



September 19, 2026

Cynthia Goss

Deputy Assistant Secretary for Planning and Evaluation (Health Policy), Performing the
Delegable Duties of the Assistant Secretary for Planning and Evaluation
Office of the Secretary
Department of Health and Human Services
Hubert H. Humphrey Building
200 Independence Avenue SW
Washington, DC 20201

Re: Docket Number: HHS–OS–2026–0332: Request for Information: Categories Used in
Federal Vaccine Recommendations and the Role of Shared Clinical Decision-Making

Dear Deputy Assistant Secretary Goss,

The National Association of Manufacturers (NAM) appreciates the opportunity to submit comments to the Department of Health and Human Services (HHS) in response to its Request for Information (RFI) on “Categories Used in Federal Vaccine Recommendations and the Role of Shared Clinical Decision-Making.”

The NAM is the largest manufacturing association in the United States, representing manufacturers of every size, in every industrial sector, and in all 50 states. Small and medium-sized manufacturers make up the vast majority of manufacturing businesses in the United States and employ approximately 40% of the nearly 13 million manufacturing workers. Manufacturing contributes \$3 trillion annually to the U.S. economy and accounts for nearly 52% of all private-sector research in the nation.¹

Manufacturers in America are both providers of health coverage and producers of the technologies that make modern medicine possible. It is the strong position of the NAM and manufacturers across America that—to support the stability and productivity of the manufacturing workforce and preserve U.S. global competitiveness—a predictable policy agenda is essential to support scientifically informed healthcare decisions and encourage sustained investment in research and development. Vaccines, and a consistent and science-based policy regime governing vaccines, are essential to maintaining the health and productivity of the manufacturing workforce, which underpins the U.S. economy. As we saw during the COVID pandemic, vaccines—which were developed and produced by manufacturers and spurred by the Trump administration—allowed manufacturers across the nation to remain open and produce economic utility for the American people during crisis.

Biopharmaceutical manufacturers discover and bring to market innovative new medicines to prevent, treat and cure challenging infectious diseases. While efficacious vaccines have been successfully developed for 34 unique infectious pathogens, the industry continues to pursue

¹ National Association of Manufacturers. (n.d.). *Facts about manufacturing expanded*. Retrieved September 8, 2026, from <https://nam.org/mfgdata/facts-about-manufacturing-expanded/>

solutions for 31 pathogens that have remained elusive, such as HIV, tuberculosis, streptococcus, Zika, Lyme disease, C. difficile, and Hepatitis C.² Because clinical success rates remain limited,³ regulatory predictability and clarity around evidence generation, regulatory processes, and vaccine recommendations are critical to incentivize developers to invest in future vaccines. As of 2023, there were 249 novel clinical programs for infectious disease vaccines, and the average cost to bring a single candidate to market costs manufacturers approximately \$2.3B.⁴

Beyond scientific discovery, long-term investments in next-generation vaccines and medical countermeasures rely heavily on a stable, predictable policy and regulatory landscape. Vaccine development is an inherently high-risk endeavor characterized by extended research timelines, substantial and sustained capital expenditures, and high clinical attrition rates. In particular, clinical success rates for vaccines were at 11% likelihood of approval during the decade from 2013 to 2022.⁵ When regulatory standards shift unpredictably or federal recommendations become ambiguous, it introduces market friction that can stall or deter critical private-sector R&D. The average investment by a biopharmaceutical company to bring a medicine to market is approximately \$2.6 billion (in 2013 dollars) over approximately 12 years.⁶ Establishing consistent, transparent, and science-based policy guardrails gives innovators the confidence needed to commit multi-billion-dollar investments toward addressing elusive pathogens, ultimately securing America's global leadership in biomedical innovation and protecting the nation against future health threats.

