EXHIBIT A

UNITED STATES DISTRICT COURT

DISTRICT OF MASSACHUSETTS

AMERICAN ACADEMY OF PEDIATRICS, *et al.*, Plaintiffs, v. ROBERT F. KENNEDY, JR., in his official capacity as Secretary of the Department of Health and Human Services, *et al.*, Defendants.	CIVIL ACTION NO.: 1:25-CV-11916

BRIEF OF DEFEND PUBLIC HEALTH AS AMICUS CURIAE IN SUPPORT OF PLAINTIFFS

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I. INTEREST OF THE AMICUS CURIAE

Amicus Curiae Defend Public Health ("DPH") is an unincorporated nonprofit association with a membership of over 7,000 members in more than 40 states, including physicians, nurses, legal scholars, current and former public health officials, and academic scientists working in biomedical and clinical research, epidemiology, and other areas of public health. Notably, DPH members have significant expertise in the following areas and on the following subjects: infectious disease epidemiology; pediatric and adult infectious disease treatment and prevention; the modeling of vaccine effectiveness and impact; vaccine hesitancy; and domestic and international health policy, including but not limited to, immunization practices. DPH members have also been involved in advising domestic and international institutions on infectious disease and immunization practice and policy matters throughout their professional careers in medicine and public health. DPH was founded in November 2024 to protect America's public health, healthcare, and biomedical research endeavors and promote sound policies and programs in those areas critical to the advancement of the health and well-being of all Americans, including those concerning immunization against infectious diseases.

II. SUMMARY OF THE ARGUMENT

In dramatically changing the Centers for Disease Control and Prevention's ("CDC") vaccination schedule on January 5, 2026, Acting CDC Director Jim O'Neill ("Director O'Neill") relied wholly on an assessment comparing the U.S. schedule to that in twenty so-called "peer countries" that was drafted by two Department of Health and Human Services ("HHS") officials. The Assessment was flawed in terms of its methodology and reasoning. First, it claimed without offering any evidence or considering other import factors that reducing the number of childhood vaccines recommended would improve trust in vaccines. Second, it failed to consider or apply best

practices for vaccine policy. Third, it erroneously claimed that the U.S. was an outlier among peer countries in terms of the number of vaccines recommended for routine use; and it relied on misleading comparisons between the U.S. and other countries to justify altering the U.S. schedule to closely match the recommendations made in Denmark.

III. INTRODUCTION

On December 5, 2025, President Donald Trump issued a directive (the "Directive") instructing the Secretary of HHS and the Director of the CDC to "review best practices from peer, developed countries for core childhood vaccination recommendations . . . [and] if they determine that those best practices are superior to current domestic recommendations, update the United States core childhood vaccine schedule to align with such scientific evidence and best practices from peer, developed countries. . . ."[1] On January 5, 2026, Director O'Neill responded to the directive by announcing a dramatic reduction in the number of immunizations subject to universal recommendation on CDC's schedule of childhood vaccines (the "Schedule").[2] More specifically, Director O'Neill divided the vaccines that had previously been recommended for all children into three broad groups: so-called consensus vaccines that would continue to be universally recommended,[3] vaccines that would only be recommended for high-risk groups,[4] and vaccines that would be subject to "shared clinical decision-making" (SCDM).[5] The number of vaccines recommended for all children was reduced from 17 to 11.[6]

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[1] Presidential Memorandum, *Aligning United States Core Childhood Vaccine Recommendations with Best Practices from Peer, Developed Countries* (Dec. 5, 2025), https://tinyurl.com/4ubxvnbr (the "Directive").
[2] U.S. Dep't of Health & Hum. Servs. Decision Memorandum, *Decision Memo to Jim O'Neill* (Jan. 5, 2026), https://tinyurl.com/4dej526b (the "Decision Memo").
[3] The consensus vaccines are the vaccines for measles, mumps, rubella, diphtheria, tetanus, pertussis, polio, *Haemophilius influenzae* type B, pneumococcal disease, human papillomavirus, and varicella. *Id.* at 2.
[4] This high-risk category includes monoclonal antibodies against respiratory syncytial virus (RSV), which are not vaccines, as well as vaccines for hepatitis A, hepatitis B, meningococcal B, meningococcal ACWY, and dengue. *Id.*
[5] The vaccines in the SCDM category are for hepatitis A, hepatitis B, rotavirus, meningococcal disease, influenza, and COVID-19. *Id.*
[6] Pien Huang & Rob Stein, *Health Officials Slash the Number of Vaccines Recommended for All Kids,* NPR (Jan. 5,

In changing the Schedule, O'Neill bypassed the Advisory Committee on Immunization Practices ("ACIP") as well as CDC immunization experts. Instead, he relied wholly on and signed a "Decision Memo" sent to him by Dr. Jay Bhattacharya, Director of the National Institutes of Health ("NIH"); Mehmet Oz, Administrator of the Centers for Medicare and Medicaid Services ("CMS"); and Dr. Marty Makary, Commissioner of Food and Drugs ("FDA"),[7] none of whom have expertise relating to immunization policy. Their memorandum, in turn, simply summarized a January 2, 2026 "Assessment of the U.S. Childhood and Adolescent Schedule Compared to Other Countries," (the "Assessment") authored by two HHS employees, Dr. Tracy Beth Høeg and Dr. Martin Kulldorff.[8] Although the Assessment promised "a scientific, evidence-based, data-driven response to the President's directive," it was deeply flawed in its methodology and reasoning.

