



February 23, 2024

The Honorable Michael Regan  
Administrator  
United States Environmental Protection Agency  
1200 Pennsylvania Avenue NW  
Washington, DC 20460

**Re: Comments on Scientific Integrity Policy Draft (Docket # EPA-HQ-ORD-2023-0240)**

Dear Administrator Regan:

The American Lung Association appreciates the opportunity to comment on EPA's Scientific Integrity (SI) Policy Draft.<sup>1</sup> We strongly support EPA's continued efforts to ensure that sound science guides agency decision-making. The Lung Association laid out our general principles for the use of science in policymaking in a 2017 letter to U.S. Senate Committee on Homeland Security and Government Affairs, noting that sound science is the backbone of EPA's work. We highlighted as key tenets the need for federal agencies to base their decisions on peer-reviewed science; for scientific data to be free from political interference; for the public to have access to science-based information; for patient privacy to be protected; and for continued public funding of science.<sup>2</sup>

We offer the following feedback both on specifics in the draft policy and on EPA's approach to science in policymaking in general.

First, the Lung Association appreciates the language in the draft policy designed to prevent political or other inappropriate interference from influencing the agency's scientific work, including both the scientific activities themselves and the use of scientific information.<sup>3</sup> These provisions are the crux of EPA's scientific work and are therefore of the utmost importance. We read these provisions not just to apply to the agency's production of scientific information and products but also their use in policymaking.

We also appreciate the fact that EPA specifically highlights benefits-cost analyses as scientific products, which necessarily rely on scientific approaches for determining values.<sup>4</sup> For EPA actions where benefit-cost analysis does play a role in the policymaking process, we strongly support continued work to strengthen the scientific underpinnings of these analyses to better account for health harms not easily quantified.

We note EPA's language on requesting scientific data: "As permitted by law and necessary to ensure all regulatory decisions are fully informed and based on the best available science, EPA

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<sup>1</sup> <https://www.federalregister.gov/documents/2024/01/24/2024-01313/scientific-integrity-policy-draft-for-public-comment>

<sup>2</sup> Wimmer, Harold (March 8, 2017.) Letter to Chairman Lankford and Ranking Member Heitkamp. [letter-to-us-senate-1.pdf.pdf \(lung.org\)](#)

<sup>3</sup> EPA. (Jan 23, 2023). [Draft Scientific Integrity Policy](#), pages 10 and 16.

<sup>4</sup> EPA. (Jan 23, 2023). [Draft Scientific Integrity Policy](#), page 12.

should request scientific data from registrants, permittees or coregulators.”<sup>5</sup> The Lung Association supports this language, particularly to ensure that regulated entities provide accurate data on their emissions. With regard to underlying data in general, we note that patient confidentiality must remain a priority. In our 2017 scientific principles letter, we noted, “Researchers who evaluate the health impacts of air pollution...collect sensitive data from participants such as family medical history, geographic location, and personal medical history...personal information about specific individuals must remain confidential. Scientists and institutions build in systems to protect this information while still maintaining open access to the collective data. The studies themselves are peer-reviewed and published in transparent processes. However, no way exists to protect patient privacy if the raw patient data are released. The federal government must continue to protect patient privacy by ensuring that patients’ sensitive information is never made public – but that does not negate the use of such data to inform policy.”<sup>6</sup> We call on EPA to ensure that patient confidentiality is protected when research data is collected or shared.

Speaking more broadly, we note that EPA’s science-based policy instruments such as rules, guidance, or advisories are effective in realizing their full benefits only when they are implemented and enforced or used as intended.

The express purpose of the proposed Scientific Integrity Policy (SI Policy) is to “ensure the integrity of all aspects of activities... to be used to enhance and promote a culture of scientific integrity at EPA.” Towards this end, in this draft SI Policy, EPA proposes a “new federal definition of scientific integrity - *the adherence to professional practices, ethical behavior, and the principles of honesty and objectivity when conducting, managing, using the results of, and communicating about science and scientific activities*”.<sup>7</sup> The definition also notes: “*Inclusivity, transparency, and protection from inappropriate influence are hallmarks of scientific integrity.*”<sup>8</sup>

EPA needs to demonstrate to the public that its policies, such as this current draft which is expected to define its work, are not merely the result of meeting dictates of an executive order or the legal requirements of a statute, but that they do indeed guide the agency’s decision-making to truly protect public health and the environment. In this regard, several components of the proposed scientific integrity definition deserve a closer inspection, particularly the management, use and communication of the results of science and scientific activities. We offer the following comments on the broader issue of scientific integrity using EPA’s air pollution regulations as an example.