In addition to providing the certainty that drives American innovation, a robust, science-based immunization schedule is essential to public health and the vitality of the American manufacturing economy. Lower vaccination rates reduce manufacturing productivity through escalating transmission risks and subsequent increases in worker absenteeism and presenteeism. For example, influenza and influenza-like illnesses alone forced approximately 50–75% of employed caregivers to miss a couple days of work per year.⁷ One study reported annual costs of influenza-related absences equating to \$42,851 per 100,000 employee health plan members.⁸ Additionally, influenza causes U.S. employers to lose around 17 million

² Thomas, D., & Wessel, C. (2024). *The state of innovation in vaccines and prophylactic antibodies for infectious diseases*. Biotechnology Innovation Organization (BIO). <https://www.bio.org/sites/default/files/2024-01/The-State-of-Innovation-in-Vaccines-and-Prophylactic-Antibodies-for-Infectious-Diseases.pdf>

³ Ibid

⁴ Deloitte. (2024, June 24). *Deloitte pharma study: R&D returns are improving* [Press release]. Deloitte Switzerland. <https://www.deloitte.com/ch/en/about/press-room/deloitte-pharma-study-r-and-d-returns-are-improving.html>

⁵ Thomas, D., & Wessel, C. (2024). *The state of innovation in vaccines and prophylactic antibodies for infectious diseases*. Biotechnology Innovation Organization (BIO). <https://www.bio.org/sites/default/files/2024-01/The-State-of-Innovation-in-Vaccines-and-Prophylactic-Antibodies-for-Infectious-Diseases.pdf>

⁶ DiMasi, J. A., Grabowski, H. G., & Hansen, R. W. (2016). Innovation in the pharmaceutical industry: New estimates of R&D costs. *Journal of Health Economics*, 47, 20–33. <https://www.sciencedirect.com/science/article/abs/pii/S0167629616000291?via%3Dihub>

⁷ M-H Blanchet Zumofen, J. Frimpter and S. A. Hansen, “Impact of Influenza and Influenza-Like Illness on Work Productivity Outcomes: A Systematic Literature Review,” *PharmacoEconomics* 41 (2023): 253–273, <https://doi.org/10.1007/s40273-022-01224-9>.

⁸ Ibid

workdays per year at an estimated \$7 billion in sick days and lost productivity.⁹ Manufacturers incur productivity losses from workers missing shifts, working while sick or leaving the workforce due to illness. This translates into lost output and disruptions in an industry that relies heavily on consistent staffing and coordinated production processes.

Absenteeism represents the most direct and measurable economic cost of worker illness. In 2015, the Centers for Disease Control and Prevention estimated that productivity losses linked to absenteeism cost U.S. employers \$225.8 billion annually, which translates into nearly \$320 billion when adjusted for inflation and nearly \$30 billion for the manufacturing industry alone.¹⁰ When faced with absenteeism, manufacturers must rely on temporary staffing, incur overtime costs or face slowdowns that can cripple critical supply chains. On the contrary, routine vaccinations increase herd immunity on manufacturing shop floors, decreasing transmission risk where employees work in close physical proximity.

To attract new talent and keep the current workforce healthy and on the job, manufacturers rely on preventative health care as vital to workforce strength. When workers are healthy, production lines run smoothly, supply chains operate efficiently and the economy grows. When manufacturing workers or their families are sick, delays spread, supply chains strain and economic impacts are felt outside the shop floor.

Beyond their vital role in sustaining the American economy and workforce, vaccines represent one of the most monumental achievements in modern public health, serving as a foundational pillar for human well-being and societal progress. By safely leveraging the body's natural immune defenses, immunization protects individuals of all ages from debilitating, preventable infectious diseases, averting millions of hospitalizations and saving countless lives over decades. Vaccines are fundamentally smart science and a profound good for humanity, ensuring that communities remain resilient against health threats and giving every generation the opportunity to live healthier, fuller, and more productive lives.

It is for these reasons that the NAM respectfully submits the following comments in response to the RFI to safeguard the economic vitality of the manufacturing industry in a federal vaccine recommendation structure that provides absolute clarity for both employers and health providers.

