Chronology of emails from *Toxicology Reports* and Elsevier regarding my published paper on Vaccines and SIDS

December 18, 2025

Dr. Neil Z. Miller
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Vaccines and sudden infant death: An analysis of the VAERS database 1990–2019 and review of the medical literature. *Toxicology Reports*, Volume 8, 2021, Pages 1324-1335.
https://doi.org/10.1016/j.toxrep.2021.06.020

Dear Dr. Miller,

Concerns from multiple parties have been raised about the publication of the article listed above, for which you are the corresponding author. As the editor of the journal, I must take seriously any allegation raised that if true would violate the journal's policies set out in our ethical statements and instructions to the author.

The concerns focus on potential research errors and misleading statements about vaccine efficacy. The allegations are listed on PubPeer and on another science blog:

https://pubpeer.com/publications/C02A9C1F937150E44015877641F4F9

https://threadreaderapp.com/thread/1455831798160764929.html

Please provide me a prompt and full response within 30 days, which I will also discuss with the parties raising these concerns.

Depending on the nature of your response, I should also inform you that I may consider it necessary to inform and involve the research institution at which the underlying research took place and the funding agency that supported the research.

Please note that if we do not have an adequate and timely response, we may be forced to conclude that the allegations are truthful.

I look forward to hearing from you soon.

Yours sincerely,

Lawrence H. Lash, Ph.D.
Editor, *Toxicology and Applied Pharmacology*

Editor, *Toxicology Reports*
Associate Editor, *Journal of Pharmacology and Experimental Therapeutics*
Associate Editor, *Pharmacology & Therapeutics*
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Dear Dr. Lash,

Thank you for your email. I acknowledge your concerns regarding my paper and intend to address them carefully. Many of the allegations you reference appear to have arisen in 2021, shortly after the paper's publication. At that time, I addressed most of these issues in a letter to Dr. Aristidis Tsatsakis.

I will review the allegations outlined in the links you provided in detail and will submit a formal response within 30 days.

Thank you for bringing these matters to my attention.

Sincerely,
Neil Miller

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Dear Dr. Miller:

Thank you for your response.

Sincerely,

Lawrence H. Lash, Ph.D.
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Editor-in-Chief, *Toxicology and Applied Pharmacology*

Editor-in-Chief, *Toxicology Reports*
Associate Editor, *The Journal of Pharmacology and Experimental Therapeutics*
Associate Editor, *Pharmacology & Therapeutics*

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Dear Dr. Lash,

Thank you for the opportunity to respond to the allegations concerning my article, *"Vaccines and Sudden Infant Death,"* published in *Toxicology Reports* [Volume 8 (2021), pages 1324-1335]. My response is provided below. Please let me know if you require any additional information or clarification.

Sincerely,

Neil Miller

1. A critic objected to the fact that the open-access publication fee for my paper was paid by Dr. Renee Tocco Hunter and the Foundation for Pediatric Health. Neither Dr. Hunter nor the Foundation had any prior knowledge of, involvement in, or influence over the study design, data analysis, interpretation, or manuscript preparation. The manuscript was fully completed before Dr. Hunter offered to cover the publication fee. This funding was disclosed and is consistent with standard open-access publishing practices.

2. A critic challenged my statement that "throughout the 1980s, sudden infant deaths continued to skyrocket," citing American SIDS Institute data showing a modest decline in SIDS mortality between 1980 and 1989. While it is accurate that rates declined slightly during that decade, SIDS mortality peaked around 1980 and remained historically elevated relative to the rarity of so-called "crib deaths" prior to the 1960s. By the late 1980s, SIDS had become the second leading cause of infant death and the leading cause of post-neonatal mortality in the United States, surpassing nearly all causes that predominated in earlier decades.

In addition, SIDS accounted for approximately 35% of sudden unexpected infant deaths (SUID) from 1969 to 1976, rising steadily to 83% by 1994 [BMC Pediatrics 20, 377 (2020)]. While alternative phrasing—such as "remained historically elevated"—could have been used, instead of "continued to skyrocket," this semantic distinction does not alter the historical context, analyses, or conclusions of the paper.