Critically, the Assessment, which constituted the sole scientific support provided for the changes that O'Neill imposed on January 5,[9] failed to utilize any generally accepted scientific methodology.[10] The Assessment also failed to offer the type of "reasoned analysis" that the Supreme Court demands of agency actions subject to arbitrary and capricious review under the Administrative Procedures Act ("APA").[11] Three significant flaws stand out: first, without offering any evidence, the Assessment asserted that trust in vaccines would increase if fewer vaccines were

2026), https://tinyurl.com/4byvjbac.

[7] Decision Memo, *supra* note 2.

[8] *See* U.S. Dep't of Health & Hum. Servs. Assessment, *Assessment of the U.S. Childhood and Adolescent Immunization Schedule Compared to Other Countries* (Jan. 2, 2026) (authored by Dr. Tracy Beth Høeg and Dr. Martin Kulldorff), https://tinyurl.com/5n4m3fwe. (the "Assessment").

[9] The Decision Memo also states that Director O'Neill "discussed immunization recommendations and policy with health officials from Japan, Germany, and Denmark." *Decision Memo*, *supra* note 2, at 1. The names of those officials or contents of those discussions are not made public.

[10] *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579, 592-93 (1993) (stressing the importance of expert's conclusions being grounded in rigorous methodology); *Samaan v. St. Joseph Hosp.*, 670 F.3d 21, 32-33 (1st Cir. 2012) (excluding expert's testimony when conclusions were not grounded in accepted scientific methods).

[11] *See e.g., Motor Vehicle Mfrs. Assn't of United States, Inc. v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983) ("Normally, an agency rule would be arbitrary and capricious if the agency has relied on factors which Congress has not intended it to consider, entirely failed to consider an important aspect of the problem, offered an explanation for its decision that runs counter to the evidence before the agency, or is so implausible that it could not be ascribed to a difference in view or the product of agency expertise.")

routinely recommended; second, it failed, as the President directed, to consider or apply best practices for developing vaccine policy; and third, it relied on misleading and erroneous comparisons to vaccine schedules in other countries, most notably Denmark, to conclude that fewer vaccines should be recommended universally in the U.S. to align with the schedules of other countries. As a result, the January 5 changes to the vaccine schedule rest on a methodologically incoherent and scientifically unfounded analysis.

IV. ARGUMENT

A. HHS' Statements Concerning Trust in Vaccines are Both Irrelevant and Misleading.

On January 5, 2026, the HHS Press Office issued a press release announcing the Decision Memo and subsequent change to the schedule based on the recommendations of the Assessment.[12] The press release noted, "peer nations that recommend fewer routine vaccines achieve strong child health outcomes and maintain high vaccination rates through public trust and education rather than mandates."[13] The Decision Memo and Assessment likewise suggest that a reduction in the number of vaccines recommended for all children will increase the public's trust in vaccines.[14] Yet, the Assessment makes unsubstantiated assumptions and misleading inferences about the relationship between the number of vaccines, vaccine mandates, and trust. Importantly, there is no evidence to support the assumption that the changes effectuated by the Decision Memo will in fact improve trust.

[12] U.S. Dep't of Health and Hum, Servs., *CDC Acts on President Memorandum to Update Childhood Immunization Schedule*, U.S. Dep't of Health and Hum. Servs. (Jan. 5, 2026), https://tinyurl.com/2s39r7fw.
[13] *Id*.
[14] Decision Memo, *supra* note 2, at 3; Assessment, *supra* note 8, at 16-17.

1. HHS's Statements on Trust are Misleading

The Assessment repeatedly claims that the public's trust in vaccines has been "lost" and that a reduced CDC schedule will "restore" that trust.[15] These claims are misleading for at least two reasons: (1) although vaccine hesitancy is not a new issue, recent research shows that confidence in childhood vaccines remains high, and (2) the suggestion that attitudes towards vaccination are contingent on any specific number of recommended vaccines or the particulars of the U.S. schedule is unsupported. In reality, there is actually reason to worry that the reduction to the schedule will increase vaccine hesitancy.

Decreases in vaccine confidence and increases in vaccine hesitancy are not new issues. In 2019, prior to the COVID-19 pandemic, the World Health Organization ("WHO") included vaccine hesitancy as one of the top 10 global health threats, defining it as "the reluctance or refusal to vaccinate despite the availability of vaccines."[16] Uncertainty during the COVID-19 pandemic alongside the rapid introduction of new mRNA vaccines likely played a part in decreasing vaccine confidence.[17] Nevertheless, a recent U.S. survey found no evidence that the public widely believes that vaccines are overused; and it found that both parents and adults without children generally had positive attitudes about vaccination.[18] Similarly, multiple U.S. polls conducted in 2025 showed that vaccine uptake and confidence remain high overall, despite slight decreases since the pandemic.[19]

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[15] Assessment, *supra* note 8, at 4, 6,10, 17.
[16] WHO, *Ten Threats to Global Health in 2019*, https://tinyurl.com/yc4c2vxk (last visited Feb. 1, 2026).
[17] *See* UNICEF, *The State of the World's Children 2023 For Every Child, Vaccination* 69 (Apr. 2023), https://tinyurl.com/4fujr3my.
[18] Eiden et al., *Attitudes and beliefs about vaccination among adults in the United States: A real-world, cross-sectional, web-based survey study*, 50 Vaccine 1, 6 & 8 (2025), https://tinyurl.com/44zh6ca2 (discussing attitudes around vaccines).
[19] The Washington Post & KFF, *Washington Post–KFF Survey of Parents Topline* 7 (2025), https://tinyurl.com/555ey33x (showing that more than 80% of parents support routine childhood vaccines for school (measles and polio specifically); Eileen Yam et al., *How Do Americans View Childhood Vaccines, Vaccine Research and Policy?*, Pew Research Center (Nov. 18, 2025), https://tinyurl.com/5b9rtysd (finding that a majority of people

