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

Leave to file granted on December 16, 2025

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, academic scientists working in biomedical and clinical research, epidemiology, and other areas of public health, legal scholars, and current and former public health officials. 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 vaccination for infectious diseases.

II. SUMMARY OF ARGUMENT

Federal vaccination policy shapes access to vaccines and health care in ways that matter every day. It determines whether families can secure routine protection, whether hospitals have the flexibility to manage emergencies, and whether health care workers can safely sustain the system. Most importantly, it affects the health of individuals, families, and communities. In 2025, federal policy towards vaccination was dramatically altered in ways that impeded Americans' access to vaccines and care. After U.S. Department of Health and Human Services ("HHS") Secretary Robert F. Kennedy Jr. (the "Secretary") abruptly fired the expert members of the Advisory Committee on Immunization Practices ("ACIP")[1] in June 2025, the newly reconstituted committee broke from longstanding scientific and governance norms. It reversed its prior universal recommendation for COVID-19 vaccination of all individuals over six months of age, instead advising that vaccination decisions be made through "shared clinical decision-making" ("SCDM").[2] This change introduced uncertainty where clarity is essential. Indeed, the change set

[1] ACIP is an independent panel that was designed to be comprised of medical and public health experts in order to provide evidence-based recommendations to the Centers for Disease Control and Prevention ("CDC") on the use of vaccines in the United States. As discussed further below, ACIP's recommendations are not just recommendations. Once adopted by the CDC, they have direct and immediate consequences for access to vaccines.

[2] SCDM refers to a collaborative approach in which health care decisions are supposed to be tailored to the individual

in motion consequences that ripple across patients, providers, and public health infrastructure.

First, this downgrade immediately introduced significant uncertainty and complexity to the process of administering COVID-19 vaccines in pharmacy settings, threatening vaccine access. Pharmacists—who play a vital role in the administration of vaccinations nationwide—now face unclear scope-of-practice rules, ambiguous liability exposure, and operational barriers in settings optimized for rapid vaccine administration rather than individualized SCDM consults. These uncertainties threaten the most efficient and widely available vaccination channel, particularly in rural and underserved communities where pharmacies often serve as the only access point.

Second, pregnant patients and children—populations at heightened risk from many infectious diseases—are most affected by these disruptions. The Vaccines for Children ("VFC") Program, which covers roughly half of U.S. children, experienced authorization delays and shipment interruptions, leaving vulnerable families without doses during critical weeks. For pregnant patients, the downgrade undermines access to a vaccine that leading medical organizations identify as an essential component of prenatal care. These barriers compound existing inequities and leave those most medically vulnerable without reliable protection.

Third, reduced vaccination coverage burdens hospitals and the health-care workforce. When uptake declines, preventable COVID-19 admissions rise, emergency departments congest and admitted patients board while waiting for inpatient beds. Lower coverage also increases nosocomial COVID-19 and heightens exposure for health-care workers, driving absenteeism, overtime, and burnout. In a system already operating near its capacity ceiling, vaccination prevents avoidable hospitalizations, preserves ICU flexibility, and supports workforce stability.

patient. Although definitions and implementation methods vary, there is broad agreement that SCDM relies on communication between clinician and patient about available care options, with the intended goal of reaching a personalized decision.

The ramifications of ACIP's reconstitution and SCDM determination cannot go unchecked. ACIP recommendations are the backbone of the nation's immunization policy because they become the official U.S. immunization schedule once adopted by the CDC. They inform standard that interacts with federal and state laws to affect accessibility, insurance, and liability.

Defend Public Health respectfully asks the Court to restore the integrity of vaccine policymaking, secure reliable access for pregnant patients and children, and strengthen hospital readiness and workforce resilience by granting Plaintiffs' requested relief.

III. FACTUAL BACKGROUND

For decades, ACIP operated under a framework designed to ensure continuity, transparency, and scientific rigor. That foundation began to erode in mid-2025, when the committee was abruptly reconstituted, its evidence-based methodologies set aside, and its recommendations reshaped without the safeguards that historically anchored vaccine policy. This progression—from wholesale membership changes to the abandonment of Grading of Recommendations Assessment, Development and Evaluation ("GRADE") and Evidence-to-Recommendation ("EtR") frameworks—marked a decisive break from norms that have guided vaccine decision-making for years and led to the downgrade of COVID-19 vaccination.

A. ACIP's Abrupt Reconstitution Broke with Longstanding Norms of Transparency and Expertise.

In June 2025, the Secretary dismissed all 17 sitting members of ACIP—a panel historically composed of experts in immunology, epidemiology, pediatrics, and infectious disease. This rapid wholesale removal was unprecedented because past administrations made changes gradually, preserving institutional knowledge and scientific continuity.