3. A critic asserted that "the actual number of infants classified as SIDS have fallen all over the world in the last 40 years." As discussed extensively in my paper, this claim does not take into account the well documented phenomenon of diagnostic substitution. Declines in SIDS diagnoses have frequently coincided with increases in deaths attributed to alternative categories.

For example, following the American Academy of Pediatrics' "Back to Sleep" campaign, the post-neonatal SIDS rate declined at an average annual rate of 8.6% from 1992 to 2001, while mortality attributed to "suffocation in bed" (ICD-9 E913.0) *increased* at an average annual rate of 11.2% during the same period [9]. Additional increases were observed in categories such as "suffocation other," "unknown and unspecified causes," and "intent unknown" [9]. Similar diagnostic substitution has been documented internationally, including in Australia, where reductions in SIDS were offset by increases in deaths attributed to asphyxia [14-16]. These patterns are acknowledged limitations in cause-of-death surveillance.

4. A critic objected to my statement that, while there are numerous official ICD categories for infant death, there is no explicit ICD category for fatal vaccine reactions. As explained in the paper, ICD revisions beginning in 1979 removed "prophylactic inoculation and vaccination" as a cause-of-death category, despite its inclusion in earlier ICD versions. Although vaccine-related injuries and deaths continue to be recognized through the federal Vaccine Injury Compensation Program (VICP), the absence of an ICD category for vaccines necessitates classification under alternative diagnoses.

Evidence from VICP proceedings indicates that some deaths initially certified as SIDS were later adjudicated as vaccine-related injuries. Over time, comparable deaths appear increasingly represented under alternative ICD categories, consistent with documented changes in diagnostic practice. The CDC itself has acknowledged that "some deaths that would have been classified as SIDS before 1999" are now classified differently, noting that inconsistent cause-of-death determination hampers surveillance and prevention efforts (CDC SUIDI Reporting Form User Manual, 2008).

5. A critic cited Moro et al. (2015) to argue that vaccination is not causally associated with SIDS. This CDC-authored study is cited and accurately summarized in my paper. Among 1,244 child death reports submitted to VAERS with documentation, the most common cause of death was SIDS, predominantly among infants aged 2-4 months. Of the 1,165 infant reports, 86.2% involved multiple vaccines administered prior to death, with a median onset interval of two days. SIDS reports were most common among children who had received DTaP, hepatitis B, inactivated polio, Hib, and pneumococcal vaccines simultaneously prior to death. The authors interpreted these findings as not indicating a concerning pattern, a conclusion that differs from alternative interpretations discussed in the present review.

The critic is correct that some studies have failed to identify a causal association between vaccination and SIDS. This point is explicitly acknowledged at the outset of my review, supported by three citations. However, the existence of null findings does not invalidate the considerable body of literature reporting positive associations, which my review evaluates in detail. My paper does not assert causality but examines patterns and inconsistencies warranting further investigation.

6. I was criticized for using a 60-day post-vaccination window in my analysis of VAERS timing data. A critic asked, "Why 60 days? Shouldn't events be spread evenly across 30 years?"

This criticism reflects a misunderstanding of both how VAERS is used and what a post-vaccination risk window is intended to test. A risk window is a standard epidemiologic tool for assessing *temporal association,* not lifetime incidence. If an adverse event is causally related to vaccination, it must occur after exposure and within a biologically plausible time frame. Events occurring years or decades later cannot reasonably be attributed to a single immunologic exposure. Thus, the relevant question is not "Why not 30 years?" but rather: *What time window is biologically plausible for vaccine-triggered events?*

Causal signals are expected to show:

a) Temporal clustering shortly after vaccination, and

b) Diminishing clustering as time from exposure increases.

No credible safety analysis expects vaccine-related events to be distributed evenly across an individual's lifetime.

The 60-day interval is methodologically justified for several reasons:

- Many biologically plausible vaccine-related adverse events occur within days to weeks; a 60-day window serves as a conservative outer boundary.
- Prior VAERS analyses commonly use 30-, 42-, or 60-day intervals, supporting methodological consistency.
- Shorter windows risk unstable estimates due to small numbers, while longer windows dilute potential signals with unrelated background mortality.

