



1600 20th Street, NW • Washington, D.C. 20009 • 202/588-1000 • www.citizen.org

March 19, 2018

The Honorable Daniel R. Levinson
Inspector General
U.S. Department of Health and Human Services
330 Independence Avenue, SW
Washington, DC 20201

RE: NIH Officials Allegedly Violated the Agency’s Policy by Soliciting Donations from Alcoholic Beverage Manufacturers to Fund Study on Health Effects of Moderate Alcohol Consumption

Dear Inspector General Levinson:

Public Citizen, a consumer advocacy organization with more than 400,000 members and supporters nationwide, respectfully requests that your office immediately launch a formal investigation into the conduct of National Institutes of Health (NIH) officials who, according to an article published by *The New York Times* (*The Times*) on March 17,¹ were involved in directly soliciting donations from alcoholic beverage manufacturers to fund a \$100 million study that is intended to assess the cardiovascular health effects of moderate alcohol consumption. The conduct described by the *The Times*, if confirmed, represents a serious violation of the NIH’s policy prohibiting solicitations of gifts by NIH employees and clearly undermines public trust in the integrity of the study and in the NIH.

Overview of the alcohol study

The NIH study in question — the “Moderate Alcohol and Cardiovascular Health Trial” — is being funded through cooperative agreement award #U10 AA025286 from the National Institute on Alcohol Abuse and Alcoholism (NIAAA) to Beth Israel Deaconess Medical Center.² The principal investigator for the alcohol study is Dr. Kenneth J. Mukamal. The alcohol study is a multinational, randomized trial comparing the effects of consuming one standard serving of alcohol daily with alcohol abstinence on the risk of cardiovascular disease, diabetes, mortality, and related outcomes among 7,800 adults worldwide who are at above-average cardiovascular risk.

¹ Rabin RC. Federal agency courted alcohol industry to fund study on benefits of moderate drinking. March 17, 2018. *New York Times*. <https://nyti.ms/2GAG6Xi>. Accessed March 18, 2018.

² National Institutes of Health. NIH Research Portfolio Online Reporting Tools (RePORT). Project information: 1U10AA025286-01. https://projectreporter.nih.gov/project_info_description.cfm?aid=9197811&icde=38618230. Accessed March 18, 2018.

Allegations of inappropriate solicitation of donations

On July 3, 2017, *The Times* first reported the troubling revelation that five of the world's largest alcoholic beverage manufacturers — Anheuser-Busch InBev, Heineken, Diageo, Pernod Ricard, and Carlsberg — had pledged at least \$67.7 million to the Foundation for the National Institutes of Health to fund the alcohol study.³ According to the July 3, 2017, article, Dr. Mukamal had claimed he was not aware that alcohol companies were supporting the trial financially. He also was quoted by *The Times* as having said, “We have had literally no contact with anyone in the alcohol industry in the planning of this.”

However, based on documents — including emails and travel vouchers — obtained from the NIH under the Freedom of Information Act and interviews with former NIH officials, *The Times* reported on March 17 that university-based scientists, including Dr. Mukamal, and senior NIAAA officials “waged a concerted campaign to obtain funding from the alcohol industry” for the alcohol study and paid “for scientists to travel to meetings with [alcohol industry] executives, where they gave talks strongly suggesting that the study’s results would endorse moderate drinking as healthy.”⁴

Importantly, section 1135 (Gifts Administration) of the NIH Policy Manual, which was last updated on October 5, 2011, explicitly “prohibits employees, either directly or through another party, from requesting or suggesting donations to the NIH or to any of its components, of funds or other resources intended to support activities.”⁵

The following are key excerpts from the March 17 article in *The Times* that detail the coordinated efforts by NIAAA officials and university-based scientists to solicit financial donations from alcoholic beverage manufacturers for the alcohol study:

It was going to be a study that could change the American diet, a huge clinical trial that might well deliver all the medical evidence needed to recommend a daily alcoholic drink as part of a healthy lifestyle.

That was how two prominent scientists and a senior federal health official pitched the project during a presentation at the luxurious Breakers Hotel in Palm Beach, Fla., in 2014. And the audience members who were being asked to help pay for the \$100 million study seemed receptive: They were all liquor company executives. ...

An N.I.A.A.A. official, now retired, said she followed up after the presentations with appeals for money, telling industry executives the research could not be done without their support.

³ Rabin RC. Is alcohol good for you? An industry-backed study seeks answers. July 3, 2017. *The New York Times*. <https://nyti.ms/2uDkXEF>. Accessed March 18, 2018.

⁴ Rabin RC. Federal agency courted alcohol industry to fund study on benefits of moderate drinking. March 17, 2018. *New York Times*. <https://nyti.ms/2GAG6Xi>. Accessed March 18, 2018.

⁵ National Institutes of Health, Office of Management. NIH Policy Manual: 1135 – Gifts Administration. October 5, 2011. <https://policymanual.nih.gov/1135#F20C5206>. Accessed March 18, 2018.

The meetings in late 2013 and early 2014 included a “working lunch” at the Beer Institute convention in Philadelphia, and two meetings at the Washington headquarters of the Distilled Spirits Council, a liquor industry trade group, as well as the presentation at The Breakers.