Further, statements in the Assessment claiming that the reduction in the number of vaccines routinely recommended will "restore trust" fail to consider the reasons why people choose not to vaccinate and fail to provide support that these schedule changes will improve vaccination uptake.[20] When WHO released its top 10 global health threats in 2019, it noted that "[t]he reasons why people choose not to vaccinate are complex; a vaccine advisory group to WHO identified complacency, inconvenience in accessing vaccines, and lack of confidence [as] key reasons underlying hesitancy."[21] The WHO vaccine advisory group listed multiple factors within these three main reasons for vaccine hesitancy; none specify a certain number of vaccines as being impactful.[22] However, the "introduction of a new vaccine or new formulation or a new recommendation for an existing vaccine" is specifically identified as a determinant of vaccine hesitancy.[23] Notably, of the vaccines that have been moved to the SCDM category, only the COVID-19 vaccine can be considered new; the others have been part of the routine immunization schedule for over twenty years (i.e., influenza) and as far back as 1991 (i.e., hepatitis B).[24] In reality, the politicization of the pandemic and the presence of mis- and disinformation, lack of vaccine access, pre-existing attitudes about healthcare, and history of healthcare interactions are more likely drivers of reduced vaccine confidence and uptake than the number of vaccines listed

surveyed [63%] are highly confident that childhood vaccines are effective at preventing illness).

[20] Assessment, *supra* note 8, at 4, 6, 17.

[21] WHO, *supra* note 16; Noni E. Macdonald & the SAGE Working Group on Vaccine Hesitancy, *Vaccine Hesitancy*: *Definition, scope and determinants*, 33 Vaccine 4161, 4161–62 (2015), https://tinyurl.com/35kuxxrp, (discussing reasons for vaccine hesitancy).

[22] MacDonald & the SAGE Working Group on Vaccine Hesitance, *supra* note 21, at 4162-63.

[23] *Id*. at 4163.

[24] Inst. Med., Immunization Safety Rev. Comm., *Immunization Safety Review: Vaccines and Autism* (2004), https://tinyurl.com/4rpvp3xu.

as universally recommended on the schedule.[25] Recent statements by the CDC casting doubt on the safety and effectiveness of vaccines may also undermine trust in vaccines.[26]

Further, as a matter of logic, if no evidence is provided that the specific number of vaccines increases hesitancy, decreasing the number of recommended vaccines to reflect the schedule of a country like Denmark – which, as we explain below, bears no relevant resemblance to the U.S. – has a low likelihood of reducing vaccine hesitancy and increasing trust. As stated above, public trust in vaccination remains high,[27] but efforts to increase that trust require tailored, evidence-based approaches. Abrupt and arbitrary changes to the schedule are more likely to drive further confusion.[28]

2. The Assessment's Statements on Mandates are Misleading and Irrelevant

The Assessment discusses vaccine mandates multiple times,[29] suggesting that the U.S. is out of alignment with other countries in terms of the number of vaccine mandates.[30] This discussion is irrelevant because existing vaccine mandates come from state law, not the schedule.[31] Although the schedule has traditionally influenced state mandates, that was because states respected ACIP's decision-making, not because they were legally bound to follow it. With the loss

[25] *See* Jane Tuckerman et al., *Effective Approaches to Combat Vaccine History*, 41, ESPID, e243, e243–45 (May 2022), https://tinyurl.com/4x3hz87y (discussing drivers of reduced vaccine confidence).
[26] For example, the CDC website now has an asterisk next to the statement "Vaccines do not cause Autism," stating "[t]he header 'Vaccines do not cause autism' has not been removed due to an agreement with the chair of the U.S. Senate Health, Education, Labor, and Pensions Committee that it would remain on the CDC website." Centers for Disease Control and Prevention, *Autism and Vaccines* (Nov. 19, 2025), https://tinyurl.com/5n8z2chs. That statement, which implies that were it not for a political deal, the CDC would make a different claim about the relationship between autism and vaccines, does not seem designed to enhance trust in the safety of vaccines.
[27] *See* Eiden et al., *supra* note 18, at 6 & 8.; KFF, *supra* note 19, at 7; Eileen Yam et al., *supra* note 19.
[28] Edwin J. Asturias et al., *Science for vaccine policy: Independent review of the September 2025 ACIP processes, deliberations and votes,* 67 Vaccine 1, 6 (2025), https://tinyurl.com/5a3s779j (explaining how "procedural chaos and low-quality recommendations" errode public trust); MacDonald & the SAGE Working Group on Vaccine Hesitance, *supra* note 19, at 4162-63.
[29]Assessment, *supra* note 8, at 10, 15, & 16.
[30] *Id*.
[31] Dorit Reis, *CDC as a Debunker: The Limits of Government in Countering Misinformation*, 25 Hous. J. Health L. & Pol'y 66, 103–04 (2025).

of respect for ACIP, at least 24 states no longer look to the CDC schedule,[32] and even before the events at issue in this litigation, no state followed it fully. For example, until January 5, the schedule included an annual influenza vaccine. No state mandated such vaccination for school-age children (although some do for daycare and pre-K children).[33] Put another way, if the Assessment's argument is that mandates negate trust in vaccines, that will not be addressed by the January 5, 2026 changes to the schedule, but would instead require state-by-state changes to existing legislation, which could occur without any change to the schedule.