Taken together, the 60-day interval represents a pragmatic balance between sensitivity and specificity in detecting temporal safety signals.

7. A critic said, "Looking at all infant deaths reported to VAERS vs the SIDS deaths from Miller's 'analysis': Isn't he actually showing a fewer deaths from SIDS than you'd expect due to this reporting bias (due to association with the vaccine)? Eg Day 1 13% vs 17% of all?"

a) This criticism is not methodologically sound and is based on a misinterpretation of both VAERS data and the purpose of the analysis. The critic assumes that the proportion of deaths occurring on Day 1 should be the same for SIDS and for all infant deaths reported to VAERS (13% vs. 17%). There is no epidemiologic basis for this assumption. SIDS is a specific diagnostic

subset of infant mortality, not a fixed fraction of all deaths, and there is no reason to expect identical post-vaccination timing distributions.

b) VAERS is a passive reporting system and does not provide population-based incidence rates. Percentages within VAERS cannot be interpreted as expected or baseline proportions. As a result, a difference between 13% and 17% does not indicate underreporting, over-reporting, or bias in either direction.

c) The analysis is designed to assess whether reported deaths cluster shortly after vaccination. Both the SIDS and all-mortality analyses show pronounced early post-vaccination clustering (Days 1-7). The presence of similar temporal patterns across diagnostic categories supports the robustness of the timing signal, regardless of differences in proportions.

d) Diagnostic uncertainty and evolving cause-of-death practices plausibly lead some sudden infant deaths to be reported as nonspecific "death" rather than explicitly as "sudden death" or "sudden infant death"—SIDS. Such misclassification would lower the proportion of deaths labeled as SIDS, and shift those cases into the all-mortality category, while preserving the same early post-vaccination timing pattern. This provides a straightforward explanation for a lower Day-1 percentage for SIDS without undermining the findings.

The 13% versus 17% comparison does not demonstrate a reporting bias and does not weaken the analysis. It conflates proportional representation with temporal association and relies on assumptions that are unsupported in passive surveillance data. The core finding—early post-vaccination temporal clustering—remains unchanged and is observed across both SIDS-specific and all-mortality analyses.

8. A critic noted that my paper did not explicitly state that a small proportion of VAERS reports originated outside the United States. VAERS primarily monitors U.S.-licensed vaccines but accepts foreign reports submitted by U.S. manufacturers. Nonetheless, the CDC itself characterizes VAERS as a *national* system. My analyses included all mortality reports from 1990-2019 to assess onset intervals. Sensitivity analyses excluding foreign reports yield substantively similar results, and the principal findings remain unchanged.

Conclusion

The objections raised by critics do not meet established criteria for retraction under COPE or ICMJE guidelines. No evidence has been presented of data fabrication, falsification, plagiarism, undisclosed conflicts of interest, or fundamental methodological error. The criticisms largely reflect interpretive disagreement, semantic preference, or acknowledged limitations of passive surveillance and cause-of-death classification systems. My paper transparently discloses all pertinent limitations, does not claim definitive causation, and places

its findings within the broader scientific literature. None of the objections invalidate the data, analyses, or conclusions, nor do they justify retraction or correction under accepted editorial standards.

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Dear Dr. Miller:

Thank you for your thorough response. I will share this with my Publisher and let you know if anything further is needed.

Best wishes,

Lawrence H. Lash, Ph.D.
Editor, *Toxicology and Applied Pharmacology*
Editor, *Toxicology Reports*
Associate Editor, *Journal of Pharmacology and Experimental Therapeutics*
Associate Editor, *Pharmacology & Therapeutics*
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''Vaccines and sudden infant death: An analysis of the VAERS database 1990–2019 and review of the medical literature''

Toxicology Reports, Volume 8, 2021, Pages 1324-1335

https://doi.org/10.1016/j.toxrep.2021.06.020

Dear Author,

The Editor-in-Chief of *Toxicology Reports* has reviewed the concerns raised regarding the above article, as well as the author response, and has concluded that they affect the article's integrity and findings, as well as they constitute potentially unsafe research for medical practice. As per the journal's policy (https://www.elsevier.com/about/policies-and-standards/article-withdrawal#7-article-removal), this

warrants removal rather than a correction. Removals preserve the integrity of the scholarly record and are not meant to apportion blame or punish authors.