Within forty-eight hours, eight new members were appointed.[3] While credentialed in

[3] Global Biodefense Staff, *Unqualified ACIP Appointees Threaten U.S. Vaccine Policy Under RFK Jr.*, Global

various fields, several lacked core expertise in vaccinology and infectious disease—disciplines essential for evaluating vaccine safety and efficacy. One appointee is a psychiatrist and nutritional scientist with limited experience in vaccine research.[4] Another is a professor of operations management whose work focuses on analytics, not clinical science.[5] A third, though medically trained, is widely known for promoting unproven claims about mRNA vaccines.[6] Leading medical associations, including the American Medical Association and the American Academy of Pediatrics, criticized the appointments as lacking transparency and scientific qualifications.[7]

The speed of this reconstitution also marked a sharp break from ACIP's established process. Historically, membership changes have followed a transparent, months-long protocol: public calls for applications, CDC-led vetting, interviews, background checks, and evaluations of ethical standing, including financial conflicts.[8] That process safeguards independence and public trust. Its abandonment signaled a profound shift in the nation's vaccine oversight framework—one that reverberated through every subsequent decision, including the downgrade of COVID-19 vaccination to shared clinical decision-making.

B. ACIP's Abandonment of Evidence-Based Frameworks Marked a Sharp Break from Scientific Norms.

ACIP previously relied on two frameworks to guide recommendations: the GRADE methodology and EtR framework.[9] Adopted in 2010, GRADE provides a systematic approach to

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Biodefense (June 23, 2025), https://tinyurl.com/3yyc3ruh; Lisa Schnirring & Mary Van Beusekom, *RFK announces new ACIP members, including vaccine critics*, CIDRAP (June 12, 2025), https://tinyurl.com/49j9eupf.

[4] Advisory Board, *ACIP Members* (June 12, 2025), https://tinyurl.com/2rjrj3ky.

[5] *See* Advisory Comm. on Immunization Prac., *ACIP Committee Members*, Ctrs. for Disease Control & Prevention https://tinyurl.com/yx2wymj7 (last visited Dec. 11, 2025); Vaidehi More, *Understanding the Debate on Health Secretary Kennedy's Vaccine Panelists*, All. for Civic Engagement (Oct. 1, 2025), https://tinyurl.com/mssb5hhn.

[6] Gavin Yarney, *The dismantling of the U.S. vaccine regulatory framework*, 62 Vaccine 127557 (2025).

[7] *See* Bobby M. Mukkamala, *AMA statement on Advisory Committee on Immunization Practices*, Am. Med. Ass'n (June 12, 2025), https://tinyurl.com/3bu54psh; Melissa Jenco, *AAP: New CDC vaccine advisers a 'radical departure' from committee's mission*, AAP News (June 12, 2025), https://tinyurl.com/34dyscht.

[8] *See* More, *supra* note 5.

[9] *See* Ctrs. for Disease Control and Prevention, *ACIP GRADE Handbook for Developing Evidence-Based Recommendations: Chapter 1: Introduction* (Apr. 22, 2024), https://tinyurl.com/5ckyj4pw; Advisory Comm. on

assess the quality of evidence, including ratings of high, moderate, low, and very low based on factors such as study design, bias risk, and result consistency.[10] GRADE ensures recommendations rest on rigorous, transparent, and reproducible analysis—not anecdote or conjecture.[11]

In 2018, ACIP added the EtR framework to complement GRADE.[12] EtR translates evidence into policy by asking structured questions about feasibility, equity, and public health impact.[13] The index of EtR framework describes information to consider in "making recommendations move from evidence to decisions."[14] Together, these frameworks created a standardized, publicly documented process for evaluating vaccine recommendations—one that has anchored ACIP's credibility for years.

That continuity ended in September 2025. When ACIP downgraded COVID-19 vaccination to SCDM for all individuals aged six months and older, [15] it did so without applying GRADE or EtR.[16] The required formal vote to suspend these frameworks was never taken, despite their longstanding adoption and endorsement.[17] Instead, the meeting that led to ACIP's SCDM recommendation was marked by informal discussion and selective citation of fringe studies, rather than the structured, evidence-based deliberation these frameworks require.[18] The absence of

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Immunization Prac., *Evidence to Recommendations Frameworks*, Ctrs. for Disease Control & Prevention https://tinyurl.com/mr3ftd3s (last visited Dec. 11, 2025).

[10] *See* Gordon H. Guyatt et al., *GRADE: An Emerging Consensus on Rating Quality of Evidence and Strength of Recommendations*, 336 BMJ 924, 926 (2008).

