May 4, 2026

Dr. Dan Ollendorf
Dr. David Rind
Ms. Madeline Booth

Dear Drs. Ollendorf and Rind and Ms. Booth,

Thank you for the opportunity to review ICER's April 7, 2026 Draft Evidence Report, *Vaccines for Covid-19: Effectiveness and Value*. We were encouraged to see that the report acknowledges the limitations of the current evidence base relative to real-world effectiveness data given time in market for NUVAXOVID™ (COVID-19 Vaccine, Adjuvanted), while recognizing differences in reactogenicity compared to other COVID-19 vaccines on the market. After reviewing the draft, we offer the following recommendations for your consideration.

1. Incorporate product-specific reactogenicity where supporting data exists

Trial and available real-world evidence data (to date) supports inclusion of differentiation by reactogenicity event type (local vs systemic) and severity (grades 1 to 4) to account for differences in severity that may impact duration, utility decrements, and downstream healthcare utilization impact of post-vaccination side effects. We recognize the careful calculations relative to costings of reactogenicity that have been included in this report, however, this is currently only assessing burden from one of the 11 solicited reactogenicity events (i.e., fever). It includes a small QALY decrement corresponding to about one day of poor health. We recommend that this work should be expanded further to consider all of the non-duplicated solicited reactogenicity events, including both local and systemic, in order to have a more complete assessment relative to this important differentiator of reactogenicity.

We also request that you include data that became available shortly after the April 7 ICER Draft Evidence Report was posted, from the recently completed double-blind, randomized, head-to-head study of NUVAXOVID compared with mNEXSPIKE. This study provides comparative tolerability and patient reported outcome data from the Phase IV Oregon Health and Sciences University COMPARE Study, NCT07051031. This study demonstrated statistically significant lower reactogenicity (including lower severity and shorter duration) for NUVAXOVID compared with mNEXSPIKE across all pre-specified endpoints (ESCMID-2026, April 18, 2026). Beyond clinical measures, this study also found that recipients of NUVAXOVID reported less disruption to daily activities.

2. Update pricing assumptions

The model should be updated to reflect the pricing noted on the current CDC Price List. Current CDC Vaccine Price List | VFC Program | CDC as of March 2, 2026.

Specifically, that file currently lists CDC contract per dose prices of $91.75 for COMIRNATY, $79.42 for Spikevax, and $63.291 for NUVAXOVID, and private-sector per dose list pricing of

$169.84 for COMIRNATY, $141.80 for Spikevax, and $168.35 for NUVAXOVID (CDC). Updating these figures in the body of the report will distinguish the CDC contract price from the Private Sector Price and allow appropriate use of consistent, sector-specific pricing across all vaccines.

3. We request removal of Sanofi funding statement for ICER Policy Summit

Given that the ICER Policy Summit program is not relevant to the clinical or economic analysis in this draft report, we request removal of the following statement: "The only life science company relevant to this review who participates in this program is Sanofi."

If it is not possible for this sentence to be removed, then we request the following revisions (**in bold**), to provide clarification on this.

"The funding for this report comes from non-profit foundations, with the largest single funder being the Arnold Ventures. No funding for this work comes from health insurers, pharmacy benefit managers (PBMs), or life science companies. ICER receives approximately 22% of its overall revenue from these health industry organizations to run a separate Policy Summit program **(i.e., not relevant to the clinical or economic analysis in this draft report**), with funding approximately equally split between insurers/PBMs and life science companies. The only life science company relevant to this review who participates in this **ICER Policy Summit** program is Sanofi. A complete list of funders and more information on ICER's support, is available on the funding page of the ICER website."

Thank you again for the opportunity to provide input. We would welcome a brief clinical discussion with your team to review these points in more detail, if this may be helpful.