You should be aware that removal means that your paper will be removed entirely online at ScienceDirect. Please find below, for your reference, a copy of the removal notice to be used, subject to final approval by Elsevier's Retraction & Removal Committee:

This article has been removed: please see Elsevier Policy on Article Withdrawal (https://www.elsevier.com/about/policies-and-standards/article-withdrawal).

This article has been removed at the request of the Editor-in-Chief.

Following post-publication concerns raised by readers regarding potential research errors and methodological flaws in this article, the journal initiated an investigation and contacted the author for clarification.

The Editor-in-Chief has determined that the author's response does not satisfactorily address the concerns raised about this article. In addition, given that this research could be used in medical practice, the Editor-in-Chief has determined that the article should be removed.

Apologies are offered to the readers of the journal.

Reasonable requests for amendments to these texts may be considered but any changes will be made only with the approval of the Editor and the Retraction & Removal Committee.

Please reply to this email within **7 days**.

Yours sincerely,

Francesco Papi, Ph.D.

Publishing Ethics Expert

Research Integrity & Publishing Ethics Centre of Expertise

ELSEVIER | Amsterdam, The Netherlands

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We have received your complaint, a copy of which is included below for your records. We will be in touch with you shortly.

The journal and publisher

Name of journal and publisher that the issue relates to

Toxicology Reports, Elsevier

Is the journal a member of COPE?

Yes

Have both the journal and publisher evaluated the issue?

Yes

Journal and/or publisher evaluation

My article/study has been published for nearly 5 years. Recently, the Editor-in-Chief claimed the paper is being completely removed due to it being "potentially unsafe research for medical practice." They also claim without providing evidence that my paper contains methodological flaws that affect its integrity and findings. It is methodologically sound.

The issue

Summary of the issue

Toxicology Reports is planning to remove my paper. They say it is "potentially unsafe research for medical practice" and has methodological flaws affecting the article's integrity and findings. None of this is true.

My article does not provide clinical guidance, recommend changes to vaccination schedules, advise clinicians or patients to alter medical behavior, or propose policy actions. It explicitly characterizes its findings as non-causal, observational, and hypothesis-generating, and repeatedly calls for further investigation.

Elsevier's Article Withdrawal policy specifies that removal is reserved for exceptional circumstances, such as: legal violations or defamation; court orders; or articles that pose a serious and immediate health risk if acted upon. Controversial findings and public health sensitivity are not listed grounds for removal.

If the journal believes that specific passages could be misconstrued, clarification or contextualization would be a proportionate response. Removal is a measure of last resort and is not an appropriate response to interpretive disagreement.

The article fully and transparently discloses its methodology and limitations. These limitations do not constitute research misconduct, methodological deception, data misrepresentation, nor do they invalidate the observations reported.

All of the data in my paper is documented in the scientific literature, and my use of VAERS to detect safety signals is done appropriately. The analysis is explicitly descriptive and intended for signal detection, consistent with internationally accepted pharmacovigilance practice. The manuscript clearly explains the limitations of passive surveillance data, including underreporting, lack of denominator data, and the inability to infer causation.

The article reports statistically significant temporal clustering of reported events within defined post-vaccination windows. This is a recognized and appropriate method for identifying safety signals. The manuscript does not claim causation.

Potential reporting bias is discussed at length. Analysis of onset intervals is a standard method for assessing whether reports are temporally clustered or diffusely distributed.

These are well-known limitations of the data source, not methodological errors. They are disclosed clearly and do not compromise the integrity of the work.

My article's integrity and findings are not compromised. Under COPE and Elsevier's guidance, compromise of the scholarly record typically involves fabrication of data, plagiarism, undisclosed conflicts of interest, or misrepresentation of methods. None of those conditions apply.