B. The Assessment Failed to Review or Apply Best Practices in Formulating its Recommendations

1. The Assessment Did Not Consider Best Practices for Vaccine Decision-Making

In his December 5, 2025 directive, President Trump instructed the Secretary of HHS and CDC Director to "review best practices from peer developed countries … and the scientific evidence that informs those practices" and "if they determine that those best practices are superior to current domestic recommendations, update the United States core childhood vaccine schedule to align with such scientific evidence and best practices …."[34] Neither the Decision Memo nor the Assessment followed that directive. They did not review or discuss the literature on "best

[32] Jennifer Kates and Josh Michaud, *The New Federal Vaccine Schedule for Children: What Changed and What Are the Implications*, Kaiser Family Foundation (Jan. 9, 2025), https://tinyurl.com/yzvjh47p.
[33] Kai Hong et al., *School Mandate and Influenza Vaccine Uptake Among Prekindergartners in New York City, 2012-2019* 1123 Am. J. Pub. Health 719, 719 (2022) ("until July 2020, there were only five states (Connecticut, New Jersey, Ohio, Pennsylvania, Rhode Island) and one city (New York City) mandating annual influenza vaccination for school entry, all at child care or pre-school levels."). An updated table can be found at immunize.org, Influenza Vaccine Requirements, https://tinyurl.com/mwajt76j (showing state mandates; https://tinyurl.com/2xsct4k3 (showing that as of May 2025, only Connecticut, New Jersey, New York City (not state), Ohio, Pennsylvania and Rhode Island required influenza vaccines for daycare).
[34] Directive, *supra* note 1.

practices,"[35] nor did they discuss the processes that other nations use to reach their decisions.[36] Most critically, they did not apply the practices that are considered by other nations to be the gold standard for developing their immunization recommendations. Instead, the Assessment, which the Decision Memo incorporated and wholly relied upon, simplistically surveyed the numbers and types of vaccines and doses recommended by and mandated in twenty so-called "peer countries"[37] and compared those findings with the schedule.[38,39]

2. Prior to 2025, ACIP Utilized the GRADE and EtR Frameworks, the Type of Evidence-Based Decision-Making Frameworks that are Considered Best Practices for Vaccine Decision-Making

Had the Assessment studied global best practices as the President requested, it would have noted that National Immunization Technical Advisory Groups (NITAGs), which advise policymakers in their own nations, utilize similar systematic approaches to develop evidence-based recommendations on immunization policy and practice.[40] In particular, many NITAGs and international organizations, such as the WHO Strategic Advisory Group of Experts on Immunization (SAGE), utilize the Grading of Recommendations Assessment, Development and Evaluation (GRADE) framework,[41] which provides a systematic approach for assessing the quality

[35] *E.g.*, Morgane Donadel et al., *National Decision-Making for the Introduction of New Vaccines: A Systematic Review*, 2010-2020, 39 Vaccine 1897, 1905–06 (2021); Publications Office of the European Union, *Current Practices in Immunisation Policymaking in European Countries* 11 (2015), https://tinyurl.com/3pkbbe8p.
[36] The Decision Memo also states that O'Neill "discussed immunization recommendations and policy with health officials from Japan, Germany, and Denmark." Decision Memo, *supra* note 2.
[37] *Id*.
[38] As noted above, the Assessment also discusses mandates, suggesting that the United States is out of alignment with other countries in terms of the number of mandates that are imposed. Assessment, *supra* note 8, at 10, 15, & 16. This discussion is misleading for at least two reasons. First, mandates come from the states, not the CDC schedule. See *supra*. Second, the list of U.S. mandates ignores the broad exemptions, including for personal or religious belief, that almost every state in the U.S. has. Directive, *supra* note 1.
[39] Although this discussion focuses on the flaws in the Assessment and the changes to the childhood vaccine schedule it recommended (which were implemented by O'Neill), ACIP also failed to follow scientifically recognized frameworks in its September and December meetings.
[40] Publications Office of the European Union, *supra* note 35; Domenico Martinelli et al., *Role of the National Immunisation Technical Advisory Groups in 13 European Countries in the Decision-Making Process on Vaccine Recommendations*, 28 Eurosurveillance, 1, 1 (Oct. 26, 2023), https://tinyurl.com/4s5zknnn.
[41] Manya Prasad, *Introduction to the GRADE tool for rating certainty in evidence and recommendations*, 25 Clin. Epidemiol. Glob. Health 1, 1–5 (Jan.–Feb. 2024), https://tinyurl.com/578dpv46.

of scientific evidence based on factors such as study design, bias risk, and result consistency.[42] In 2016, the international GRADE working group introduced the Evidence to Decision (EtD) framework to complement GRADE. EtD is designed to enable evidence to be used in a structured and transparent way and to take into account the magnitude of the desirable and undesirable effects of the intervention (in this case, the vaccine), the certainty of the evidence of these effects, and how much affected individuals value the outcomes considered in these analyses in order to ensure structured and transparent discussions.[43]

The EtD framework includes three main sections: (1) formulating the question, (2) assessing the evidence and additional considerations for each criterion, and (3) drawing conclusions.[44] It proposes specific sets of criteria for recommendations that account for the perspective (individual patient vs. population perspective), type of decision (e.g. scale up of coverage, introduction of new test), and type of intervention (clinical, health system or public health), which can be tailored to the needs of the specific organization and decision.[45] After applying the criteria, decision-makers who utilize the framework should openly state their conclusions, note the strength of the supporting evidence, and provide a justification for their recommendations.