[11] *See id.*

[12] *See* Grace Lee et. al., *Updated Framework for Development of Evidence-Based Recommendations by the Advisory Committee on Immunization Practices*, 67 Morbidity & Mortality Wkly. Rep. 1271, 1271 (2018).

[13] *See id.*

[14] Advisory Comm. on Immunization Prac., *supra* note 9.

[15] *ACIP Recommends COVID-19 Immunization Based on Individual Decision-making*, U.S. Dep't of Health & Hum. Servs. (Sept. 19, 2025), https://tinyurl.com/yxjnuuhs. Notably, in May 2025 the Secretary issued a backdated Directive which called for "healthy" children and pregnant people to be taken off the CDC schedule for COVID-19 vaccination. In August 2025, the CDC revised its immunization schedule to comply with the Directive, bypassing ACIP entirely. This decision was hastily ratified by the newly-formed ACIP in its September announcement. *See* Third Am. Compl. 3–5, Dkt. No. 139; Mot. to Dismiss 4, Dkt. No. 145.

[16] Jay K. Varma, *Inside the ACIP Shake-Up: How Former CDC Experts Reacted to RFK Jr.'s New Vaccine Committee*, Medium (Sept. 22, 2025), https://tinyurl.com/8sucvn22.

[17] *Id.*

[18] *Id.* ("The members' questions, concerns, and musings are very interesting. They're worthy of very thoughtful

GRADE and EtR is not a procedural footnote; it represents a fundamental departure from the norms that have safeguarded vaccine policymaking for decades.

C. CDC's Adoption of SCDM Introduced Uncertainty with Far-Reaching Consequences.

On October 6, 2025, the CDC adopted ACIP's recommendation and integrated it into the national immunization schedule.[19] The update marked a significant shift. According to CDC's own guidance, some vaccines are recommended universally—"routine, catch-up, or risk-based"—while others are classified under SCDM, meaning they should be offered only after an individualized discussion between provider and patient.[20] Until 2025, very few vaccines were designated SCDM. On its website, CDC explains that vaccines placed in the SCDM category provide "no or minimal benefits" for the general population.[21] The impact of this decision is compounded by the FDA's August 2025 decision to limit its approval of the COVID-19 vaccine to adults 65 and older and to younger people with certain underlying health conditions, effectively moving a large portion of routine COVID-19 vaccinations into off-label territory.[22]

The real-world implications of these changes are profound. Although ACIP recommendations and CDC adoptions of them are often described as "advisory," they interact with federal and state laws in ways that affect insurance coverage and provider authority.[23] Changing a vaccine's recommendation from universal to SCDM introduces legal uncertainty about eligibility,

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undergraduate students.").

[19] *CDC Adopts Individual-Based Decision for Immunization Schedule*, Ctrs. for Disease Control & Prevention (CDC) (Oct. 6, 2025), https://tinyurl.com/57xsf8ep.

[20] Advisory Committee on Immunization Practices (ACIP), *ACIP Shared Clinical Decision-Making Recommendations*, Ctrs. for Disease Control & Prevention (Jan. 7, 2025), https://tinyurl.com/mpdufhd8.

[21] *Id*.

[22] *See* Rob Stein, *The latest COVID vaccines come with new FDA limits*, NPR (Aug. 27, 2025), https://tinyurl.com/2srvye6d.

[23] Public Health Service Act § 2713, 42 U.S.C. § 300gg-13; Richard Hughes IV & Dorit R. Reiss, *Imperfect Access: Structural Barriers and External Threats to Preventative Care*, 34 Annals of Health L. & Life Sci. 101, 112 (2025).

reimbursement, and pharmacists' authority to administer the vaccine as they had.[24] That uncertainty is real. It affects access in ways that fall hardest on those who are most medically vulnerable: pregnant people, children, older adults, immunocompromised individuals, and communities with limited resources.[25] For these populations, the downgrade is neither a mere suggestion nor a technical adjustment; it is a barrier to protection.