Sincerely,

Ayman

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May 4, 2026

RE: Public Comment on ICER's Draft Evidence Report

To Whom it May Concern:

The Alliance for Aging Research ("Alliance") appreciates the opportunity to comment on the Institute for Clinical and Economic Review's (ICER's) *Draft Evidence Report* for Vaccines for COVID-19. As the leading nonprofit organization dedicated to changing the narrative to achieve healthy aging and equitable access to care, we are encouraged by several aspects of this report. We are particularly encouraged by the recognition that COVID-19 vaccination has significant societal and payor value, and that vaccines deliver their greatest clinical and economic value to adults 65 and older. Our comments focus on ensuring the final report fully reflects the value of vaccination for older adults and people of all ages, uses frameworks that don't systematically underreport that value, and communicates its findings in a way that supports rather than undermines the public health case for vaccination.

The Public Health Landscape and Case for Vaccines

In our comments on the Draft Scoping Document, the Alliance noted that today's environment surrounding public confidence in vaccines is being strained by increasingly inconsistent, ambiguous, and unfoundedly negative messaging from policymakers and public health institutions. In the Draft Evidence Report, ICER notes the divergence between current ACIP recommendations and those of professional societies and state public health departments, but offers no explanation for it. Given the evolving governance context surrounding federal advisory processes and the resulting public confusion, additional explanation would materially improve the report's clarity and usefulness for decision-makers.

There is also a factual error here. The report states that FDA label indications are aligned with CDC recommendations, but this is incorrect on two counts: the prior CDC recommendation supported shared clinical decision-making for all individuals six months and older, and the schedule CDC was recently required to revert to by court order is likewise not aligned with current label language. This factual error is worth correcting because it understates how unsettled the current guidance landscape actually is. This report must function to clarify this confusion, not muddy it further.

The draft report assigns evidence ratings of "C+" or "C++" (Comparable or Incremental benefit) to COVID-19 vaccination for most adults under 65 without comorbidities. While ICER notes that these ratings are not policy recommendations, that distinction will not trickle down to the

consumer level in the current media environment. A national report from a prominent health economics organization concluding that COVID-19 vaccines provide only "comparable" benefit for most working-age adults will be excerpted, amplified, and weaponized by bad faith actors in ways that are entirely predictable. For this reason, we urge ICER to include explicit, prominent language in the final report emphasizing that the FDA's approvals of COVID-19 vaccines as safe and effective reflect extensive clinical evaluation, years of real-world data, and continuous post-market surveillance. ICER must prominently say that this report's subgroup-specific findings do not undermine that record. This statement should also note the case for herd immunity and the younger population's responsibility to protect the older adults they encounter by getting vaccinated. The scientific case for vaccination, particularly for older adults and high-risk individuals, is strong. The final report should leave no ambiguity about that.

QALY and evLY Are the Wrong Tools for Evaluating a Preventive Intervention

In our December 2025 scoping comments, the Alliance warned that QALY- and evLY-based frameworks are fundamentally flawed tools for evaluating preventive interventions because they measure improvements after a person is already sick rather than the value of prevention of the condition. The draft evidence report confirms this concern in practice. Although QALYs can include prevention in principle, they systematically understate the value of vaccines because the metric emphasizes realized quality-of-life changes rather than avoided catastrophic events, population risk reduction, and long-term public health benefit.

The incremental QALY and evLY gains in the base case are vanishingly small because the real clinical story about vaccines is hospitalizations prevented, deaths averted, and long-term sequelae (i.e. conditions like long COVID) avoided. ICER's own sensitivity analysis confirms this: the dominant drivers of cost-effectiveness are vaccine effectiveness against hospitalization and the probability of hospitalization following a COVID-19 exposure. The quality-of-life improvement the QALY is designed to capture is essentially a rounding error in this analysis. Yet cost per QALY and cost per evLY remain the headline metrics, while cost per hospitalization avoided is presented as a secondary output.