Prior to 2025, ACIP (which is the NITAG in the U.S.) followed a similar approach to other NITAGs and the WHO SAGE. In developing its recommendations, it relied on GRADE to

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[42] *See* Gordon H. Guyatt et al., *GRADE: An Emerging Consensus on Rating Quality of Evidence and Strength of Recommendations*, 336 BMJ 924, 926 (2008).
[43] *Id*.
[44] Pablo Alonso-Coello et al., *GRADE Evidence to Decision (EtD) Frameworks: A Systematic and Transparent Approach to Making Well Informed Healthcare Choices. 1: Introduction*, 353 BMJ 1, 2 (June 28, 2016), https://tinyurl.com/jdd9a3un; Pablo Alonso-Coello et al., *GRADE Evidence to Decision (EtD) Frameworks: A Systematic Approach to Making Well Informed Healthcare Choices. 2*: *Clinical Practice Guidelines*, 353 BMJ 1, 1 (June 30, 2016), https://tinyurl.com/m5mkssfp.
[45] Alonso-Coello et al., *GRADE Evidence to Decision (EtD) Frameworks: A Systematic and Transparent Approach to Making Well Informed Healthcare Choices. 1: Introduction*, *supra* note 44 at 3.

evaluate the quality of the scientific evidence for each vaccine under consideration.[46] In 2018, ACIP supplemented its use of GRADE with an additional framework known as Evidence to Recommendation (EtR) for translating the information in the studies into specific policy recommendations.[47] The EtR framework is similar to the EtD approach used by other NITAGs, but is tailored to the needs of ACIP.[48]

It uses the following questions to guide its recommendations:

1) Is the problem of public health importance?
2) How substantial are the desirable anticipated effects?
3) How substantial are the undesirable anticipated effects?
4) Do the desirable effects outweigh the undesirable effects?
5) What is the overall certainty of this evidence for the critical outcomes?
6) Does the target population feel that the desirable effects are large relative to undesirable effects?
7) Is there important uncertainty about or variability in how much people value the main outcomes?
8) Is the intervention acceptable to key stakeholders?
9) Is the intervention a reasonable and efficient allocation of resources?
10) What would be the impact on health equity?
11) Is the intervention feasible to implement?[49]

The pre-2025 childhood and adolescent vaccine schedule, which O'Neill changed, relied on the GRADE and EtR frameworks to assess proposed changes to the adult and childhood immunization schedules. The previous schedules showed clearly which vaccines were recommended at what age, with clear, specific provisions for catch-up vaccination and different risk groups.[50] Most vaccines on the schedule were recommended for routine use, since their benefits clearly outweighed the risk for the relevant population groups.

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[46] *Id*.
[47] Grace Lee et al., *Updated framework for Development of Evidence-Based Recommendations by the Advisory Committee on Immunization Practices*, 67 Morb. Mortal. Wkly. Rep. 1271, 1271 (2018), https://tinyurl.com/3keprskc.
[48] *Id*.; Jenny Moberg et al., *The GRADE Evidence to Decision (EtD) framework for health system and public health decisions*, 16 Health Res. Pol'y Syst. 1, 3 (May 29, 2018), https://tinyurl.com/336hzma8.
[49] ACIP, *ACIP Evidence to Recommendations Framework*, https://tinyurl.com/53wc2knc (last visited Feb. 1, 2026).
[50] CDC, *Recommended Child and Adolescent Immunization Schedule for Ages 18 Years or Younger: United States 2025*, https://tinyurl.com/nhc9wmkh (last accessed Feb. 2, 2026); CDC, *Healthcare Professionals: Child and*

A minority of vaccines were recommended for only some populations based on their very specific risks and benefits. For example, Dengvaxia, the vaccine for protection against dengue, a disease that is uncommon in the U.S., was not routinely recommended for most children. However, because Dengvaxia significantly reduces the risk of hospitalization from a subsequent infection for children 9 years of age and older, it was recommended for children in that age group who live in areas with endemic dengue (Puerto Rico, Guam, U.S. Virgin Islands, etc.) and had a laboratory-confirmed prior dengue infection.[51] The ACIP workgroup determined that the vaccine should be recommended only to this group because it can also increase risk of hospitalization in children who have never previously had dengue.[52] By using standardized frameworks for evidence-based risk-benefit analyses, ACIP made a well-supported, transparently-developed recommendation that clearly defined and distinguished the group of American children who would benefit from dengue vaccination from those who would not benefit or would be put at increased risk from the vaccine.

Likewise, prior to 2025, SCDM was reserved for the rare vaccines that might benefit a group of people but would not provide widescale population benefits. For the childhood schedule, this applied only to meningococcal serogroup B (menB) vaccines prior to 2025.[53] Although meningococcal disease is not common in the U.S., the risk is significantly higher in university settings[54] and the vaccine's risks are also relatively low. Hence, ACIP recommended SCDM, which calls for clinicians discussing with patients their specific risks of menB (e.g., were they

Adolescent Immunization Schedule by Age, https://tinyurl.com/5bmym6z8 (last accessed Feb. 2, 2026).

[51] Gabriela Paz-Bailey et al., *Dengue Vaccine: Recommendations of the Advisory Committee on Immunization Practices, United States, 2021*, 70 Morb. Mortal. Wkly. Rep. 1, 5 (Dec. 17, 2021), https://tinyurl.com/yc5v4atf.

[52] *Id*.

[53] There are two types of meningococcal vaccines used in the United States. Before the schedule change, ACIP had a routine recommendation for adolescents for MenACWY, which covered meningococcal serogroups A, C, W and Y. The recommendation discussed here (and cited in footnote 56, *infra)* is the vaccine against serogroup B of the disease, MenB. *See* Sarah Schillie & Lucy A. McNamara, *Meningococcal Vaccination in the United States: Past, Present and Future*, 27 Pediatric Drugs 331, 332–33 (2025).

