterred some qualified researchers from applying...” If there is evidence that this occurred, it should be included in the report. Otherwise, this is a speculative statement that is inappropriate to include in the report.
- The report does not put into perspective the relationship of the collaborative effort to the entire extramural research effort. The monies provided by the collaborative partner represent about 6/100,000 of 1 percent (0.000057%) of NIH’s extramural research budget for fiscal year 2002.

We also offer a number of technical comments that we believe improve the clarity and accuracy of the final report.

GAO Recommendation

The Director of NIH and the Administrator of EPA should develop formal policies for evaluating and managing potential conflicts of interest when entering into research agreements with nongovernmental organizations, particularly those that represent regulated industry.

1/31/05

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NIH Response

We concur with this recommendation. As noted in the report, NIH has policies and processes to ensure the integrity of scientific review and that grant funds are awarded and administered appropriately. However, we agree that a formal policy should be developed for evaluating and managing potential conflicts of interest when entering into agreements to fund extramural research with industry or organizations that represent industry. Because this is an issue that is important to NIH, we plan to establish a high-level working group to develop such a policy.

GAO Recommendation

The Director of NIH should further revise the NIH gift acceptance policy to require NIH officials to evaluate gifts, particularly from organizations that represent regulated industry, for potential conflicts of interest and to document the basis for their decisions, including what, if any, steps are needed to manage potential conflicts.

NIH Response

We concur with this recommendation. NIH will clarify and make consistent the actions officials must take to evaluate conflicts of interest when accepting gifts and include these updated procedures in a revision to NIH Policy Manual 1135, *Gifts Administration*. The revisions will include:

1. Making mandatory, consistently throughout the policy manual, the requirement for approving officials to use the "Gift Acceptance Validity Survey" and the "NIH Gift Pre-Acceptance Checklist" assessment tools to evaluate conflicts of interest before accepting a gift; and
2. Requiring reviewing officials to formally document their decisions and any plans to manage potential conflict.

GAO Contacts and Staff Acknowledgments

GAO Contacts

Anu Mittal, (202) 512-3841
Cheryl Williams, (404) 679-1991

Staff Acknowledgments

In addition to the individuals listed above, key contributions to this report were made by Amy Dinger, Karen Keegan, Judy Pagano, Carol Herrstadt Shulman, Barbara Timmerman, Mindi Weisenbloom, and Eugene Wisnoski. Also contributing to this report were Anne Dievler and Jim Lager.

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