This is precisely the distortion the Alliance has documented. When a model's entire value case depends on variables the primary metrics barely capture, the metrics are wrong for the intervention. For adults 85 and older, the report shows 3.36 fewer hospitalizations per 1,000 vaccinated persons. This is a clinically and economically compelling finding on its own terms. It should not have to be filtered through a framework designed for curative treatments to be considered meaningful.

We renew our request that ICER:

- Elevate cost per hospitalization avoided, deaths averted, and long COVID cases prevented as co-equal primary outcomes in the final report, not supplementary metrics.

- Provide explicit transparency about how QALY- and evLY-driven conclusions systematically understate the value of preventive interventions, particularly for older adults.
- Integrate productivity impacts, caregiver burden, and broader societal benefits into the base case formulation rather than isolating them in a scenario analysis.

ICER's Decision to Omit the HIDI

The HIDI was created precisely because standard cost-effectiveness analysis fails to capture the health equity context, as noted in sections above for older adults and individuals with disabilities, and additionally for other subgroups like people of color or individuals with lower income. Data on this topic is inherently complex, variable, and resistant to clean quantification. That is the defining reason that equity analysis must be done in the first place, and to use it as a reason not to complete the HIDI analysis in this report is confounding.

What makes this particularly hard to accept is that COVID-19 is not a disease for which subgroup-stratified data is scarce. There are hundreds of published studies documenting how COVID-19 burden varies by race, ethnicity, income, geography, and disability status. As ICER notes, the data is variable, but the HIDI was designed specifically to address these limitations. Declining to apply the measure here with this volume of available evidence does not make sense.

If it cannot be applied to a disease with a large, well-documented, racial and socioeconomic specific burden because the data is imperfect, it is difficult to imagine the conditions under which ICER would apply the HIDI. This leads us to the question that the Alliance has asked since the measure was debuted: what is the point of the HIDI? A measure that is invoked selectively and excused when the data is inconvenient does nothing to improve the inequities that are inherent to HTA analysis.

Technical Concerns Regarding Model Inputs and Assumptions

We note specific concerns about aspects of the underlying assumptions within the model. Individually, each represents a defensible if debatable methodological choice. Taken together, however, they reflect a pattern of conservative data sourcing that systematically understates the value of COVID-19 vaccination.

1. Long COVID

The report models long COVID sequelae, and we credit ICER for extending the analysis beyond the initially proposed one year to capture long-term effects. However, the implementation contains two significant problems that work in the same direction, and both cause the model to understate the benefit of vaccination.

First, the model relies on a 2020 study as a key input for long COVID rates and characteristics, despite the substantial body of more recent evidence that has emerged as clinical understanding

of long COVID has progressed. Using the earliest available data, when newer and more representative data exist is a conservative choice that must be corrected or at least acknowledged.

Second, and more consequentially, the model does not appear to reflect the well-documented finding that vaccination reduces the probability of developing long COVID, not just the probability of developing severe acute disease. By treating the long COVID pathway as equivalent between vaccinated and unvaccinated populations causes the model to undercount one of vaccination's most important benefits.

We urge ICER to incorporate updated long COVID incidence data and to ensure the model reflects the vaccine's protective effect against post-acute sequelae in the final report.

2. Adverse Event Cost Assumptions

The model assumes that adverse events from vaccination, including routine side effects like injection site pain, fatigue, and headache require a doctor's visit. This assumption is not consistent with clinical guidelines or real-world practice. Most post-vaccination reactions are manageable at home and do not end up needing a provider visit. Modeling them as if they are not manageable at home artificially worsens the cost-effectiveness ratio.

