

April 11, 2018

The Honorable Alex M. Azar II  
Secretary  
U.S. Department of Health and Human Services  
200 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 Secretary Azar:

The undersigned consumer advocacy, science, and public health organizations respectfully urge you to request that the Department of Health and Human Services (HHS) Inspector General 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,<sup>1</sup> were directly involved in 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 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.

The NIH study in question — the “Moderate Alcohol and Cardiovascular Health Trial” — is a randomized trial comparing the effects of consuming one standard serving of alcohol daily with alcohol abstinence on the risk of cardiovascular disease, diabetes, and death among 7,800 adults age 50 or older worldwide.<sup>2</sup>

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.<sup>3</sup> According to the July 3, 2017, article, the lead researcher for the alcohol study 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*

---

<sup>1</sup> 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 April 9, 2018.

<sup>2</sup> 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](https://projectreporter.nih.gov/project_info_description.cfm?aid=9197811&icde=38618230). Accessed April 9, 2018.

<sup>3</sup> 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 April 9, 2018.

reported on March 17 that university-based scientists, including the alcohol study's lead researcher, and senior National Institute on Alcohol Abuse and Alcoholism (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."<sup>4</sup>

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."<sup>5</sup>

Moreover, according to *The Times*, the NIAAA signed an agreement with the Foundation for the National Institutes of Health (FNIH) for the alcohol study "that said, 'Under no circumstances shall [NIAAA] or its representatives communicate directly with any Donor in order to raise funds for the project or to disclose to any Donor any information' about 'the name and affiliation of the awardee' or 'details and information relevant to the award.'"<sup>6</sup>

According to *The Washington Post (The Post)*, on March 20, NIH Director Dr. Francis Collins announced at an unrelated briefing to reporters that he had assigned a group of advisers to examine whether any improprieties were committed with respect to the alcohol study.<sup>7</sup> In a letter to the editor published by *The Post* on March 30, NIH Principal Deputy Director Dr. Lawrence Tabak clarified that the Office of Management Assessment — a component of the NIH Office of the Director — will be conducting an internal investigation into "any process irregularities in the identification of funding sources" for the alcohol study.<sup>8</sup>

Such an internal NIH investigation into the allegations of serious misconduct by senior agency officials cannot be credible. Indeed, among the key unanswered questions is whether anyone within the NIH Office of the Director was aware of this campaign or played a significant role in the alleged solicitation of industry funds. There is ample reason to be concerned about the involvement of the NIH Office of the Director in this matter: According to *The Times*, the "request for collaboration" from NIAAA, which initiated the process of obtaining funding from

---

<sup>4</sup> Rabin RC. Federal agency courted alcohol industry to fund study on benefits of moderate drinking. March 17, 2018. *The New York Times*. <https://nyti.ms/2GAG6Xi>. Accessed April 9, 2018.

<sup>5</sup> National Institutes of Health, Office of Management. NIH Policy Manual: 1135 – Gifts Administration. October 5, 2011. <https://policymanual.nih.gov/1135#F20C5206>. Accessed April 9, 2018.

<sup>6</sup> Rabin RC. Federal agency courted alcohol industry to fund study on benefits of moderate drinking. March 17, 2018. *The New York Times*. <https://nyti.ms/2GAG6Xi>. Accessed April 9, 2018.

<sup>7</sup> Goldstein A. NIH will examine ethics of its study on the health effects of a daily glass of wine. April 3, 2018. *The Washington Post*. [https://www.washingtonpost.com/national/health-science/nih-will-examine-ethics-of-its-study-on-the-health-effects-of-a-daily-glass-of-wine/2018/03/20/db8f2806-2c78-11e8-b0b0-f706877db618\\_story.html?utm\\_term=.6c21902753e1](https://www.washingtonpost.com/national/health-science/nih-will-examine-ethics-of-its-study-on-the-health-effects-of-a-daily-glass-of-wine/2018/03/20/db8f2806-2c78-11e8-b0b0-f706877db618_story.html?utm_term=.6c21902753e1). Accessed April 9, 2018.

<sup>8</sup> Tabak LA. The NIH is taking its liquor investigation completely seriously. March 30, 2018. *The Washington Post*. [https://www.washingtonpost.com/opinions/the-nih-is-taking-its-liquor-investigation-completely-seriously/2018/03/29/99d7cd68-32cd-11e8-b6bd-0084a1666987\\_story.html?utm\\_term=.0f955b8801c1](https://www.washingtonpost.com/opinions/the-nih-is-taking-its-liquor-investigation-completely-seriously/2018/03/29/99d7cd68-32cd-11e8-b6bd-0084a1666987_story.html?utm_term=.0f955b8801c1). Accessed April 9, 2018.

April 11, 2018

Letter to Secretary of Health and Human Services

the alcohol industry through the FNIH, was submitted to a joint NIH-FNIH steering committee, which is based in the NIH Office of the Director.<sup>9</sup>

Thus, the NIH, especially in light of what is already known, has conflicts of interest that would preclude a thorough and unbiased internal investigation into this matter.

An independent investigation by the HHS Inspector General is necessary to ensure public confidence in the integrity of the investigation and that all culpable NIH officials are held accountable.

Thank you for your prompt attention to this important matter.

Sincerely,

Public Citizen  
Annie Appleseed Project  
Campaign for a Commercial-Free Childhood  
Center for Science in the Public Interest  
Franciscan Action Network  
Government Accountability Project  
Jacobs Institute of Women's Health  
National Center for Health Research  
National Women's Health Network  
PharmedOut, Georgetown University Medical Center  
Project On Government Oversight  
Union of Concerned Scientists  
US Alcohol Policy Alliance  
Woodymatters

cc: The Honorable Francis S. Collins, M.D., Ph.D., Director, National Institutes of Health

---

<sup>9</sup> Rabin RC. Federal agency courted alcohol industry to fund study on benefits of moderate drinking. March 17, 2018. *The New York Times*. <https://nyti.ms/2GAG6Xi>. Accessed April 9, 2018.