[54] Lauren M. Weil et al., *Risk Factors for Serogroup B Meningococcal Disease Among College Students*, 10 Open Forum Infectious Diseases 1, 1 (Dec. 2, 2023), https://tinyurl.com/499yv7dw.

going to college and residing in a dormitory?).[55] The vaccine was also recommended for those at high risk who are aged 10 and over.[56]

SCDM, however, can impede access even when its recommendation follows from an evidence-based process. For example, a single dose of the respiratory syncytial vaccine (RSV) was recommended subject to SCDM for adults aged 60 and older at the June 2023 ACIP meeting.[57] At the June 2024 meeting, ACIP replaced SCDM with risk-based recommendations, since clinicians reported difficulty and confusion implementing SCDM.[58]

The discussion above demonstrates that the schedule prior to the changes at issue in this lawsuit was developed through a process that involved a thorough, science-based, transparent assessment of the evidence that reflected global best practices. Generally, presentations using the GRADE and EtR frameworks were made at several ACIP meetings before a vote occurred, granting committee members the opportunity to examine the data, evaluate the data, and deliberate on issues.[59] If more data was needed, ACIP could and did ask for it. Stakeholders were given a chance to present evidence and address it before ACIP voted on and CDC endorsed recommendations for specific vaccines.

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[55] Jessica R. MacNeil et al., *Use of Serogroup B Meningococcal Vaccines in Adolescents and Young Adults: Recommendations of the Advisory Committee on Immunization Practices*, 64 Morb. Mortal. Wkly. Rep. 1171, 1174–75 (2015), https://tinyurl.com/yc6fets4.

[56] The increased-risk group for menB is specifically defined as "persons who have persistent complement component deficiencies; persons who have anatomic or functional asplenia; microbiologists who routinely are exposed to isolates of *Neisseria meningitidis*; and persons identified to be at increased risk because of a serogroup B meningococcal disease outbreak"; Monica E. Patton et al., *Updated Recommendations for Use of MenB-FHbp Serogroup B Meningococcal Vaccine — Advisory Committee on Immunization Practices, 2016*, 66 Morb. Mortal. Wkly. Rep. 509, 513 (2017), https://tinyurl.com/3kkmz3br.

[57] Michael Melgar et al., *Use of Respiratory Syncytial Virus Vaccines in Adults Aged ≥60 Years: Updated Recommendations of the Advisory Committee on Immunization Practices – United States, 2023*, 72 Morb. Mortal. Wkly. Rep. 793, 793–801 (2023), https://tinyurl.com/29bww45w.

[58] Amadea Britton et al., *Use of Respiratory Syncytial Virus Vaccines in Adults Aged ≥60 Years: Updated Recommendations of the Advisory Committee on Immunization Practices – United States*, 2024, 73 Morb. Mortal. Wkly. Rep. 696, 699–700 (2024), hhttps://tinyurl.com/2r3a47rb.

[59] Edwin J. Asturias et al., *supra* note 28.

3. The Recommendations Offered in the Assessment Were Not Based on the GRADE and EtR Frameworks; Nor Were They Grounded in Any Scientifically Recognized Decision-Making Framework

The Assessment offers no indication that its authors relied on the GRADE or EtR frameworks in reaching their recommendations to dramatically alter the schedule.[60] In addition, many factors that are critical to the frameworks were left unaddressed. Notably, the Assessment does not consider the impact of the various changes it proposes for population health. For the decision downgrading the recommendation for rotavirus disease, for example, the authors do not even attempt to estimate the impact of their decision to recommend SCDM on childhood hospitalizations or deaths. Instead, after noting the history of a prior version of the vaccination and that Belgium, Denmark, and Portugal do not recommend it universally, the Assessment states "[r]easonable people can reach different conclusions about recommending the rotavirus vaccine for all children."[61]

The Assessment's discussion of other vaccines is similarly cursory in relation to desirable and undesirable effects of the vaccines and the changes that are recommended. There are occasional references to specific studies, but there is no thorough review of the literature or overall assessment of the evidence; and there is no real discussion of the certainty of the evidence or its limitations. There is also no discussion or application of any consistent framework. This is a process significantly inferior to the one that ACIP used previously.[62] These failures are not simply technical process flaws; by failing to adhere to a clear framework, and without considering the

[60] *Id.*
[61] *Id*. at 21.
[62] *See, e.g.*, Advisory Committee on Immunization Practices, *ACIP Grading of Recommendations Assessment, Development and Evaluation (GRADE) for Hepatitis B (HepB) Vaccine in Adults (ACIP)* (Sept. 9, 2024), https://tinyurl.com/4dvda32m.

totality of the evidence, the Assessment was vulnerable to biased and motivated reasoning, a far cry from the best practices that the President sought.

V. The Assessment Relied on Erroneous and Misleading Comparisons to the Vaccine Schedules in Other Countries to Conclude that Fewer Vaccinations Should be Recommended by the CDC

1. The Assessment Relies Heavily on a Misleading Tally of Vaccine Recommendations in Twenty So-Called "Peer Countries"

In lieu of a discussion of best practices among peer nations, the Assessment offers a simplistic tallying of the number of vaccines recommended by different countries, and the unsupported argument that the U.S. should follow not the decision-making methodology those countries use, but the recommendations that some other nations follow. In so doing, the Assessment ignores the fact that even though most countries utilize relatively similar systematic frameworks, *supra*, the frameworks themselves allow for different recommendations in different countries, as they take into account country-specific issues such as the burden of the disease, stakeholder acceptability, and the feasibility of implementing a given recommendation.[63] Many countries also consider costs and cost-effectiveness,[64] while some countries consider the structure of national health care and vaccine delivery systems.[65] As the European Centers for Disease Control has explained:

> Based on the scientific evidence available, each country tailors its immunisation programs and vaccination schedules to the local context and needs. These local considerations include a wide range of aspects concerning the vaccine itself (safety, efficacy, effectiveness) and the local disease epidemiology. In addition, countries also consider programmatic aspects, such as the need to integrate vaccination within the specific health system services, expected uptake by target groups, expected demand, costs and social

[63] Alonso-Coello, *GRADE Evidence to Decision (EtD) Frameworks: A Systematic and Transparent Approach to Making Well Informed Healthcare Choices. 1: Introduction, supra* note 44.
[64] Donadel, *supra* note 35, at 1905.
[65] Publications Office, *supra* note 35.

considerations, such as equitable access.[66]

As a result, countries that utilize relatively similar methodologies may arrive at different conclusions about whether to recommend a given vaccine universally, not because they differ in their assessment of the vaccine's health risks and benefits, but because they are making decisions for different epidemiological, economic, and cultural environments. For the U.S. in particular, such considerations would need to take into account that the U.S. population has a lower life expectancy and reduced access to health care than the populations in many other high-income countries; the U.S. also has a relatively weak public health infrastructure for infectious disease surveillance.[67]

The Assessment overlooks these critical nuances, substituting a simplistic tallying of the number of vaccines recommended in the 20 countries it designates as "peer countries"[68] for any consideration of what constitutes best practices or why particular vaccines are or are not recommended in those countries. What emerges is an analysis that departs dramatically from best practices, or indeed, the practice followed in any peer country, and instead simply confirms pre-existing beliefs. It is also riddled with errors. As one example, the Assessment states that Belgium does not recommend the rotavirus vaccine. This is incorrect. That vaccine has been recommended in Belgium since 2007.[69]

Given the lack of any recognizable scientific methodology in the Assessment, it is not surprising that it draws unsubstantiated comparisons and conclusions when comparing the pre-2025 U.S. schedule with the recommendations of other nations. For example, comparing the U.S.

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[66] European Centre for Disease Prevention and Control, *Vaccine Monitoring*, https://tinyurl.com/y4r575wu (last visited Feb. 9, 2026).
[67] Irene Papinicolas et al., *Comparing U.S. Prevention Efforts to Other High-Income Countries*, 10 Lancet Pub. Health e988, e988 (2025), https://tinyurl.com/5cce5hez. *See generally* Marc Lipsitch et. al., *Infectious disease surveillance needs for the United States: lessons from Covid-19*, 12 Front Public Health. 1408193 (July 2024).
[68] The Assessment fails to explain how or why it designated certain countries to be on the list of peer countries. Its list does not comport with other widely used groupings of countries, for example, the 27 countries of the European Union or the 38 countries of the OECD.
[69] WHO, *Introduction of Rotavirus*, https://tinyurl.com/38w5jmny (last visited Feb. 9, 2026).

to the 20 peer countries, it argues that the U.S. is an "outlier" in terms of the number of vaccines given and doses recommended.[70] However, Table 2 in the Assessment, which presents the data that presumably proves this point, is misleading. For example, it lists the COVID-19 vaccine as one that is recommended in the U.S., even though the CDC had previously downgraded this vaccine from one that is universally recommended to one subject to SCDM.[71] Without counting the COVID-19 vaccine, the total number of vaccines recommended by the U.S. when the Assessment was written would have been 16, the same number that Table 2 shows as recommended in Greece, and only one more than is recommended in Australia, Canada, Spain, and the United Kingdom.

Further, because the COVID-19 and influenza vaccines are given annually, their inclusion in Table 2's tally of doses gives the erroneous impression that the U.S. recommends far more vaccine doses than other countries. If the COVID-19 and influenza doses were removed, the total number of doses of all vaccines recommended in the United States would be 52, fewer than the total number in many countries, and close to the numbers recommended in several peer countries that do not recommend the COVID-19 or influenza vaccines (e.g., Switzerland, 46; Italy, 47; France, 45-46).[72]

2. Contrary to the Assessment's Claim, the U.S. Was Not an Outlier with Respect to Vaccine Recommendations Prior to January 2026, But Is Now an Outlier.

The U.S. schedule *prior* to the January 5, 2026 change was also well within the mainstream of peer countries in other important ways. For example, eight of the peer countries discussed in

[70] Assessment, *supra* note 8, at 15.
[71] CDC, *CDC Immunization Schedule Adopts Individual-Based Decision-Making for COVID-19 and Standalone Vaccine for Chickenpox in Toddlers* (Oct. 6, 2025), https://tinyurl.com/ytjzxewa.
[72] Assessment, *supra* note 8, at 15.

the Assessment recommend the influenza vaccine for children,[73] one of the vaccines that, following O'Neill's Decision Memo, is no longer recommended for all children. Likewise, 15 out of the 20 peer countries recommend vaccinating against meningococcal disease, as did the U.S. prior to the January 5 changes.[74] With the changes implemented on January 5, the U.S. became the outlier with respect to that vaccine.

The U.S. has also become an outlier with respect to the Hepatitis B vaccine. In December 2025, CDC ended its universal recommendation for the Hepatitis B vaccine, opting instead to recommend SCDM, except for children whose mother test positive for the virus or whose infection status is unknown.[75] According to Table 2 of the Assessment, that leaves the U.S. as one of only three peer countries to not include a universal recommendation for the Hepatitis B vaccine for infants. Likewise, following the January 5 change to the schedule, the U.S. is now one of only two of the 20 peer nations that the Assessment compares to the U.S. that does not universally recommend the rotavirus vaccine.[76]

Even by the Assessment's own methodology, which seems to give great weight to the total number of vaccines recommended, the changed schedule moves the U.S. out of alignment with countries that the Assessment considers to be peers. The new schedule, for example, recommends only 11 vaccines be administered to all children, a number that is lower than that in any so-called peer country, except Denmark.[77]

3. The Assessment's Reliance on Denmark as a Model for U.S. Vaccine Policy Ignores Significant Distinctions Between Denmark and the United States.