The downstream effect is visible in the scenario analyses: the societal perspective scenario produces a worse cost-effectiveness ratio than the payer perspective, which is counterintuitive and highly uncommon among HTA analyses. **Vaccination against a contagious disease should look better, not worse, when societal costs are considered. The fact that the societal perspective performs poorly is a signal that the adverse event and productivity loss assumptions are asymmetrically capturing costs without adequately capturing benefits.**

3. Infection Rate

The base case assumes a 5% annual symptomatic COVID-19 infection rate, drawn from CDC surveillance data. The Alliance is concerned that this figure underestimates actual burden of infection. Symptomatic infection surveillance systematically undercounts total infections because asymptomatic and mildly symptomatic cases are less likely to be tested and reported. **If the true infection rate is higher than modeled, the absolute benefit of vaccination is correspondingly larger than the analysis shows. We urge ICER to address this limitation explicitly.**

4. Productivity Loss Assumptions

The model accounts for the time cost of vaccination as a productivity loss in the societal perspective scenario. This is a reasonable consideration in principle, but the application does not reflect how COVID-19 vaccination occurs in the United States. Most people receiving a COVID-19 vaccine do so in the context of an existing healthcare encounter: a routine pharmacy visit, a flu shot appointment, a scheduled primary care visit, grocery shopping, or a medication pickup.

In these settings, the marginal time cost of adding a COVID-19 vaccine is minimal and should not be modeled as a full standalone productivity loss.

Furthermore, standard cost-effectiveness practice for medication assessments does not count the time spent traveling to a pharmacy and picking up a prescription as a productivity loss. **Applying a stricter standard to vaccination than to other interventions introduces an inconsistency that disadvantages vaccines in the analysis. We urge ICER to revise the productivity loss assumptions to reflect co-administration norms in the U.S. and to ensure the societal scenario is internally consistent in how it treats costs and benefits.**

Access Recommendation

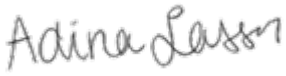
We urge ICER to include explicit language in the final report stating that realizing the cost-effectiveness value identified in this analysis requires zero cost-sharing for the patient, and that any policy analysis relying on this report should account for access barriers that may prevent vaccination rates from achieving the levels assumed in the model.

Conclusion

COVID-19 vaccines have consistently demonstrated significant effectiveness, with the greatest protection against death and severe disease concentrated in older adults. We are encouraged by this report finding the same. We hope that ICER will reverse some of the more conservative assumptions and decisions surrounding data-sets.

We appreciate the opportunity to comment and look forward to continued engagement as this process moves forward.

Sincerely,



Sue Peschin
President & CEO

Adina Lasser
Director of Public Policy & Government Relations

APhA
American Pharmacists Association

May 4, 2026

[Submitted via email to publiccomments@icer.org]

Institute for Clinical and Economic Review (ICER)
14 Beacon Street, Suite 800
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Re: Comments for An Assessment of COVID-19 Vaccines Draft Evidence Report

Dear ICER Review Team:

The American Pharmacists Association (APhA) is the largest association in the United States, advancing the entire pharmacy profession and representing our nation's over 340,000 pharmacists, 30,000 student pharmacists, and more than 400,000 pharmacy technicians. APhA has been at the forefront of pharmacist-provided vaccination services for over thirty years and appreciates the opportunity to provide comments for the ICER COVID-19 draft evidence report.

APhA recognizes ICER's efforts to rigorously examine the available evidence to assess the comparative clinical effectiveness and cost-effectiveness of COVID-19 vaccines and preventive strategies for the 2026–2027 respiratory season. This work is particularly important for informing evidence-based decision-making for COVID-19 recommendations and policies among healthcare professionals, including pharmacists, who play an essential role in vaccine delivery, patient education, and access to immunization services across diverse care settings.

We offer the following feedback to highlight the importance of socioeconomic considerations in health equity analysis, the report's potential influence on policy and recommendations, and the need to ensure the executive summary contains pertinent information applicable for policy makers.