Maintaining Adequacy of the Current Categories

As HHS considers potential changes to the federal vaccine recommendations framework, the NAM encourages the Department to preserve the framework's core strengths. These include a comprehensive and systematic review of the totality of available evidence, clear and practical

⁹ Centers for Disease Control and Prevention. (2017, December 5). *Flu fighter: Lisa Delaney*. U.S. Department of Health & Human Services. https://archive.cdc.gov/www_cdc.gov/flu/resource-center/partners/flu-fighter-lisa-delaney.htm

¹⁰ CDC Foundation, "Worker Illness and Injury Costs U.S. Employers \$225.8 Billion Annually," Jan. 28, 2015, accessed May 5, 2026, <https://www.cdcfoundation.org/pr/2015/worker-illness-and-injury-costs-us-employers-225-billion-annually>. NAM calculations adjust dollar values for inflation using the Consumer Price Index from the BLS, <https://www.bls.gov/cpi/>.

recommendation categories that are applied consistently, meaningful opportunities for patient and provider discussion, and reliable coverage and access to recommended vaccines. These principles are essential to establishing, maintaining, and increasing confidence in vaccines and ensuring individuals have appropriate evidence to discuss and make the most informed vaccination decisions with their providers.

Federal vaccine recommendations should continue to be developed through established, transparent, and replicable evidence review processes, such as the Advisory Committee on Immunization Practices (ACIP)'s Evidence to Recommendations (EtR) framework and use of the Grading of Recommendations Assessment, Development and Evaluation (GRADE) approach, as appropriate. These processes provide a consistent and structured means of evaluating burden of vaccine-preventable disease, the balance of the benefits and risks of vaccination, the strength and certainty of evidence, and the potential individual and population-level impacts of the vaccine.

Clear recommendation categories not only help communicate whether a vaccine is recommended, but also the population for which it is recommended and the strength of the evidence supporting its use. A well-designed framework, like the EtR, is not only informed by but further supports understanding by providers, payers, and other stakeholders, when it is appropriately used in recommendation development. Maintaining and applying a consistent approach to evaluating and communicating recommendations is important for promoting clarity, reducing confusion, and sustaining public confidence in vaccination.

The current federal framework—comprising routine (universal), risk-based, and shared clinical decision-making (SCDM) categories—serves a necessary function when applied correctly. The NAM urges HHS to maintain the current framework; unfortunately, recent expansions of SCDM to core adult and pediatric vaccines have created operational and clinical ambiguity.

Routine recommendations establish a clear default to vaccinate based on age or indication, providing clarity to clinicians, school systems, and employers. By contrast, SCDM carries "no default". Applying SCDM to broad populations communicates ambiguity to clinicians and the public, often being misinterpreted as a downgrade in safety, efficacy, or necessity.

As HHS acknowledges in the RFI, national physician surveys indicate that 90% to 95% of providers find implementing SCDM recommendations significantly more time-consuming than routine recommendations.¹¹ Clinicians must navigate complex electronic health record (EHR) forecasting tools that frequently misclassify or fail to display SCDM recommendations altogether. Most importantly, the physician survey concluded that SCDM recommendations create confusion for patients.

Shifting vaccines from routine to SCDM leads to measurable drops in immunization rates, which negatively affects manufacturers since 91% of manufacturing employees receive health

¹¹ Kempe et al., Shared Clinical Decision-Making Recommendations for Adult Immunization: What Do Physicians Think?, 36 J. Gen. Intern. Med. 2283 (2021), <https://link.springer.com/article/10.1007/s11606-020-06456-z>.

insurance through their employer.¹² For example, there was a decline in pneumococcal vaccine utilization from over 70% to under 60% following SCDM implementation in less than one year.¹³