[73] *Id*.
[74] *Id*.
[75] CDC, *CDC Adopts Individual-Based Decision-Making for Hepatitis Be Immunization for Infants Born to Women who Test Negative for Hepatitis B Virus* (Dec. 16, 2025), https://tinyurl.com/2hyrh5da.
[76] Intern'l Vaccine Access Ctr, *VIEW-hub*, https://tinyurl.com/he942zvu (last visited Feb. 9, 2026).
[77] Assessment, *supra* note 8, at 15.

That the changed schedule moves the U.S. vaccine schedule close to that of Denmark is not coincidental. In December 2025, Tracy Beth Høeg, one of the two authors of the Assessment, gave a presentation to ACIP comparing the U.S. schedule unfavorably to that in Denmark, suggesting that Denmark achieves high levels of vaccination by recommending fewer vaccines.[78] President Trump's December 5 memorandum likewise called out Denmark, as did the HHS press release announcing O'Neill's decision to alter the schedule.[79]

Denmark's approach, however, serves as a poor model for the U.S. schedule.[80] First, its population is smaller than New York City's.[81] Denmark's population is also far more homogenous than the U.S. population.[82] In addition, in contrast to the U.S. which has a largely private, market-driven system, Denmark has a universal, tax-funded healthcare system that emphasizes free access.[83] That makes it is easier for Danes to have and pay for the type of conversations with their healthcare providers that the CDC now recommends for the Hepatitis A, Hepatitis B, rotavirus, meningococcal, influenza, and COVID-19 vaccines. It also means that Danish families are better able to access and pay for treatments for vaccine-preventable diseases than U.S. families. In addition, the Danish Vaccination Register tracks all vaccinations, allowing for automatic, personalized electronic reminders sent via e-Boks (a national email system) to residents or parents ensuring close to 100% of citizens are reached with these communications.[84] Yet, even with these

[78] *Id*. at 10.
[79] *CDC Acts on President Memorandum*, *supra* note 12; Directive, *supra* note 1.
[80] Lone Graff Stensballe, *Context Matters: Comparing the United States and Denmark in Vaccine-Preventable Disease Risk*, 3 Ann Intern Med. 1, 1 (Feb. 3, 2026), https://tinyurl.com/3udhnzma.
[81] U.S. Census Bureau, *U.S. Census Bureau QuickFacts: New York City, New York; New York; United States*, https://tinyurl.com/4puyp4w6 (last visited Feb. 9, 2026); Statistics Denmark, *Population Figures, Stat. Den. (Den.)*, https://tinyurl.com/kbtf74ks (last visited Feb. 9, 2026).
[82] Georgios Athanasiadis et al., *Nationwide Genomic Study in Denmark Reveals Remarkable Population Homogeneity*, 204 Genetics 711, 711–12 (Oct. 2016), https://tinyurl.com/3pk6y4h2.
[83] Hans Okkels Birk et al., *Denmark: Health system review*, 42 Health Sys. in Transition 1, at PDF 17 (2024), https://tinyurl.com/5n6maw8v.
[84] T. Funk et al, *Effect of a proactive childhood vaccination reminder system on vaccination coverage and uptake in Denmark: A register-based cohort study*, 54 Vaccine 126934, 1 (Apr. 2025).

advantages, Denmark's decision not to recommend some vaccines universally has had adverse consequences. For example, despite the strengths of the Danish health system, the rate of hospitalization for rotavirus is nearly 10-times higher than that in the U.S.[85]

Such factors, and many more, suggest that the choices that are correct for Denmark are not necessarily sound for the U.S. In the least, a scientifically meaningful re-assessment of the U.S. schedule would need to consider the material differences and similarities between the two nations without simply concluding that the U.S. schedule should (for the most part) mirror Denmark's because that country has relatively high levels of trust in vaccines. And to the extent that a scientifically meaningful review sought to compare the U.S. schedule to that in other nations, it should look more closely to larger, more diverse nations, such as Canada and the United Kingdom, than small homogenous countries such as Denmark. Most importantly, a methodologically sound review of the schedule would utilize and clearly state that it was utilizing the type of internationally-recognized decision-making frameworks that ACIP followed prior to 2025. The Assessment that O'Neill relied upon did none of those things. Instead, it recommended – and the Decision Memo imposed – dramatic changes to the nation's vaccine schedule based on little more than fallacious comparisons and motivated reasoning.

VI. CONCLUSION

For the above-stated reasons, Amicus Curiae Defend Public Health respectfully request that Plaintiffs' requested relief be granted.

[85] Minesh Shah et al., *Annual changes in rotavirus hospitalizations rates before and after rotavirus vaccine implementation in the United States*. 13.2 PLOS One 1, 1 (2018), https://tinyurl.com/y7muj36p; Gry St-Martin et al., *Selection and Interpretation of Scientific Evidence in Preparation for Policy Decisions: A Case Study Regarding Introduction of Rotavirus Vaccine Into National Immunization Programs in Sweden, Norway, Finland, and Denmark*, 6 Frontiers in Pub. Health 1, 1 (2018), https://tinyurl.com/hm2tnttd.

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Respectfully submitted,

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CERTIFICATE OF SERVICE

In accordance with Local Rule 5.4(c), I hereby certify that this document filed through the ECF system will be sent electronically to the registered participants on the Notice of Electronic Filing (NEF) on February 9, 2026.

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