

May XX, 2025

Robert F. Kennedy Jr.
Secretary
Department of Health and Human Services
200 Independence Avenue, SW
Washington, DC 20201

Dear Secretary Kennedy:

We, the undersigned medical, scientific, and patient and consumer advocacy organizations, write to share our concern with plans by the United States Department of Health and Human Services (HHS) to examine supposed links between autism spectrum disorder (ASD) and vaccines. Despite announcing these intentions, there has been no public information about how the study will be conducted, who will be involved, what data they will examine, and if any public meetings or comments will be part of the process.

While we believe that an examination of vaccines and ASD is not a good use of taxpayer dollars, we do want to express our support for the scientific process and principles that should guide any rigorous scientific inquiry, including those undertaken by HHS. As clinicians, scientists, patients and concerned stakeholders, we believe in upholding the highest standards of the scientific process so that we have the best data and knowledge base to guide the care we provide for our patients to improve their health and quality of life.

In general, the basic principles that guide scientists and research are respect for the integrity of knowledge, collegiality, honesty, objectivity, and openness. These principles form the fundamental elements of the scientific method, such as formulating a hypothesis, designing an experiment to test the hypothesis, and collecting and interpreting data. The National Academies of Science have also stated that “individual scientists have a fundamental responsibility to ensure that their results are reproducible, that their research is reported thoroughly enough so that results are reproducible, and that significant errors are corrected when they are recognized.”ⁱ

If systematic reviews are being done, the techniques outlined in *The Cochrane Handbook for Systematic Reviews of Interventions* are considered by most experts to be a fair and robust way to weigh evidence. This handbook includes guidance on the standard methods applicable to every review (planning a review, searching and selecting studies, data collection, risk of bias assessment, statistical analysis, GRADE and interpreting results), as well as more specialized topics (non-randomized studies, adverse effects, complex interventions, equity, economics, patient-reported outcomes, individual patient data, prospective meta-analysis, and qualitative research). It is imperative that any systematic review follow the guidelines laid out in the *Cochrane Handbook*.

While performing an analysis of the existing data, another important tenet is that the people conducting the research need to have the required expertise. Well performed analyses rely on people who have experience with both the scientific process and knowledge of the topic being studied. Physicians and scientists who have dedicated their careers to immunization and have garnered significant expertise that is not easily replaceable will naturally have bodies of work on immunization and that experience and acquired knowledge is why they are considered experts. There is no reason why a person with such a background cannot conduct research that follows proper scientific and ethical guidelines. On the contrary, researchers who have had numerous studies retracted or have published research that was not able to be replicated should not be included in such a high-profile study.

Once the initial analysis is completed, a peer review process is essential. This process is a critical component of scientific research, as it is used to validate data and findings before they are released to the public. Peer review serves as a quality control mechanism, ensuring that only robust, accurate and meaningful scientific work is published. As Mohty and Melo (2025) point out, the effectiveness of peer review rests on at least three foundational principles: (i) disclosure of conflicts of interest, (ii) scientific expertise, and (iii) constructive feedback.ⁱⁱ To maintain transparency, peer reviewers must disclose any conflicts of interest they may have, including financial, professional, or personal biases that could affect their impartiality. Disclosing these conflicts protects the integrity of the peer review process and maintains trust among authors, editors, and readers. As mentioned previously, those conducting research and those providing peer review must have expertise and knowledge on the topic being researched to have the ability to provide any useful assessment of the data and research findings. Finally, peer reviewers must be able to provide constructive feedback and be allowed to provide their opinions on the research findings without reservations, pointing out what they see as the strength and weaknesses of the research findings. Following these three principles allows peer review to point to gaps in knowledge that could lead to focused recommendations for future study.

At its roots, all scientific inquiry requires good faith and a bona fide search for answers. It is important that a study is designed and directed by investigators who operate in a state of scientific uncertainty, not pre-judging the outcome of the study. As such, investigators should have the qualifications and expertise to carry out the study, and strive to prevent bias from affecting the design, conduct or reporting of the results of the study. Investigators need to disclose all conflicts of interest, vigorously guard against scientific misconduct and maintain complete records and comply with all regulatory, legal, and ethical standards for research.

While sound scientific research should never be discouraged, we also know that the question of whether vaccines are linked to ASD has already been exhaustively studied. A robust review of the literature, from studies all around the world conducted by independent researchers and published in peer-reviewed journals, shows no correlation between ASD and vaccines. With the overwhelming scientific evidence showing no link between vaccines and autism, it would be a better use of public resources to expand access to federally-funded educational, medical and family support services that assist people with ASD – programs that are currently not reaching enough people – than spending more federal dollars on this thoroughly studied topic.

As HHS moves forward with any studies concerning autism and any association between vaccines and other environmental toxins, we urge HHS to conduct the study with transparency, utilizing a group of researchers with the needed expertise and knowledge, and following all accepted scientific and ethical principles.

Sincerely,

ⁱ National Academy of Sciences (US), National Academy of Engineering (US) and Institute of Medicine (US) Panel on Scientific Responsibility and the Conduct of Research. Responsible Science: Ensuring the Integrity of the Research Process: Volume I. Washington (DC): National Academies Press (US); 1992. 2, Scientific Principles and Research Practices. Available from: <https://www.ncbi.nlm.nih.gov/books/NBK234526/>

ⁱⁱ Mohty M, Melo JV. How to perform a high-quality peer review. Clin Hematol Int. 2025 Feb 3;7(1):10-13. doi: 10.46989/001c.128601. PMID: 39911608; PMCID: PMC11797007.