In addition, recommendations targeted to specific high-risk populations often do not translate to adequate vaccination rates in these groups. For example, when determining whether to recommend a universal hepatitis B vaccination strategy for adults, the ACIP's Hepatitis B WG highlighted evidence that, despite the existing high-risk recommendation, risk groups (e.g., people with diabetes) had consistently low hepatitis B vaccination coverage.¹⁴ Further, in a national provider survey, 68% of providers noted that patients not disclosing high-risk behaviors was "definitely" or "somewhat" a barrier to vaccination, potentially indicating a driver of lower hepatitis B vaccination rates in target risk groups.¹⁵

As the single most cost-effective public health intervention available today, routine vaccinations help reduce manufacturer healthcare costs.¹⁶ In the NAM's Q2 2026 Manufacturers' Outlook Survey, 70% of respondent manufacturers identified health insurance costs as a primary business challenge—a concern that rises to nearly 78% among medium-sized manufacturers.¹⁷ Preventative vaccination mitigates these cost surges by reducing downstream medical visits, emergency department care, and complex hospitalizations. Maintaining the current categories will moderate downstream medical costs through higher vaccination rates that can help moderate employer-sponsored insurance expenses, limit unexpected healthcare claims, support a stable and productive manufacturing workforce and lower costs to the broader U.S. healthcare system.

Reducing Confusion for Patients and Providers with Vaccination Categories and Recommendations

While the RFI presents potential options for age de-emphasized recommendations, it is critically important to preserve vaccine access for infants. Specifically, excluding infants from recommendations overlooks those with high-risk conditions that may not immediately manifest (e.g., chronic kidney disease, congenital asplenia, and asthma, which were noted as risk conditions for invasive pneumococcal disease in the ACIP's pneumococcal vaccination recommendations), increasing their risk for severe vaccine-preventable disease outcomes.¹⁸

¹² National Association of Manufacturers (NAM). (n.d.). *Facts about manufacturing expanded*. Retrieved September 1, 2026, from <https://nam.org/mfgdata/facts-about-manufacturing-expanded/>

¹³ Global Healthy Living Foundation. (2025, March 24). *Enhancing adult vaccine uptake: Challenges in shared clinical decision making and risk-based recommendations*. https://ghlf.org/issues/vaccines/enhancing_adult_vaccine_uptake/

¹⁴ Ladak, F., Gjelsvik, A., Feller, E. *et al.* Hepatitis B in the United States: ongoing missed opportunities for hepatitis B vaccination, evidence from the Behavioral Risk Factor Surveillance Survey, 2007. *Infection* **40**, 405–413 (2012). <https://doi.org/10.1007/s15010-011-0241-2>

¹⁵ Daley, M., Hennessey, K., Weinbaum, C., *et al.* Physician Practices Regarding Adult Hepatitis B Vaccination: A National Survey." *Am J Prev Med* **36**, 491–496 (2009). <https://doi.org/10.1016/j.amepre.2009.01.037>

¹⁶ Boccalini, S. (2025). Value of vaccinations: A fundamental public health priority to be fully evaluated. *Vaccines*, **13**(5), 479. <https://doi.org/10.3390/vaccines13050479>

¹⁷ National Association of Manufacturers. (2026). *2026 second quarter manufacturers' outlook survey*. Retrieved September 6, 2026, from <https://nam.org/2026-second-quarter-manufacturers-outlook-survey/>

¹⁸ Farrar, J., Gierke, R., Andrejko, K., *et al.* Use of 20-Valent Pneumococcal Conjugate Vaccine Among U.S. Children: Updated Recommendations of the Advisory Committee on Immunization Practices – United States,

This is a key rationale for why all current immunization recommendations for infants are routine; vaccination decisions thus begin with a clear recommendation to facilitate robust discussion between parents and healthcare providers about the benefits and risks for the infant.

If new or modified categories are introduced, HHS must ensure they do not trigger unintended coverage cutoffs. Federal Statute requires that commercial health plans, Medicaid programs and Medicare Part D plans cover vaccines recommended by the ACIP without cost-sharing.^{19 20}

²¹ Reclassifying core vaccines under modified non-routine categories introduces administrative friction, billing confusion and potential coverage gaps for working families.