IV. ARGUMENT

A. SCDM Introduces Liability Risks That Undermine Pharmacy-Based Access.

1. Pharmacies Are Central to Vaccine Access—SCDM Threatens That Role.

Pharmacies have been indispensable to the nation's COVID-19 vaccination effort. As of August 2023, pharmacists have administered more than 300 million COVID-19 vaccinations across the country,[26] and approximately 37% of all COVID-19 vaccines provided to children as of June 2022.[27] According to CDC data, large pharmacy chains and independent networks delivered nearly 68% of all COVID-19 vaccines administered from September 2022 to September 2023.[28] In the 2024 to 2025 season, the CDC estimates 90% of vaccinations were given at pharmacies.[29] Pharmacists' key role in vaccination efforts is not surprising: 90% of Americans live within 5 miles of a pharmacy.[30] For rural communities, the availability of a vaccine at a pharmacy often determines whether access exists at all.[31] This trend is only expected to grow as non-metro regions

[24] Michael D Hogue et. al., *Shared clinical decision making on vaccines: Nothing has really changed for pharmacists,* 60 J. Am. Pharmacists Ass'n e91, e92 (2020).
[25] *See infra* Section IV.
[26] Ctrs. for Disease Control & Prevention, *Federal Retail Pharmacy Program for COVID-19 Vaccination* (Aug. 18, 2023), https://tinyurl.com/2f8v6ucp.
[27] Yoonjae Kang et. al., *Where do children get vaccinated in the U.S.? Parental experiences, attitudes, and beliefs about place of vaccination with a focus on pharmacies and schools*, 62 Vaccine 126801, 1 (2025).
[28] Roua El Kalach et. al., *Federal Retail Pharmacy Program Contributions to Bivalent mRNA COVID-19 Vaccinations Across Sociodemographic Characteristics — United States, September 1, 2022–September 30, 2023*, 73 Morbidity & Mortality Wkly. Rep. 286, 287 (2024).
[29] Lauren Gardner, *The Fall Trip to the Pharmacy for a Covid Shot May Be Strewn with Obstacles,* Politico (Aug. 22, 2025), https://tinyurl.com/y6brrdnw.
[30] El Kalach et. al., *supra*, note 28 at 286.
[31] Sura O. AlMahasis et al., *Pharmacy-Based Immunization in Rural USA During the COVID-19 Pandemic: A Survey*

face an accelerating decline in access to traditional primary care providers.[32]

This critical access channel is newly imperiled. Many state laws governing pharmacists' authority to administer vaccines are tied directly to ACIP recommendations.[33] When COVID-19 vaccination moved to SCDM, pharmacists' authority to provide vaccines under those laws became less clear.[34] Pharmacists who once operated under clear, universal guidance now confront ambiguous standards that discourage—and in some states may even preclude—vaccination.[35] The SCDM designation also introduces liability concerns.[36] The result is predictable: fewer access points for COVID-19 vaccination and greater strain on a system already operating near capacity.

Pharmacists' ability to administer vaccines is determined by their scope of practice, which, in turn, is regulated by state law.[37] Critically, states often tie pharmacists' scope of practice to CDC designations and ACIP recommendations.[38] For example, in Maine, pharmacists are permitted to administer vaccines, "recommended by the United States Centers for Disease Control and Prevention Advisory Committee on Immunization Practices, or successor organization, for administration to a person 18 years of age or older."[39] In Vermont, pharmacy technicians can administer vaccines "pursuant to the schedules and recommendations of the Advisory Committee on Immunization Practices' recommendations for the administration of immunizations, as those recommendations may be updated from time to time."[40]

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of Community Pharmacists from Five Southeastern States, 41 Vaccine 2503, 2504 (2023).

[32] Health Res. & Servs. Admin., Bureau of Health Workforce, *State of the Primary Care Workforce, 2024* (Nov. 2024), https://tinyurl.com/3dxh4366.

[33] *See* Jennifer Kates et al., *Tracking State Actions on Vaccine Policy and Access*, KFF (Sept. 24, 2025), https://tinyurl.com/3m6a5cy6.

[34] *See* Spreeha Choudhury, *Implications for Pharmacies Navigating Shared Clinical Decision-Making in Vaccination*, Pharmacy Times (June 13, 2024), https://tinyurl.com/2s43rbpu.

[35] *Id*.

[36] *See infra* Section IV.A.2.

[37] *See* Jennifer Kates et al., *supra* note 33.

[38] *Id.*

[39] 32 M.R.S. § 13831(2) (2025).

[40] 26 Vt. Stat. § 2042a (2024).

