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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

Subject: *National Institute of Environmental Health Sciences—American Chemistry Council Donation*

This responds to your request for our opinion regarding the authority of the National Institute of Environmental Health Sciences (NIEHS)¹ to accept a conditional gift from the American Chemistry Council (ACC), a nonprofit organization that represents the United States chemical industry. In July 2001, ACC donated funds to NIEHS to use to award grants for research projects studying environmental developmental toxicants. *Memorandum of Understanding Between the American Chemistry Council and the National Institute of Environmental Health Sciences*, July 26, 2001 (hereinafter MOU).

Under 42 U.S.C. § 328, the Secretary of the Department of Health and Human Services (HHS) and his delegates may accept gifts, including conditional gifts. Our review of the MOU, the Request for Applications (RFA) that NIEHS issued in conjunction with the MOU, and applicable law does not establish that NIEHS agreed to any conditions that would be inconsistent with its responsibility to make final determinations on grant awards. To effectuate the overall collaborative NIEHS/ACC objective to stimulate mutually desired research, NIEHS, in the MOU, agreed to provide ACC the opportunity to review grant applications for responsiveness to the RFA, provide input to NIEHS in the negotiation and award of the grant applications, and monitor the

¹ NIEHS is a research institute within the National Institutes of Health, Department of Health and Human Services.

progress of the awarded grant projects. We do not read the provisions of the MOU to provide ACC with anything more than the opportunity to provide advice and input to NIEHS as NIEHS implements its statutory authority consistent with the mutually agreed upon research objectives.

To ensure transparency in the grants process, and to avoid any appearance of a conflict of interest between future donors and NIEHS's statutory responsibilities, we suggest that NIEHS develop formal policies and procedures regarding the level of participation a donor may have in the grants process and articulate these policies and procedures clearly in the RFA and MOU. We also suggest that NIEHS work with donors to ensure that before making a donation, the donor has adequate knowledge of the grants process and how NIEHS may use its donation, so that the donor can consider all of the restrictions and other conditions it might wish to place on its donation before it provides the donation to NIEHS.

BACKGROUND

NIH's mission is to improve human health by increasing scientific knowledge related to disease and health. *NIH Grants Policy Statement*, Dec. 1, 2003, at 16.² It accomplishes this primarily through the conduct and support of biomedical and behavioral research and research training. NIH funds research conducted at NIH (intramural research) and research conducted by scientists at universities, nonprofit research organizations, for-profit organizations, and state and local governments (extramural research). As explained in the recent GAO report *Federal Research: NIH And EPA Need to Improve Conflict of Interest Reviews for Research Arrangements with Private Sector Entities*, GAO-05-191 (Washington, D.C.: Feb. 25, 2005), federal and nonfederal partners, through collaboration, 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.

In July 2001, ACC, a nonprofit trade organization that represents most major United States chemical companies,³ entered into a MOU with NIEHS to finance a 3-year research initiative studying environmental developmental toxicants of potential

² See also *NIH Grants Policy Statement*, March 2001, at 36. The *NIH Grants Policy Statement* that was in effect when ACC donated funds to NIEHS for the research projects studying environmental developmental toxicants was dated March 2001. The policy statement was revised in December 2003.

³ ACC "is committed to improved environmental, health and safety performance through Responsible Care [the industry's initiative to improve participating companies' environmental health and safety performance], common sense advocacy designed to address major public policy issues, and health and environmental research and product testing." <http://www.americanchemistry.com> (last visited June 10, 2005).

importance to public health intervention and/or prevention strategies.⁴ MOU at 1. Pursuant to the MOU, ACC agreed to donate \$1.5 million to NIEHS. MOU at 3. The agreement explained that “[t]he condition on the [gift] is that all the funds provided by the ACC will be used solely for the agreed upon RFA [Request for Application] initiative(s) to directly fund in part the total cost budget of the RFA for each year of support provided to the funded grant applications.” *Id.*