Weighing Risks of Shared Clinical Decision-Making

HHS should recognize that provider counseling on vaccines already exists with parents, patients, and caregivers across all vaccine recommendation types. Counseling is a fundamental component of informed vaccination decisions, even when a vaccine is routinely recommended, and should complement rather than replace evidence-based recommendations. HHS and the Centers for Medicare and Medicaid Services (CMS) should support appropriate mechanisms, including appropriate recognition of current procedural terminology (CPT) coding for vaccine counseling, so clinicians have the capacity to support patient and caregivers with their informed understanding of a vaccine's benefit.

The NAM recommends that HHS keep SCDM as an intermediate tool reserved for specific vaccines where the population-level benefit is modest or highly variable based on individual clinical risk. SCDM is appropriate for clinical scenarios where benefit varies significantly by personal exposure or prior immunity—such as human papillomavirus vaccination for adults aged 27 to 45—and should not be used as a substitute for routine recommendations when a strong public health and economic rationale exist.

A survey of pediatricians revealed that fewer than half of primary care physicians realize that SCDM-designated vaccines remain covered by private insurance and the Vaccines for Children program.²² This knowledge gap creates real barriers to care. Acknowledging this gap, medical specialty societies representing vaccinating providers develop and maintain resources, including specific guides on shared decision-making for vaccination, and are best poised to develop these

2023. *Morb Mortal Wkly Rep* **72**, no. 39 (2023).

https://stacks.cdc.gov/view/cdc/133252/cdc_133252_DS1.pdf.

¹⁹ 42 USC 1396o-1: State option for alternative premiums and cost sharing.

[https://uscode.house.gov/view.xhtml?req=\(title:42%20section:1396o-1%20edition:prelim\)](https://uscode.house.gov/view.xhtml?req=(title:42%20section:1396o-1%20edition:prelim)).

²⁰ 42 USC 300gg-13: Coverage of preventive health services.

<https://uscode.house.gov/view.xhtml?req=granuleid:USC-2015-title42-section300gg-13&num=0&edition=2015>.

²¹ 42 USC Chapter 7, Subchapter XVIII, Part D: Voluntary Prescription Drug Benefit Program.

<https://uscode.house.gov/view.xhtml?req=granuleid%3AUSC-prelim-title42-chapter7-subchapter18-partD&saved=L3ByZWxpbUB0aXRsZTQyL2NoYXB0ZXI3L3N1YmNoYXB0ZXIxOC9wYXJ0RA%3D%3D%7CZ3JhbnVsZWIKOIVTQy1wcmVsaW0tdGI0bGU0Mi1jaGFwdGVyNy1zdWJjaGFwdGVyMTgtcGFydEQ%3D%7C%7C%7C0%7Cfalse%7Cprelim&edition=prelim>.

²² O'Leary, S. T., Allison, M. A., Vogt, T., Hurley, L. P., Crane, L. A., Brtnikova, M., McBurney, E., Beaty, B. L., Crawford, N., Lindley, M. C., Stokley, S. K., & Kempe, A. (2020). Pediatricians' experiences with and perceptions of the Vaccines for Children program. *Pediatrics*, 145(3), e20191207. <https://doi.org/10.1542/peds.2019-1207>

and similar resources based on the needs communicated by their members.²³ To make SCDM function effectively without suppressing appropriate uptake, HHS may endorse and disseminate standardized clinical decision aids, establish uniform coding and electronic health record display standards, and conduct targeted provider education verifying that coverage without cost-sharing remains intact.

If HHS considers revising SCDM terminology or structure, it should conduct meaningful stakeholder engagement and pilot any proposed changes with clinicians, pharmacists, patients, payers, and health systems before implementation to ensure that it improves understanding and access. For example, SCDM has led to confusion at the state level regarding pharmacy access and ability to implement such recommendations. By testing and refining these concepts while incorporating lessons learned on the ground, HHS can prevent well-intentioned policy updates from unintentionally disrupting patient care.

