Dear Dr. McNutt:

We write today to urge the National Academies of Sciences, Engineering, and Medicine to strengthen its conflict-of-interest policy. Specifically, we request that the National Academies expand the conflict-of-interest eligibility requirements that individuals must submit to the National Academies and expand what type of information the National Academies must disclose to the public. We have included detailed recommendations in this letter.

The Project On Government Oversight (POGO) is a nonpartisan independent watchdog that investigates and exposes waste, corruption, abuse of power, and when the government fails to serve the public or silences those who report wrongdoing. We champion reforms to achieve a more effective, ethical, and accountable federal government that safeguards constitutional principles.

It’s past time for major ethics reform at the National Academies. That’s the conclusion of a recent POGO investigation and related reporting by Kaiser Health News, as well as others.1 Unfortunately, the National Academies has failed time and again to effectively mend its inadequate conflict-of-interest policy. While the National Academies implemented a new conflict-of-interest policy in September 2021, the new policy falls short of preventing individuals who have potentially problematic interests and relationships from serving on National Academies committees.2

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The Need for Ethics Reforms at the National Academies

The National Academies, which receives most of its funding from the government, is supposed to provide objective, expert advice to the government and the nation on questions of public policy. However, the value of its advice has been compromised by undisclosed conflicts of interest that raise questions about whether its experts are impartial enough to be credible.

A National Academies report on drug pricing issued in February 2021 is a case in point. At Congress’s request, and at a cost of $1.2 million to U.S. taxpayers, a National Academies committee studied allegations that drug companies were overcharging for intravenous drugs, including drugs for cancer, by selling the drugs in excessively large vials that forced patients to pay for extra drugs that would end up discarded. The committee recommended that Congress refrain from requiring drug makers to repay patients or the federal government for portions of unused drugs that go to waste — portions that add to the drug companies’ profits.

POGO’s investigation revealed that at least half the 14 people on the National Academies committee had current or past financial ties to drug companies that went unmentioned in the committee’s report. As POGO’s David Hilzenrath wrote, “committee members had served on drug company boards of directors, consulted for drug companies, and performed research funded by drug companies.” For example, “while he was serving on the committee, one of the seven, Dr. Anupam Jena, was also serving as an expert witness for Merck in a lawsuit” POGO reported. “At a rate of $875 per hour, he provided research and testimony as part of Merck’s defense.” The company was accused of illegally delaying competition that would drive down the price of a drug. Merck also produces overly large doses of drugs, the excess of which is discarded at cost to the patient.

In addition to the seven with undisclosed ties to the pharmaceutical industry, two committee members had what the National Academies described as “Unavoidable Conflicts of Interest.” The committee disclosed that it allowed those two to participate despite the conflicts of interest. Together, the two committee members with disclosed conflicts of interest and the seven with undisclosed ties made up a majority of the 14-member committee.

Further, as Kaiser Health News reported in August 2021, the National Academies itself has received millions of dollars from drug companies. In its report on alleged overcharges by drug makers, the National Academies neglected to provide the whole picture regarding its own financial ties to those drug companies.

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This isn’t the first time the National Academies appointed committee members with potential conflicts of interest. In a 2011 report, while opioid abuse was on the rise and drug makers were peddling prescription opioids, the National Academies’ Institute of Medicine made a case for expanding access to pain relief. According to reports, within three years of working on the opioids study, nine of the 19 members of that study’s panel had financial ties or relationships to manufacturers of narcotic painkillers.6

Issues to Address

POGO strongly believes that the National Academies should adopt more appropriate standards.

A sound ethics policy must address several questions, such as:

- Where is the National Academies getting its funding?
- What should committee members — and prospective committee members — disclose to the National Academies?
- What relationships or financial interests should disqualify people from serving on committees of the National Academies?
- What exceptions, if any, should be allowed?
- What should the National Academies disclose to the public — about itself and about the people it appoints to its committees?

Guiding Principles

POGO’s policy recommendations were informed by the following guiding principles.

A sound policy should be built on an appropriately broad definition of the relationships it covers. The National Academies’ definition is too narrow. In addition, it includes potentially gaping loopholes.

A sound policy should cover an appropriately wide time span. Past relationships can show patterns. They can also hint at the future. If someone has a history of taking money from the pharmaceutical industry, they might be interested in doing so again. They might have reason to curry favor with — and avoid crossing — once and future sponsors. They might identify disproportionately with, feel indebted to, or be biased toward their benefactors.

As the National Academies myopically sees it, only current relationships and financial interest above a certain amount are disqualifying. A sound policy would disqualify anyone who had any current financial interest, or a prior or current relationship with an entity that would be affected by the work of the National Academies.