Health equity is appropriately introduced in Section 2.2 of the Draft Evidence Report; however, the associations described warrant further clarification and consideration. While the relationship between race and vaccination uptake remains inconclusive in the available evidence, the report identifies a clearer, more consistent correlation between lower income and lower vaccination rates.[1] This is of particular importance as most patients, particularly in rural and underserved areas, first turn to pharmacists for health questions or concerns. Often, pharmacists are the only health

[1] Dinero RE, Monti WB, Kmush BL. Regional political climate's moderating role in the association between political conservatism and COVID-19 vaccine hesitancy in the United States. PLoS One. 2026;21(2):e0342063. doi:10.1371/journal.pone.0342063

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care providers for miles.[2] These findings underscore the importance of examining underserved populations, such as those with limited access to healthcare and those with low socioeconomic status, as distinct and meaningful drivers of inequitable access and outcomes. We encourage ICER to more explicitly address these associations and reflect them in the questions for deliberation and voting, including by adding a specific question under special ethical priorities, such as these edits to question 3:

> *Apart from issues related to disease severity, unmet need, and race/ethnicity, are there particular ethical obligations* ***to consider socioeconomic factors, including income, that may influence access to vaccination and health outcomes?***

Secondly, the Draft Evidence Report's conclusions appear incomplete and do not fully account for all supporting documentation included in the report. While the report emphasizes that COVID-19 vaccination meets commonly accepted cost-effectiveness thresholds by reducing hospitalizations among adults aged 50 years and older, the findings related to pediatric and maternal populations are missing. Table ES.3 assigns an evidence rating of B+ to vaccination of children aged 6–12 months and to vaccination during pregnancy.

In addition, Table ES.1 indicates that estimated annual COVID-19–associated hospitalization rates for the 2024–2025 season among children aged 6–12 months were higher than those observed across individuals aged 50–64 years. These findings suggest meaningful clinical benefit for these populations that is not sufficiently reflected in the report's conclusions. Although this Draft Evidence Report does not constitute policy or recommendations, its conclusions will inform future policy and coverage decisions. Accordingly, it is important for the report to clearly acknowledge that vaccination during pregnancy and vaccination of children aged 6–12 months are expected to provide important health benefits and reduce the risk of hospitalization during the 2026–2027 respiratory season.

Lastly, the Executive Summary does not fully reflect the breadth of findings in the Draft Evidence Report, despite being the primary focus for many readers, including policymakers, clinicians, and other stakeholders. While the report acknowledges the exclusion of certain early clinical and real-world studies evaluating COVID-19 vaccine effectiveness, it does not sufficiently justify these exclusions or assess how their omission may influence the overall conclusions. Early evidence played a critical role in shaping vaccination policy, clinical practice, and public trust, and should therefore be addressed more fully, or its exclusion more transparently explained.

Additionally, the Executive Summary does not include definitions or explanations of evidence ratings; key details on how evidence grades are defined and applied appear later in the report. This limits readers' ability to interpret ICER's conclusions appropriately. Several methodological decisions, particularly study inclusion criteria, exclusion thresholds, and evidentiary standards, are also not clearly explained, further challenging the assessment of the robustness and applicability of the findings. Given that COVID-19 vaccination decisions rely on a comprehensive understanding of effectiveness, public health impact, and real-world implementation, these omissions and limitations may unintentionally understate the full value of vaccination in clinical practice. We encourage ICER to revise the Executive Summary to more fully reflect the report's findings and clearly communicate its analytic approach, thereby reducing the risk of misinterpretation and better informing future policy, coverage, and clinical decision-making.

[2] Lucas A. Berenbrok, et al., *Access to Community Pharmacies: A Nationwide Geographic Information Systems Cross-Sectional Analysis*, 62 Journal of the American Pharmacists Association 1816 (2022). Available at: https://www.japha.org/action/showPdf?pii=S1544-3191%2822%2900233-3.

Thank you for the opportunity to provide comments regarding the draft evidence report. We look forward to an ongoing collaboration.

Most sincerely,

Brigid K. Groves

Brigid K. Groves, PharmD, MS
Vice President, Professional Affairs