Upholding Sound Science for Setting Recommendations

The NAM strongly urges HHS, the U.S. Center for Diseases Control (CDC), and ACIP to anchor all federal vaccine recommendations in sound science. Decades of research and studies affirm vaccines' safety, efficacy and importance not only in preventing illness but also in averting the long-term health consequences that may follow. The CDC estimates that U.S. children born between 1994 and 2021 who are vaccinated according to the recommended immunization schedule will prevent 472 million illnesses and 29.8 million hospitalizations over the course of their lifetimes.²⁴

The NAM urges HHS to continue utilizing ACIP recommendations for the age-based routine immunization schedule as the standard. The CDC states that children “do not receive any known benefits from following schedules that delay vaccines” and, further, make them more vulnerable to severe outcomes from vaccine-preventable diseases.²⁵ Additionally, delaying or staggering the child immunization schedule may negatively impact the manufacturing workforce since the economic benefits of vaccination begin in infancy. Healthier children are more likely to have higher labor force participation and occupational success over their lifetimes.²⁶ Preventing illness and hospitalization in childhood lowers the risk of chronic health complications later on, contributing to a more resilient labor force.²⁷ Among approximately 117 million children born in the United States between 1994 and 2023, routine childhood vaccinations, not including

²³ American Academy of Family Physicians. “Shared decision-making and clinical guidance.” N.d. Accessed September 6, 2026. <https://www.aafp.org/clinical-insights/immunizations-and-vaccines/immunizations-schedules-resources#shared>.

²⁴ Zhou, F., et al (2024). Health and economic benefits of routine childhood immunizations in the era of the vaccines for children program — United States, 1994–2023. *MMWR. Morbidity and Mortality Weekly Report*, 73(31), 682–685. <https://doi.org/10.15585/mmwr.mm7331a2>

²⁵ CDC. “About Vaccines for your Children.” August 9, 2024. Accessed September 15, 2026. <https://www.cdc.gov/vaccines-children/about/index.html>.

²⁶ B. W. Ward, “Multiple chronic conditions and labor force outcomes: A population study of US adults,” *American Journal of Industrial Medicine* 58, no. 9 (2025): 943–954.

²⁷ Debra L Blackwell, Mark D Hayward and Eileen M Crimmins, “Does childhood health affect chronic morbidity in later life?,” *Social Science & Medicine* 52, no. 8 (2001): 1269–1284, ISSN 0277-9536, [https://doi.org/10.1016/S0277-9536\(00\)00230-6](https://doi.org/10.1016/S0277-9536(00)00230-6).

influenza, COVID-19 and RSV, are estimated to have prevented 508 million lifetime cases of illness, 32 million hospitalizations and more than 1.1 million deaths over those children's lifetimes.²⁸ The estimated net economic savings totaled \$540 billion in direct costs and \$2.7 trillion in societal costs. Notably, the measles vaccine had the single greatest impact, preventing roughly 13.2 million hospitalizations.²⁹ Further, a study of a cohort of children born in 2017 found that routine pediatric vaccination leads to approximately \$41.7 billion in lifetime fiscal benefits, including averted tax revenue losses of \$30.6 billion, disability savings of \$1.6 billion and reduced special education costs of \$910 million.³⁰ For example, over just a single year, a delay in hepatitis B vaccine birth dose to 2 months would potentially lead to an estimated 1,437 preventable hepatitis B infections among children, 304 cases of liver cancer, and 482 HBV-related deaths.³¹ And in 2025 alone, estimates show measles cost the U.S. health system over \$166.1 million, or \$76,155 per measles case.³² Thus, the manufacturing economy benefits from a robust approach to child immunization.