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A sound policy should make the broadest possible disclosure to the public. It shouldn’t make readers of the National Academies’ reports search far and wide for information that could call into question the impartiality of the reports’ authors. It should rely on sunlight as the best disinfectant. It should let the public judge based on the facts — instead of asking the public to trust the National Academies’ demonstrably poor judgment regarding what information it should disclose to the public.

A sound policy should allow necessary exceptions — but require the National Academies to publicly justify them.

With all of that in mind, we recommend the reforms listed below.

**Recommended Reforms**

*POGO proposes the following recommendations to expand the conflict-of-interest eligibility requirements that individuals must submit to the National Academies.*

1. **Eliminate the minimum threshold for what constitutes a financial conflict.** The National Academies’ conflict-of-interest policy states, “Financial interests do not include any financial asset with a value of less than $15,000.” This means that, under the current policy, a person appointed to a committee studying pharmaceutical issues could hold up to $14,999.99 of stock in each of an unlimited number of pharmaceutical companies. The National Academies should eliminate exemptions for individuals who possess less than $15,000 in current relevant financial assets and instead disqualify an individual from serving on a committee if they own any such assets. An individual should also be disqualified if their spouse, domestic partner, or dependent child holds such a financial interest. Indeed, it is both sensible and common practice in conflict-of-interest policies to impute the financial interests held by close family members — a category that others may advocate further extending to include parents and adult children — to the individual being considered for appointment to various boards, panels, and committees. Limiting the scope of this prohibition to the financial interests of spouses, partners, and dependents is a reasonable compromise.

2. **Adopt a broader definition of potentially problematic interests and relationships.** Under the current policy, financial holdings considered disqualifying are those “that could be affected directly and predictably by the outcome of the committee’s work.” Likewise, committee members must disclose to the National Academies, and the National Academies must disclose in its reports, relationships “with an entity that has a financial interest that could be affected directly and predictably by the outcome of the committee’s work.”

That is an overly narrow view of what could pose a conflict of interest. First, it takes a one-sided view. It focuses on relationships and interests affected by a committee’s work but not interests and relationships that could affect a committee’s work. Second, by quibbling over how directly and predictably interests could be affected, the National Academies could allow a wide range of conflicts of interest.
In contrast, and as POGO’s investigation notes, “the International Committee of Medical Journal Editors (ICMJE) has historically taken a broader view of financial relationships warranting disclosure by authors.” It has defined them as involving third parties “whose interests may be affected by the content of the manuscript.” [Emphasis added.]

The National Academies should take a broader view, too. It should define potentially problematic interests and relationships as all that could influence a committee member, could influence public perceptions of a committee member’s objectivity, or could be affected by the committee’s work.

3. **Close potential loopholes involving research support.** In its current policy, the National Academies recognizes that research support can pose a conflict of interest. But the wording of its related policy could exempt a lot of problematic research support from the disclosure and disqualification requirements. The following wording needs to be changed to prevent conflicts of interest.

- The current policy exempts “research support that is awarded on the basis of merit without restrictions on the conduct of the research or the publication of the results.” Those exemptions could serve as massive loopholes. A doctor who depends on research support from a drug company is conflicted with respect to that company, whether or not the money comes with particular strings attached and whether or not the company claims the funding was awarded on the basis of merit. The National Academies should eliminate those exemptions.
- The policy also requires disclosure of “research support,” and it declares ongoing “research support for the individual” to be a potentially disqualifying conflict of interest. The definition of “research support” and “research support for the individual” should explicitly include payments to an institution or organization to support an individual’s research. That would be consistent with the approach the federal government takes through Open Payments, a public database created to disclose conflicts involving doctors and pharmaceutical companies. Further, it should be written broadly enough to require disclosure that, for example, a committee member works for the American Cancer Society, and the American Cancer Society gets millions of dollars from drug companies.

4. **Prohibit potentially problematic interests and relationships.** The National Academies should adopt a single, broader definition of what we’ll refer to as potentially problematic interests and relationships. This definition should close the loopholes we’ve identified. It should encompass all interests — including any current financial holdings — and relationships that could influence a committee member, could influence public perceptions of a committee member’s independence or objectivity, or could be affected by the committee’s work.

With respect to prior relationships, the current policy has two major weaknesses. First, the time frame for prior relationships that must be disclosed is only five years. This is too short and should be extended to 10 years. And second, prior relationships within that time frame must be disclosed, but are not disqualifying. This fails to acknowledge that prior relationships could be easily renewed. Any relationship that fits the description of potentially problematic interests and
relationships should be disqualifying if it was active at any time during the 10-year period before the committee begins its work, or if it arises while the individual is serving on the committee.

In addition, any current financial holding that fits the definition should disqualify an individual from serving on a National Academies committee.