The RFA for Developmental Toxicology Exploratory Research Grants, NIEHS RFA-ES-01-006, June 14, 2001, states that the overall objective of the research initiative to study environmental developmental toxicants is “to stimulate research on the mechanism of action of developmental toxicants using the state of the art tools of genomics, proteomics and model organisms including transgenic and gene knock out genetic animal models.” RFA at 1. “The new information obtained . . . will be used to accelerate research in developmental toxicology, advance new approaches in molecular epidemiology and improve qualitative and quantitative risk assessment processes for evaluating the potential for exposure induced developmental defects.” *Id.* at 1. The RFA also states that

“[t]he present initiative RFA addresses the mutual research goals of the NIEHS and the ACC to improve the quantity, quality, and timeliness of data from investigations on the mechanisms of developmental toxicants. Thus, this jointly sponsored RFA represents a unique collaboration of Government and Industry to support novel, high potential research that will contribute to the improvement of the health of the American people by improving the quantity and quality of the data on developmental toxicants that is available for use in the risk assessment process.”

Id. at 3.

Pursuant to NIH/NIEHS policy, after grant applicants submit applications in response to the RFA, NIEHS staff review all submitted grant research applications to determine whether they are complete, conform to administrative requirements, and contain the information necessary for a detailed review. *NIH Grants Policy Statement*, Dec. 1, 2003, at 27.⁵ Applications that are in compliance are accepted for

⁴ The general purpose of NIEHS is the conduct and support of research, training, health information dissemination, and other programs with respect to factors in the environment that affect human health, directly or indirectly. 42 U.S.C. § 2851. The Applied Toxicological Research and Testing Program, a program within NIEHS, conducts applied research and testing regarding toxicology. 42 U.S.C. § 2851-1. The directors of the national research institutes, acting on behalf of the Secretary of NIH, have the authority to enter into grants, contracts, and cooperative agreements to encourage and support research, investigations, experiments, demonstrations, and studies in the health sciences relating to causes, diagnosis, treatment, control, and prevention of physical and mental diseases. 42 U.S.C. §§ 241, 284(b)(1).

⁵ See also *NIH Grants Policy Statement*, March 2001, at 35.

further review. *Id.* NIEHS is required by statute and policy to conduct scientific and technical peer review of all grant applications that meet the administrative requirements and whose direct cost does not exceed \$50,000. 42 U.S.C. § 284(b)(2)(B). In addition to review by the peer review panel, if the direct cost exceeds \$50,000, the grant must be recommended by the advisory council for the national research institute involved. *Id.* NIEHS may make a grant award only if the grant proposal has been recommended by the peer review panel, and if applicable, the advisory council. *Id.*; *NIH Grants Policy Statement*, Dec. 1, 2003, at 26.⁶ The Public Service Health Act authorizes only the Secretary of HHS, acting through the director of each national research institute, to make grants for research. 42 U.S.C. § 284(b)(2)(B); *NIH Grants Policy Statement*, Dec. 1, 2003, at 32.⁷

The MOU states that both ACC and NIEHS “will review all [grant] applications received for responsiveness to the purpose and intent of the RFA” prior to the acceptance of the application, and that “[t]hose applications judged responsive will be accepted by the NIH/NIEHS for peer-review evaluation.” MOU at 3. The MOU also provided ACC “the opportunity . . . to provide input to the NIEHS in the negotiation and award of the grant applications, and to assist in the monitoring of progress of the awarded grant projects.” MOU at 4. According to the Deputy NIH Legal Advisor, ACC, in fact, did not exercise its opportunity to review applications prior to acceptance to determine if they were responsive to the purpose and intent of the RFA. Letter from Patricia A. Kvochak, Deputy NIH Legal Advisor, to Susan A. Poling, Managing Associate General Counsel, GAO, Nov. 15, 2004 (Kvochak letter). NIEHS, pursuant to its policy, conducted a review of the research applications prior to their acceptance to determine compliance with administrative requirements and then informed ACC that the applications met the administrative requirements. *Id.*

ACC, however, did review the grant proposals subsequent to review and recommendation by an independent peer review panel. Kvochak letter. After review by the peer review panel, NIEHS presented to ACC a funding plan and a copy of each grant proposal. At that point, ACC requested that NIEHS not use its donation to fund two of the research proposals. NIEHS agreed to ACC’s request and chose to use its fiscal year appropriations to cover the full cost of the two proposals.⁸ Kvochak letter.