If the journal believes that additional context is warranted, established and proportionate editorial options include: a corrigendum or clarification; an editorial note or commentary by independent experts. These mechanisms preserve

transparency and scientific debate while maintaining the integrity of the scholarly record. Complete removal is an exceptional remedy and is not justified by the issues raised in this case.

The editor allowed me to respond to critic's allegations, but claimed my responses were not satisfactory. I assert they were. Tomorrow, I will email my concerns to the editor. I can send my email to COPE as well.

The article does not meet Elsevier's or COPE's criteria for removal. Therefore, I'm requesting that the proposed removal be withdrawn (by the editor) and that any remaining concerns be addressed through proportionate editorial mechanisms consistent with publication-ethics standards.

Competing interests

None

Is there any legal action ongoing in relation to this issue, at either the journal, publisher, or institution level

No

Is there, or has there been, any involvement by the author and/or submitter's institution, or any other relevant regulatory body in this issue?

No

Outcome and supporting information

Please state what outcome you are seeking from this process, keeping in mind that COPE is not a regulatory body

A would like COPE to help facilitate a fair outcome. I request that the proposed removal be withdrawn (by the editor) and that any remaining concerns be addressed through proportionate editorial mechanisms consistent with publication-ethics standards.

Upload supporting information

main-author-response-to-editorial-concerns.doc (44.5 KB)
response-to-critics-tox-rep-2026-miller.doc (42.5 KB)

I confirm that I understand COPE's remit and role, and that I accept the principles above.

Yes

Submit

Your email

neilzmiller@gmail.com

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Author Response to Editorial Concerns

Re: Proposed Article Removal – "Vaccines and Sudden Infant Death"
Toxicology Reports, Volume 8 (2021), pp. 1324–1335

Dear Dr. Lash, Dr. Papi, and Members of the Retraction & Removal Committee,

I am writing to formally appeal the editorial determination that my published article, *"Vaccines and Sudden Infant Death,"* may warrant removal on the grounds of alleged methodological flaws and "potentially unsafe research for medical practice." This appeal is submitted pursuant to Elsevier's Editorial Decision Appeals Policy and relevant COPE guidance.

After reviewing the Editor-in-Chief's determination, I respectfully submit that **article removal is not supported by Elsevier policy, COPE guidance, or established publication-ethics standards.** The concerns raised reflect interpretive disagreement rather than defects that compromise the article's integrity, invalidate its findings, or meet the threshold for removal.

This response addresses the two stated grounds for removal:

1. Alleged risk to medical practice; and
2. Alleged methodological flaws affecting the article's integrity and findings.

1. Allegation of "Potentially Unsafe for Medical Practice"

The article does **not** provide clinical guidance, recommend changes to vaccination schedules, advise clinicians or patients to alter medical behavior, or propose policy actions. It explicitly characterizes its findings as **non-causal, observational, and hypothesis-generating**, and repeatedly calls for further investigation.

Observational safety-signal analyses—particularly those using passive surveillance data—are routinely published in medical and toxicological journals, including by regulatory agencies, for the express purpose of identifying patterns that may warrant further study. Publication of such analyses does not constitute medical advice or unsafe practice.

Elsevier's Article Withdrawal policy specifies that **removal is reserved for exceptional circumstances**, such as:

- Legal violations or defamation;
- Court orders; or
- Articles that pose **a serious and immediate health risk if acted upon.**

The present article does not meet these criteria. Controversial findings, disputed interpretations, or public-health sensitivity are **not listed grounds for removal** under Elsevier policy or COPE guidance. Where concern exists regarding interpretation or context, COPE and Elsevier identify alternative remedies—such as corrections, expressions of concern, or editorial commentary—that preserve the scholarly record while informing readers.

If the journal believes that specific passages could be misconstrued, clarification or contextualization would be a proportionate response. **Removal is a measure of last resort** and is not an appropriate response to interpretive disagreement.

2. Alleged Methodological Flaws

The article fully and transparently discloses its methodology and limitations. These limitations do not constitute research misconduct, methodological deception, data misrepresentation, nor do they invalidate the observations reported.