A more individualized approach with SCDM can come at the expense of herd immunity in instances where it has been implemented. Analyses of immunization policy emphasize that replacing universal recommendations with individualized frameworks creates friction and lowers aggregate uptake, which directly compromises population-level immunity thresholds.³³ Public health experts note that when vaccines—such as those for Hepatitis B or Hepatitis A—are moved to an SCDM framework, overall uptake frequently declines because vaccination becomes optional. In many cases, shop floor workers are in close proximity to one another, and a higher rate of vaccination among them will increase the benefits of herd immunity. And more limited infections and illnesses lead to less absenteeism, presenteeism and attrition. A robust immunization approach thus increases productivity with herd immunity.

Rebuilding Trust and Communication

The NAM urges public health agencies to practice clear, candid communication by transparently sharing what is known, what remains uncertain, and what ongoing studies seek to clarify. Research demonstrates that transparently communicating uncertainty builds long-term institutional trust without harming compliance.

Public confidence in vaccine recommendations relies not only on the evidence supporting them, but also on the integrity and transparency of the process used to evaluate that evidence. The NAM encourages HHS to continue relying on qualified experts with relevant scientific, clinical,

²⁸ Zhou, F., et al 2024.

²⁹ Ibid

³⁰ M. P. Connolly, N. Kotsopoulos, C. Roberts, et al., "Public economic gains from tax-financed investments in childhood immunization in the United States," *PLOS Global Public Health* 3, no. 10 (2023): e0002461, <https://doi.org/10.1371/journal.pgph.0002461>.

³¹ Hall, E. W. (2025). Economic evaluation of delaying the infant hepatitis B vaccination schedule. *medRxiv*. <https://doi.org/10.1101/2025.11.24.25340907v1>

³² Wells, C. R., Pandey, A., Ye, et al (2026). The health and economic repercussions of declining MMR coverage in the United States. *medRxiv* [Preprint]. <https://doi.org/10.64898/2026.02.19.26346619v1>

³³ Shen, A. K., Michel, J. J., Langford, A. T., & Sobczyk, E. A. (2021). Shared clinical decision-making on vaccines: out of sight, out of mind. *Journal of the American Medical Informatics Association*, 28(11), 2523–2525. <https://doi.org/10.1093/jamia/ocab147>

and public health expertise to assess evidence and make recommendations that rebuild trust in vaccines.

Transparent, consistently applied, evidence-based processes help the public understand recommendation development, evidence considerations, benefit/risk assessment, and remaining uncertainties. These practices can build trust by demonstrating that recommendations result from the systematic and objective evaluation of evidence.

Federal vaccine recommendations are advisory guidelines intended to inform clinical decisions and insurance coverage, not federal mandates. Communicating this distinction clearly helps reduce public reactance while maintaining voluntary vaccine acceptance. Sustaining U.S. leadership in biopharmaceutical innovation benefits from renewed trust, a stable regulatory ecosystem and consistent scientific standards. The biopharmaceutical industry invests billions of dollars annually in risky vaccine development programs. Unpredictable shifts in ACIP recommendations, erosion of the Vaccine Injury Compensation Program (VICP) liability protections, or regulatory instability at the FDA threaten future R&D pipelines, leaving manufacturers and the workforce vulnerable to emerging infectious health threats.

A healthy, vaccinated workforce is the foundation of a resilient American economy. Manufacturers urge HHS to support policies grounded in sound science that provide regulatory certainty for innovators, safeguard seamless access and insurance coverage for working families, and maintain clear, evidence-based immunization standards. Please consider the NAM a resource to HHS as it undertakes next steps on these policy issues. Routine vaccination remains one of the most effective tools for reducing the burden of infectious disease on the workforce and advancing a more prosperous, secure and economically strong America.

Sincerely,

A handwritten signature in black ink, appearing to read 'Jo My'.

Jeremy Isenberg

Director, Healthcare Policy

A handwritten signature in black ink, appearing to read 'Jake Kuhns', with a stylized, flowing script.

Jake Kuhns

Vice President, Domestic Policy