ANALYSIS

ACC provided a gift to NIEHS that was conditioned on joint review by NIEHS and ACC of grant applications for responsiveness and that was conditioned on providing

⁶ See also *NIH Grants Policy Statement*, March 2001, at 34.

⁷ See also *NIH Grants Policy Statement*, March 2001, at 38.

⁸ In total, NIEHS obligated \$3.7 million from its annual appropriations for the research initiative studying environmental developmental toxicants. Of this amount, NIEHS used \$2.5 million for these two grant awards. Kvochak letter, p.3.

ACC both the opportunity for input in the award of grants and the opportunity to assist in monitoring the progress of grant proposals.

Without statutory authority, an agency may not accept gifts of goods or services for its own use (*i.e.*, for retention by the agency or credit to its own appropriations). B-286182, Jan. 11, 2001; B-255474, Apr. 3, 1995; 16 Comp. Gen. 911 (1937). In addition, an agency may not accept a conditioned gift, except pursuant to express authority provided by Congress. *Story v. Snyder*, 184 F.2d 454 (D.C Cir.), *cert. denied*, 340 U.S. 866 (1950).

Congress provided the Secretary of HHS the authority to accept conditional gifts. 42 U.S.C. § 238(a). The statute provides that “[t]he Secretary of Health and Human Services is authorized to accept on behalf of the United States gifts made unconditionally by will or otherwise for the benefit of the [Public Health] Service or for the carrying out of any of its functions. Conditional gifts may be so accepted if recommended by the Surgeon General, and the principal of and income from any such conditional gift shall be . . . used in accordance with its conditions.” 42 U.S.C. § 238.⁹ The Secretary delegated to the Assistant Secretary for Health the authorities to accept gifts vested in the Secretary. *See Memorandum from the Assistant Secretary for Health, NIH, to the Public Health Service Agency Heads*, July 10, 1995. Subsequently, the Assistant Secretary for Health delegated to the Public Health Service Agency heads, for their respective agencies, the authority under 42 U.S.C. § 238(a) to accept conditional gifts. *Id.* This included the Director of the National Institutes of Health, *id.* at 2, who subsequently delegated the authority to research institute directors and deputy directors. *NIH Policy Manual 1135: Gifts Administration*, Dec. 19, 2001 at 7.

The research initiative on environmental developmental toxicants was a collaborative project between ACC and NIEHS. The gift instrument—the MOU—placed certain conditions on the gift ACC made to NIEHS to ensure that the gift was used consistently with the aims and goals that ACC and NIEHS jointly developed:

- Both ACC and NIEHS “will review all [grant] applications received for responsiveness to the purpose and intent of the RFA” prior to the acceptance of the application, and that “[t]hose applications judged responsive will be accepted by the NIH/NIEHS for peer-review evaluation.” MOU at 3.

⁹ In 1966, the functions of Surgeon General of the Public Health Service were transferred to the Secretary of Health, Education, and Welfare. Reorg. Plan No. 3 of 1966 §§ 1, 3; 42 U.S.C. § 202 note. In 1979, the Department of Education Reorganization Act, Pub. L. No. 96-88, 93 Stat. 668 (Oct. 17, 1979), redesignated the Department of Health, Education, and Welfare as the Department of Health and Human Services. 20 U.S.C. § 3508.

- ACC will have “the opportunity . . . to provide input to the NIEHS in the negotiation and award of the grant applications, and to assist in the monitoring of progress of the awarded grant projects.” MOU at 4.

NIEHS is responsible for awarding grants and administering them per statutory requirements and may not delegate its grant award authority to nongovernmental entities. We read the conditions in the MOU as providing ACC only with the opportunity to provide advice and input to NIEHS as NIEHS implements its statutory grant award authority and not as delegating decision authority to ACC.