Use of VAERS:
The analysis is explicitly descriptive and intended for signal detection, consistent with internationally accepted pharmacovigilance practice. The manuscript clearly explains the limitations of passive surveillance data, including underreporting, lack of denominator data, and the inability to infer causation.

Temporal Clustering:
The article reports statistically significant temporal clustering of reported events within defined post-vaccination windows. This is a recognized and appropriate method for identifying safety signals. The manuscript does **not** claim causation.

Absence of Incidence Rates:
The lack of denominator data is an inherent characteristic of VAERS and is explicitly acknowledged. No incidence rates or causal estimates are presented.

Reporting Bias:
Potential reporting bias is discussed at length. Analysis of onset intervals is a standard method for assessing whether reports are temporally clustered or diffusely distributed.

These are well-known limitations of the data source, not methodological errors. They are disclosed clearly and do not compromise the integrity of the work.

3. Article Integrity, Findings, and COPE Standards

The Editor-in-Chief's letter states that the concerns raised "affect the article's integrity and findings."

Under COPE and Elsevier guidance, compromise of the scholarly record typically involves issues such as:

- Fabrication or falsification of data;
- Plagiarism or duplicate publication;
- Undisclosed conflicts of interest that materially mislead readers; or
- Fundamental misrepresentation of methods or data sources.

None of these apply here.

With respect to the article's findings, the paper reports:

1. Temporal clustering of reported infant deaths and SIDS following vaccination;
2. Statistical significance of that clustering under stated assumptions;
3. Identification of a potential safety signal warranting further study; and
4. Explicit non-claims of causation.

Post-publication criticisms do not negate the reported timing distributions or the existence of clustering. Rather, they challenge interpretation and public-health implications, not the accuracy of the reported observations. COPE guidance is explicit that **disputed conclusions or controversial interpretations do not constitute grounds for removal.**

4. Proportionate Editorial Responses

If the journal believes that additional context is warranted, established and proportionate editorial options include:

- A corrigendum or clarification;
- An editorial note or commentary by independent experts;
- An expression of concern during further evaluation; or
- Publication of scholarly responses presenting alternative interpretations.

These mechanisms preserve transparency and scientific debate while maintaining the integrity of the scholarly record. **Complete removal is an exceptional remedy** and is not justified by the issues raised in this case.

5. Request for Specific Justification

Given the seriousness of article removal, I respectfully request clarification on the following points:

1. Which specific statements or analyses are deemed “potentially unsafe for medical practice?”
2. By what mechanism do they pose a direct and immediate risk, rather than constituting scientific discussion?
3. Which specific Elsevier or COPE criteria for removal are being invoked?
4. Which specific methodological flaws are alleged to affect the article’s integrity and findings?

Absent identifiable factual inaccuracies, data-integrity issues, or ethical violations, removal on the basis of perceived implications rather than demonstrable defects is inconsistent with Elsevier policy.

6. Response to Allegations Raised by a Critic

Eight allegations were raised by a single critic. I previously addressed them in detail at the Editor-in-Chief’s request and respond again here in summary:

1. Objection to the individual who paid the open-access publication fee. This is not relevant to the scientific content and requires **no correction**.
2. Objection to the phrase "continued to skyrocket.” **This can be revised to “remained historically elevated,”** or similar language.
3. Assertion that SIDS rates have fallen. Apparent changes in SIDS rates largely reflect diagnostic reclassification rather than substantial changes in infant mortality. These limitations are well known and acknowledged in the scientific literature and cause-of-death surveillance. In addition, CDC-based data and analyses confirm this. **No correction is necessary.**
4. Objection to the statement that there is no explicit ICD category for fatal vaccine reactions. This statement is accurate. Since 1979, infant death certifiers have not had a dedicated ICD category for vaccine-caused infant deaths. **No correction is required.**
5. Citation of Moro et al. to assert that vaccines do not cause SIDS. Moro et al. was cited to allow readers to independently assess its conclusions. **No correction is required.**
6. Objection to the use of a 60-day post-vaccination window. The 60-day window is methodologically justified and consistent with signal-detection practice. **No correction is required.**

7. Objection to findings regarding Day 1 clustering (13% SIDS versus 17% all infant deaths). There is no methodological basis for expecting identical post-vaccination timing distributions across categories. **No correction is required.**
8. Objection to the omission of foreign reports in VAERS. **Table 1 can be corrected to include the percentage of foreign demographic data.**

Thus, two minor corrections are potentially warranted—one grammatical and one reflecting a limited oversight. These limited issues do not justify removal of the article.