Among the authorities requiring EPA to adopt a scientific integrity policy is the 2021 Presidential Memorandum, whose stated goal is “(e)nsuring that science-based decisions are informed by

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<sup>5</sup> EPA. (Jan 23, 2023). [Draft Scientific Integrity Policy](#), page 19.

<sup>6</sup> Wimmer, Harold (March 8, 2017.) Letter to Chairman Lankford and Ranking Member Heitkamp. [letter-to-us-senate-1.pdf.pdf \(lung.org\)](#).

<sup>7</sup> EPA. (Jan 23, 2023). [Draft Scientific Integrity Policy](#), page 8.

<sup>8</sup> Based on the definition in [A Framework for Federal Scientific Integrity Policy and Practice - Guidance by the Scientific Integrity Framework Interagency Working Group of the National Science and Technology Council](#). Jan 2023, page 12.

the best available science.”<sup>9</sup> However, we point out that EPA’s recent decisions on the ozone and PM<sub>2.5</sub> National Ambient Air Quality Standards (NAAQS) run contrary to the above goal. EPA suspended the most recent ozone NAAQS reconsideration process and in doing so dismissed the findings and near-unanimous (17-1) recommendations of its independent scientific advisory panel (the Clean Air Scientific Advisory Committee, or CASAC) to strengthen the ozone NAAQS.<sup>10</sup> The ozone CASAC panel, which comprised a diverse group of expert scientists in the field, developed their policy recommendations in a systematic scientific process involving extensive, thoughtful deliberations of the latest scientific evidence. This process, which was conducted over a period of more than a year, also included public participation in which the Lung Association provided both oral<sup>11</sup> and written comments.<sup>12</sup> In abruptly canceling the ozone NAAQS reconsideration and starting the process anew,<sup>13</sup> EPA overruled science and scientific process, and ignored overwhelming public support for stronger ozone standards to protect public health and welfare. Further, in the recent final rule on the PM<sub>2.5</sub> NAAQS, EPA revised the annual standard from 12 to 9 mg/m<sup>3</sup> despite compelling scientific evidence supporting a lower limit.<sup>14</sup> The agency also chose not to revise the short-term standard, contrary to the recommendations of a majority of the PM CASAC panel<sup>15</sup> and contrary to the agency’s own regulatory impact analyses, which showed much greater public health benefits with stronger PM<sub>2.5</sub> NAAQS for both long-term and short-term exposures.<sup>16</sup>

In this draft SI Policy, EPA details seven specific areas to promote scientific integrity at the agency, among which is “2. Reviewing Science, Including the Use of Federal Advisory Committees”.<sup>17</sup> EPA must seriously consider and act on the recommendations of a robust and broadly represented CASAC. Strict adherence to scientific data and scientific analyses should underlie EPA’s rulemaking process in setting national air pollution standards. This is the core of

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<sup>9</sup> White House. (Jan 27, 2021). [Presidential Memorandum on Restoring Trust in Government Through Scientific Integrity and Evidence-Based Policy Making](#).

<sup>10</sup> Clean Air Scientific Advisory Committee (CASAC). (Jun 9, 2023). [CASAC Review of the EPA’s Policy Assessment \(PA\) for the Reconsideration of the Ozone National Ambient Air Quality Standards](#); EPA-CASAC-23-002.

<sup>11</sup> American Lung Association (05/23/2023). [Public comment during Chartered CASAC and CASAC Ozone Panel Meeting To discuss the 05-02-23 Draft CASAC Review of the EPA’s Policy Assessment \(PA\) for the Reconsideration of the Ozone National Ambient Air Quality Standards \(External Review Draft Version 2\)](#)

<sup>12</sup> ALA *et al.* (Apr 14, 2023). [Comment on the Draft Policy Assessment for the Reconsideration of the Ozone National Ambient Air Quality Standards - EPA-HQ-OAR-2018-0279-0609](#); Tracking Number: Igg-r3g7-ljex

<sup>13</sup> EPA. (Aug 21, 2023). [EPA Initiates New Review of the Ozone National Ambient Air Quality Standards to Reflect the Latest Science](#) – news release.