The National Academies should be allowed to make exceptions if it determines they are necessary. When making exceptions, the National Academies should be required to publicly disclose each of the potentially problematic interests and relationships it has condoned and explain the reasons for the exception. The National Academies should be required to include all of that information in its committee reports. This exemption process would be the same as the existing exemption process by which individuals with “unavoidable conflicts” are permitted to serve on a National Academies committee, and these proposed exemptions must be likewise proactively disclosed so that members of the public can make their own determination about the impartiality of these experts.

5. **Require disclosure of who is funding “middlemen.”** Individuals who also do work for consulting firms, speakers bureaus, and the like should be required to disclose to the National Academies any and all potentially relevant parties who paid those intermediaries for their services, and the National Academies should be required to disclose that information to the public. Middlemen should not obscure conflicts of interest. For example, it wouldn’t be enough for a doctor to say on a disclosure form that he received fees from a consulting firm called Analysis Group if the doctor knew, or should reasonably know, that the work was actually funded by Merck and Genentech.

6. **Disqualify individuals who cannot disclose relevant relationships due to confidentiality concerns.** A National Academies committee member who served as an expert witness for Merck and Genentech told POGO that his work as an expert witness was confidential and that he was not able to speak about individual cases. The National Academies should not appoint individuals who are unable to disclose or speak about relevant relationships due to confidentiality agreements, because the National Academies should be able to — and must — disclose all relevant relationships to the public.

7. **Extend disclosure requirements to people who make presentations or submissions to committees.** The National Academies routinely holds meetings akin to public hearings to receive input from scholars and interested parties; however, those presenters are not required to disclose potential conflicts. For example, in its report on alleged drug overcharges, the National Academies extensively cited a presentation by a Harvard professor, but the report didn’t mention that the professor heads a Harvard program on healthcare policy funded partly by drug companies. The National Academies should require presenters to disclose potentially problematic interests and relationships in their presentations, and that information should be disclosed in National Academies’ reports.

8. **Eliminate the five-year limitation for disclosure of relevant publications and public statements.** The National Academies recognizes in its conflict-of-interest policy that past statements a committee member has made on an issue a committee is studying can be relevant.
They can show bias or preconceived notions. In addition, people may be motivated to stand by and defend positions they have staked out in the past. The National Academies requires disclosure of relevant statements and publications going back five years. That’s not far enough. Prospective committee members should disclose to the National Academies, and the National Academies should disclose to the public, all relevant prior statements.

The National Academies defines relevant statements and publications as those taking a position on an issue central to the committee’s work. That, too, is an overly narrow definition. All statements and publications related to the committee’s work should be disclosed. They should be disclosed when nominees are announced for public comment and in committee reports.

When possible, the National Academies should link to the past statements and publications. And, beyond providing links or citations, the National Academies should quote or paraphrase any positions committee members have taken on issues the committee is studying so the public doesn’t have to search for needles in haystacks.

*POGO proposes the following recommendations to expand what type of information the National Academies must disclose to the public.*

9. Require the National Academies to disclose its own funding. In its reports on matters of public policy, the National Academies should disclose all funding it has received from interested parties, including companies in relevant industries. The National Academies shouldn’t make readers of its committee reports look elsewhere for that information.

10. Require the National Academies to disclose potentially problematic interests and relationships for committee nominees at the time of nomination. Before appointing committee members, the National Academies publicly announces the slate of people it is proposing to appoint and allows 20 days for public comment on the nominees. However, such announcements typically include only cursory biographical information for each nominee. The announcements do not ordinarily mention potential conflicts of interest. At the outset of the public comment period, the National Academies should publicly disclose all potentially problematic interests and relationships, both current and those going back 10 years, of the people it is considering appointing to a committee. The National Academies should leave those disclosures online permanently instead of erasing them.

11. Require the National Academies to post its public access files. Under current law, the National Academies is required to maintain a public access file containing materials a committee reviewed in the course of its research. But, in the case of the committee on pharmaceutical policy, the public access file wasn’t actually public. POGO had to request and wait for copies of its contents. The National Academies should be required to post its public access files online for all to see without being asked.

**Conclusion**

We urge the National Academies to implement the recommendations outlined in this letter to strengthen its conflict-of-interest policy by expanding the conflict-of-interest eligibility
requirements that individuals must submit to the National Academies and expanding what type of information the National Academies must disclose to the public.

POGO’s investigation, as well as related reporting by Kaiser Health News, raises serious concerns regarding the impartiality of individuals sitting on National Academies committees. If the National Academies hopes to live up to its mission to provide independent, objective advice on science, engineering, and medicine, it must take all possible steps to ensure that individuals who have problematic interests and relationships are not permitted to serve on National Academies committees or otherwise influence the committees’ reporting.

We look forward to your response.

Sincerely,

Danielle Brian
Executive Director

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