Conclusion

The article does not meet Elsevier's or COPE's criteria for removal. Its limitations are transparently disclosed, the methodology is appropriate for its stated purpose, the findings are accurately reported, and the article does not provide clinical guidance or medical instruction. Disagreement over interpretation or public-health implications does not justify erasure of a peer-reviewed contribution from the scientific record.

I therefore request that the proposed removal be withdrawn and that any remaining concerns be addressed through proportionate editorial mechanisms consistent with publication-ethics standards. **Note:** A formal complaint was filed with COPE.

Sincerely,
Neil Miller

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Dear Mr. Miller:

We have carefully considered the concerns raised about the manuscript and do not believe that it warrants any further consideration. The decision to remove the publication was based on careful review and consultation with experts. We stand by the decision that the recommendations and conclusions made in your paper pose potential risks to public health and should not be allowed to stand.

Sincerely,

Lawrence H. Lash, Ph.D.
Editor, *Toxicology and Applied Pharmacology*
Editor, *Toxicology Reports*
Associate Editor, *Journal of Pharmacology and Experimental Therapeutics*
Associate Editor, *Pharmacology & Therapeutics*
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Dear Dr Miller,

I am writing to you regarding your submission to COPE regarding concerns about the notification for retraction you received for your article in the journal *Toxicology Reports* titled 'Vaccines and sudden infant death: An analysis of the VAERS database 1990–2019 and review of the medical literature'. I acknowledge receipt of your submission, I have raised it to the attention of a member of the Facilitation and Integrity subcommittee for their input.

Per the framework of the Facilitation and Integrity subcommittee, any review by COPE is focused on the procedural aspects of the journal's follow up and we will not complete evaluations of the scholarly content of the article. Per the expectations of the Facilitation and Integrity process, we expect that there will be no public commentary about this matter (for example, on social media, blogging sites, Pubpeer or other) while the issue is active with COPE.

With best wishes,

Iratxe
Iratxe Puebla
Facilitation and Integrity Officer
Committee on Publication Ethics (COPE)
www.publicationethics.org
Registered charity No 1123023
Registered in England and Wales, Company No 6389120
Registered office: COPE, New Kings Court, Tollgate, Chandler's Ford, Eastleigh, Hampshire, SO53 3LG, UK

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Dear Dr Miller,

I am writing regarding the concerns that you raised to COPE about the notification you received from the journal *Toxicology Reports* about the removal of your publication titled 'Vaccines and sudden infant death: An analysis of the VAERS database 1990–2019 and review of the medical literature'. A member of the COPE Facilitation and Integrity subcommittee has looked at your submission and has advised that it does not fall within the remit of what the subcommittee can review.

COPE's role is to provide advice for member editors and journals and to promote a better understanding of publication ethics. While COPE considers concerns raised in relation to member journals, our review is limited to the process followed by the journal. Editorial decisions on whether to publish an article or not, or the decision to publish a correction to the record for a published article, are beyond our remit.

In this case, we understand that your concerns relate to the fact that the journal has notified an intention to remove the article, and that you feel that the criticisms raised about your work and which constitute the grounds for this retraction and/or removal are not valid, as you view the concerns as relating to methodological choices and limitations of the approach applied. Based on the information you provided, the journal gave the concerns they received about your study due consideration and pursued follow up on the concerns. The journal contacted you for comments and pursued a post-publication review that considered the article, the concerns received, and your response. Upon this review, the editor reached a determination that the conclusions are not supported and that this undermines the standing of the publication.

With regard to the intention to remove the article, we interpret this as meaning that the journal will retract the article and remove the article content. The COPE Retraction guidelines note that article removals should only be undertaken in exceptional situations, but do note this is an appropriate step in rare cases where the article *'could have a serious health risk to the general public or the environment'*. We understand that the editor reached a determination that this circumstance applies in this instance.