<sup>14</sup> Chen, J. *et al.* (Dec, 2023). [Long-Term Exposure to Low-Level PM<sub>2.5</sub> and Mortality: Investigation of Heterogeneity by Harmonizing Analyses in Large Cohort Studies in Canada, United States, and Europe](#). *Environ Health Perspect.* 131(12):127003. “increased mortality risk associated with PM<sub>2.5</sub> exposure down to the lowest observed level of 3.7 µg/m<sup>3</sup> with a steep slope observed from 7 to 9 µg/m<sup>3</sup>”

<sup>15</sup> CASAC. (Mar 18, 2022). [CASAC Review of the EPA’s Policy Assessment for the Reconsideration of the National Ambient Air Quality Standards for Particulate Matter](#) (External Review Draft); EPA-CASAC-22-002

<sup>16</sup> EPA. (Dec, 2022). [Regulatory Impact Analysis for the Proposed Reconsideration of the National Ambient Air Quality Standards for Particulate Matter PM<sub>2.5</sub> NAAQS](#); EPA-452/P-22-001

<sup>17</sup> EPA. (Jan 23, 2023). [Draft Scientific Integrity Policy](#), page 13

scientific integrity. EPA's commitment to scientific integrity must match its application and realization; it must, in the agency's own words, "ensure EPA decisions are based on or informed by science that has completed independent peer review and has been finalized."<sup>18</sup>

On the matter of inclusivity and transparency within its scientific integrity paradigm, EPA could improve upon its current practices. The agency's work to conduct "meaningful public engagement"<sup>19</sup> could be improved by: making public-facing agency action documents easier to navigate and analyze in order to provide comment within a short timeframe; presenting all relevant documents at the same time in one place; and providing working links to all appropriate resources in a rulemaking. EPA notes in the draft SI policy that "Standard Operating Procedures (SOPs) and processes that determine the development or review of scientific products should be adhered to and applied consistently, including EPA's quality directives and standards, and all appropriate scientific guidelines."<sup>20</sup> EPA needs to adopt a SOP with a set of uniform standards on document preparation and presentation to the public, as current resources vary widely among the different units of EPA.

We also suggest creating a dedicated webpage for the Agency's own scientific and technical publications as well as research that it sponsors, whether or not they are peer-reviewed. EPA must ensure that the agency's regulatory actions and interactions build public confidence in EPA and help people understand and trust science that informs public health protection requirements.

Further on the issue of transparency, the SI Policy asks EPA staff to "Ensure that comments received on draft scientific documents during any interagency review are made in writing and made public."<sup>21</sup> Finally, on communicating scientific data, the SI Policy says: "Agency experts should communicate on matters associated with their work or area(s) of expertise in an accurate and clearly understandable manner... As resources allow, offer communication and media training to Agency employees to expand their ability to clearly communicate their scientific findings and understand their role in communicating."<sup>22</sup> We ask EPA to consider making staff scientists and policy drafters available in community and townhall meetings on proposed rulemakings to help the public understand the science underlying the proposals, in addition to providing plain language summaries of the proposals soliciting public comment.

The draft SI Policy "outlines the Agency's expectations for developing and communicating scientific information to the public, to the scientific community, to Congress, and to the news media by further providing for and protecting the EPA's longstanding commitment to the timely dissemination of its scientific information —uncompromised by political interference or inappropriate influence."<sup>23</sup> EPA must take care to avoid the presence or appearance of inappropriate influence of and agency capture by political or business interests whose activities contribute to environmental threats that EPA is charged to protect the public from.

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<sup>18</sup> EPA. (Jan 23, 2023). [Draft Scientific Integrity Policy](#), page 14

<sup>19</sup> American Lung Association *et al.* (Jan 16, 2024). Comment on [Achieving Health and Environmental Protection Through EPA's Meaningful Involvement Policy, EPA-HQ-OEJECR-2023-0326-0027](#); Tracking Number: lrh-5lwl-02y9

<sup>20</sup> EPA. (Jan 23, 2023). [Draft Scientific Integrity Policy](#), page 11

<sup>21</sup> EPA. (Jan 23, 2023). [Draft Scientific Integrity Policy](#), page 15

<sup>22</sup> EPA. (Jan 23, 2023). [Draft Scientific Integrity Policy](#), pages 16 and 17

<sup>23</sup> EPA. (Jan 23, 2023). [Draft Scientific Integrity Policy](#), page 16

In closing, the agency's effective use of "the results of science and scientific activities" in all its actions (rules, guidances, advisories, etc.) that affect public health and environment is the true measure of the agency's commitment to scientific integrity. Such a demonstration free of any other influence is essential to ensure the realization of the proposed SI elements in EPA's updated SI Policy.

Thank you.