Dr. Kenneth J. Mukamal, an associate professor of medicine at Harvard Medical School and now the lead investigator of the study, and Dr. John Krystal, a Yale University neuroscientist, argued that a long-term randomized controlled trial could dispel lingering doubts about the benefits of moderate daily drinking. ...

The presentations gave the alcohol industry an opportunity to preview the trial design and vet the investigators. Indeed, the scientist leading the meetings was eventually chosen to head the huge clinical trial. ...

But [current NIAAA Director George Koob’s] predecessor, Dr. Ken Warren, who helped organize and participated in some of the meetings [with alcoholic beverage manufacturers] as acting director of the alcohol abuse institute, acknowledged in an interview that the scientists’ presentations were meant to both “demonstrate to the industry that the study was feasible” and “to determine if they had interest in taking part” as funders. ...

In an interview, Dr. Lorraine Gunzerath, a retired senior adviser to Dr. Warren, took credit for coming up with the idea of reaching out to the alcohol industry for funding.

Clinical trials like this one don’t fall neatly under the mission of the alcohol abuse institute, she said. “We were supposed to be preventing alcoholism, so to spend that kind of money on research for a possible good use of alcohol was something that would never fly,” she said. ...

All the N.I.H. had to do was “make a business case to the industry that it would be to their benefit, even if they couldn’t actually control the trial’s outcome,” Dr. Gunzerath said.

She arranged for the university scientists to address executives at alcohol industry meetings. ...

After the scientists’ presentations, which were provided to The Times by Dr. Gunzerath, she would speak briefly to say that “it would be nice if we could get money from the industry,” but explain that funds would have to flow through the foundation.

On Sept. 30, 2013, Dr. Gunzerath sent an email headed “URGENT! Response needed ASAP!” to Dr. Mukamal, inviting him to Philadelphia to address the annual meeting of the Worldwide Brewing Alliance, to get the brewers’ “buy in” and “extra overall funding potential as well.”

Conclusions and requested actions

The conduct described by *The Times* appears to represent clear violations of the NIH policy prohibiting its employees from requesting or suggesting donations to the NIH of funds intended to support activities. For NIH officials to directly solicit donations from multiple alcoholic beverage manufacturers that have a direct interest in the outcome of the alcohol study undermines public trust in the integrity of the study and in the taxpayer-funded agency. It is well-recognized that research sponsored by industry consistently yields results favoring the interests of industry, despite researchers' beliefs that they are immune to such influence.

We therefore urge your office to immediately launch a formal investigation into the matters described in *The Times* article. The investigation should address the following important questions, among others:

- (1) Who else at NIAAA, besides Drs. Gunzerath and Warren, participated in or was aware of the campaign to obtain funding from alcohol beverage manufacturers for the alcohol study?
- (2) Was anyone within the NIH Office of the Director aware of this campaign?
- (3) The NIH policy on gifts administration references a "Gifts Transmittal Checklist" that must be completed by the NIH official authorized to accept the gift for gifts valued at over \$5,000.⁶ The first question in the checklist asks the following:

Will acceptance of the gift, to a reasonable person, compromise the integrity of or the appearance of the integrity of a Governmental program or of any official involved in that program? Note: For purposes of this analysis, you must consider the identity of the immediate donor of the gift to the agency, and may consider the identity of any entity that may have funded the donor. For example, if a gift comes to the agency from a private foundation, it is not necessary to determine if another entity supported the foundation's gift. However, if the agency knows that a donor's source of funds is from an entity or individual with whom the agency does not want to be affiliated, the agency, as a discretionary matter, may chose to decline the gift even though the donor poses no concerns.

- (a) Which NIAAA officials completed and signed the checklist, and were those individuals aware of the campaign by some NIAAA officials to solicit donations from multiple alcoholic beverage manufacturers to fund the alcohol study?
- (b) Acceptance of the donations from alcoholic beverage manufacturers would, to a reasonable person, compromise the integrity of, or the appearance of the integrity of, NIAAA's program related to the management and oversight of the alcohol study. On

⁶ National Institutes of Health. Gift Transmittal Checklist, NIH Policy Manual 1135 - GIFTS ADMINISTRATION Appendix 2 Issuing Office: OFM 443-3184. https://oma.od.nih.gov/Lists/DMSFormsList/Attachments/296/NIH-2914-1_04-10-17.pdf. Accessed March 18, 2018.

what basis did the individuals who completed and signed the checklist conclude otherwise?

- (c) Did any of the individuals who completed and signed the checklist consult with the Department of Health and Human Services' Office of the General Counsel?
- (4) Is this an isolated event, or have NIAAA officials previously solicited donations from the alcoholic beverage industry?
- (5) Should the NIH policy on gifts administration be amended to also prohibit individuals who are not NIH employees from soliciting donations from private, for-profit companies to fund grants or other awards for which those individuals may apply?

We hope you share our concern regarding this troubling matter, and we look forward to a favorable response to our urgent request.

Please contact us if you have any questions or need additional information.

Sincerely,



Michael A. Carome, M.D.
Director
Public Citizen's Health Research Group

Cc: The Honorable Alex Azar, U.S. Secretary of Health and Human Services
The Honorable Francis S. Collins, M.D., Ph.D., Director, National Institutes of Health