These steps are aligned to COPE expectations for concerns raised on articles after publication. The determination on whether the concerns are such that they undermine the standing of the article falls within the remit of editorial decision making, and editorial decisions fall beyond the scope of what COPE can review. As a result, COPE cannot pursue this matter.

Thank you for raising this matter to the attention of COPE.

With best wishes,

Iratxe
Iratxe Puebla
Facilitation and Integrity Officer
Committee on Publication Ethics (COPE)
www.publicationethics.org

Registered charity No 1123023
Registered in England and Wales, Company No 6389120
Registered office: COPE, New Kings Court, Tollgate, Chandler's Ford, Eastleigh, Hampshire, SO53 3LG, UK

On behalf of
Facilitation and Integrity subcommittee

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Re: Proposed Article Removal – "Vaccines and Sudden Infant Death"

Dear Dr. Lash, Dr. Papi, and Members of the Retraction & Removal Committee,

I have been informed by the Committee on Publication Ethics (COPE) that editorial decisions fall outside the scope of matters it reviews, as COPE's role is limited to providing guidance to member editors and journals.

In light of this, I respectfully request that if the decision is made to remove my article on the grounds of alleged "potential risks to public health" or to "medical practice," the rationale provided accurately reflect the basis for that decision.

Specifically, I ask that the *removal not be justified by claims of methodological flaws affecting the integrity or findings of the article,* as I have consistently addressed and refuted such assertions. Independent review, including analysis assisted by artificial intelligence tools, has likewise not identified methodological defects that would compromise the article's validity.

Clarity and accuracy in the stated grounds for removal are essential to maintaining transparency and fairness in the editorial process.

Sincerely,

Neil Miller

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Dear Dr. Miller,

Thank you for your email. Your statement regarding COPE's role is unclear to me. As I noted in our prior correspondence, the decision to remove the article was made by the Editor, with the support of Elsevier's Research Integrity and Publishing Ethics team, in accordance with Elsevier policies and COPE guidelines. For reference, the relevant Elsevier policies can be found here: https://www.elsevier.com/about/policies-and-standards/article-withdrawal.

Your assertion that AI tools and independent experts have not identified major issues is not aligned with the journal's position; the journal has reached conclusions that are markedly different on this matter.

Best regards,

Francesco Papi, Ph.D.

Publishing Ethics Expert

Research Integrity & Publishing Ethics Centre of Expertise

ELSEVIER | Amsterdam, The Netherlands

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Dear Dr. Papi,

The proposed removal notice states that my article contains **"research errors and methodological flaws."** I respectfully submit that this characterization is inaccurate. Independent expert review, as well as analysis using AI-based evaluation tools, has not identified substantiated methodological deficiencies of the kind described.

If the Editor's concern is that the article could "be used in medical practice," that is a separate and distinct issue. Such a concern relates to potential public harm—which I dispute—rather than to the integrity of the research methodology itself. I therefore respectfully request that the notice accurately reflect this distinction, rather than attribute unsupported claims of research or methodological error to the article.

To date, I have not been provided with specific, documented evidence identifying the alleged flaws that would warrant the complete removal of my article. In the absence of clearly articulated and substantiated errors, I am concerned that the current wording may unjustly harm my professional reputation.

Best regards,

Neil Miller

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Dear Dr. Miller,

Thank you for your reply. The journal's investigation has identified methodological flaws and research errors, including misinterpretation and biased selection and analysis of data. Because the data and findings could be harmful if applied in clinical practice, the Editor has determined that removal of the article is warranted. This decision is final, and we will not engage further on this matter.

Best regards,

Francesco Papi, Ph.D.

Publishing Ethics Expert

Research Integrity & Publishing Ethics Centre of Expertise

ELSEVIER | Amsterdam, The Netherlands

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Dear Francesco:

Thank you for taking care of this. Your reply is perfect.

Best wishes,

Larry

Lawrence H. Lash, Ph.D.

Professor

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End of correspondence