As explained in the background section above, pursuant to NIH/NIEHS grants policy, after grant applicants submit applications in response to the RFA, NIEHS staff review all submitted grant research applications to determine whether they are complete, conform to administrative requirements, and contain the information necessary for a detailed review. *NIH Grants Policy Statement*, Dec. 1, 2003, at 27.¹⁰ While the MOU provides ACC the opportunity to provide input and advice regarding the responsiveness of the applications to the RFA, there is nothing in the MOU that delegates to ACC NIEHS’s determination that an application is or is not responsive. NIH officials stated, however, that ACC, in fact, did not review the research applications at this point in the process.

If the research application is complete, the next step in the process is peer review. NIEHS is required by statute and policy to conduct scientific and technical peer review of all grant applications. 42 U.S.C. § 284(b)(2)(B). The purpose of the peer review panel is to provide a fair and objective review process in the overall interest of science. *NIH Grants Policy Statement*, Dec. 1, 2003, at 26.¹¹ NIEHS may make a grant award only if the grant proposal has been recommended by the peer review panel, and if applicable, the advisory council. 42 U.S.C. § 284(b)(2)(B); *NIH Grants Policy Statement*, Dec. 1, 2003, at 26.¹²

After the peer review process, ACC requested that NIEHS not use its donation to fund two grant proposals recommended by the peer review panel. ACC requested that NIEHS not use its donation for the first project because it involved research on primates. It requested that NIEHS not use its donation for the second project because it involved a chemical related to the ACC industry, and ACC was concerned that funding this research might look like a conflict of interest. Kvochak letter, and subsequent conversation with the Deputy NIH Legal Advisor, Dec. 7, 2004. NIEHS acceded to ACC’s request and funded the two grant proposals through its own appropriation. *Id.* All of the applications recommended by the peer review panel were funded.

¹⁰ See also *NIH Grants Policy Statement*, March 2001, at 35.

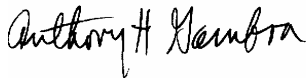
¹¹ See also *NIH Grants Policy Statement*, March 2001, at 34.

¹² See also *NIH Grants Policy Statement*, March 2001, at 34.

The MOU and NIEHS only permitted ACC to advise and provide input to NIEHS in its grants award process, not to overrule NIEHS's grant award decisions. However, to ensure transparency in the grants process, and to avoid any appearance of a conflict of interest between future potential donors and NIEHS's statutory responsibilities, we suggest that NIEHS develop formal policies and procedures regarding the level of participation a donor may have in the grants process and articulate these policies and procedures clearly in the RFA and MOU. We also suggest that NIEHS work with donors to ensure that before making a donation, the donor has adequate knowledge of the grants process and how NIEHS may use its donation, so that the donor can consider all of the restrictions and other conditions it might wish to place on its donation before it provides the donation to NIEHS.

CONCLUSION

The Secretary of HHS and his delegates have authority to accept gifts, including conditional gifts. The conditions articulated in the MOU did not delegate to ACC any of NIEHS's statutory grant award authority but only provided ACC with the opportunity to provide advice and input to NIEHS in the review and award of grant applications. In order to avoid any appearance of a conflict of interest in the future, we suggest that NIEHS develop formal policies and procedures regarding donor participation in the grants process, and that it work with donors to ensure they consider all of the conditions they might wish to place on their donation before they provide the donation to NIEHS.



Anthony H. Gamboa
General Counsel

DIGEST

The Secretary of the Department of Health and Human Services and his delegates have authority to accept gifts, including conditional gifts, so long as they do not offend existing statutory or regulatory provisions. NIEHS may not delegate its grants award authority to nongovernmental entities. While the MOU provides ACC the opportunity to advise and provide input, it does not delegate to ACC any decision authority. To avoid any appearance of a conflict of interest, we suggest that NIEHS develop grants policies and procedures regarding the level of participation a donor may have in the grants process and work with donors to ensure that they consider all of the restrictions and other conditions they might wish to place on their donation before providing the donation to NIEHS.