In those states where scope of practice is tied to ACIP recommendations, the SCDM classification complicates pharmacists' ability to provide immunizations. When ACIP recommended the COVID-19 vaccine universally, pharmacists in these states could provide the vaccine confidently and automatically because this was the "default," reflecting a shared understanding in the medical community that COVID-19 vaccination was a benefit to the person receiving it.[41] Now, as the CDC itself explains:

> [T]here is no default—the decision about whether or not to vaccinate may be informed by the best available evidence of who may benefit from vaccination; the individual's characteristics, values, and preferences; the health care provider's clinical discretion; and the characteristics of the vaccine being considered. There is not a prescribed set of considerations or decision points in the decision-making process.[42]

This is not a recommendation but the negation of one. In addition to using phrases like "clinical discretion" and "best available evidence" without definition, ACIP's new recommendation asks pharmacists to weigh numerous vague variables and hypotheticals to conduct an individualized assessment that could be questioned by future regulators.[43]

These individualized assessments are particularly difficult for pharmacists. As discussed above, the SCDM recommendation requires providers to engage patients in collaborative discussions about the risks, benefits, and personal preferences related to vaccination.[44] Such conversations, which require time, privacy, and an appropriate environment, are difficult to manage and unrealistic in high-volume pharmacy settings where pharmacists juggle multiple responsibilities beyond consultations.[45] Under a universal recommendation, pharmacists followed

[41] CDC, *ACIP Shared Clinical Decision-Making Recommendations* (Jan. 7, 2025), https://tinyurl.com/bdny5hcf.
[42] *Id*.
[43] *Impact of the Advisory Committee on Immunization Practices Recommendations on State Law*, Ass'n of State & Territorial Health Officials (June 23, 2025), https://tinyurl.com/39pabff2.
[44] *See* Choudhury, *supra* note 34.
[45] *Id*.

a simple, highly efficient process for vaccinating patients. Now, in states with scope of practice laws tied to ACIP recommendations, the pharmacists' once-straightforward role becomes uncertain and complex. Pharmacists must now create an evidentiary foundation for vaccine recommendation. Under SCDM, pharmacists are expected to make recommendations based on independent authority that stretches the boundaries of their scope of practice.[46] Faced with uncertainty and potential pitfalls, pharmacists might avoid SCDM vaccines entirely.

2. SCDM May Impact Pharmacists' Authority and Immunity Granted by the PREP Act.

The Public Readiness and Emergency Preparedness Act ("PREP") authorizes the Secretary of HHS to issue declarations that provide liability immunity for the manufacture, distribution, and administration of designated medical countermeasures during a public health emergency.[47] Congress granted this liability protection because it recognized that liability concerns could deter manufacturers from manufacturing and clinicians from administrating vaccines and other medical countermeasures during public health emergencies.[48] The PREP Act also allows HHS to expand who may administer these countermeasures, in some instances overriding state scope of practice laws.[49] These temporary measures are designed to empower health care providers to respond rapidly and decisively during public health emergencies, carrying out essential duties without the burden of potential litigation for good-faith actions.[50] However, the PREP Act's immunity provisions depend upon the issuance and language of a declaration issued by the Secretary of HHS.

Notably, these protections were invoked in early 2020 to address the developing COVID-

[46] *Id.*
[47] Public Readiness and Emergency Preparedness Act ("PREP Act"), Pub. L. No. 109-148, div. C, § 2, 119 Stat. 2818 (2005) (codified at 42 U.S.C. §§ 247d-6d to -6e).
[48] *See* Assessing the National Pandemic Flu Preparedness Plan: Hearing before the Comm. on Energy and Commerce, 109th Cong. 20 (2005).
[49] CRS Legal Sidebar LSB10443, The PREP Act and COVID-19: Statutory Authority to Limit Liability for Medical Countermeasures (Apr. 13, 2022), https://tinyurl.com/2r2pk2ne.
[50] PREP Act, *supra* note 47.

19 crisis through the COVID-19 PREP Act Declaration ("COVID-19 PREP Declaration").[51] Shortly thereafter, HHS used the COVID-19 PREP Declaration to grant pharmacists broad authority and immunity to order and administer COVID-19 and other routine childhood vaccines with PREP immunity.[52] In December 2024, in its twelfth amendment to the COVID-19 PREP Declaration, HHS extended pharmacists' authority and immunity to provide COVID-19 and influenza vaccines until December 2029 ("Twelfth Amendment").[53] The Twelfth Amendment limited the liability protection for pharmacists who administer COVID-19 vaccines to situations when those vaccines are (1) FDA-authorized and (2) provided in accordance with CDC/ACIP recommendations.[54] Whether this protection remains under the current administration is anyone's guess, creating uncertain liability risks that endanger access.

Complicating the Twelfth Amendment's first prong requiring FDA authorization, on August 27, 2025, following the Secretary's directive, the FDA limited its approval for the COVID-19 vaccine to individuals over 65 or those with an underlying health condition.[55] As a result, if a clinician administers the vaccine to someone outside these groups—such as a healthy 25-year-old—that would be considered "off-label." As noted above, under the language of the Twelfth Amendment, liability protection is only available for pharmacists when they administer FDA-authorized vaccinations.[56] Consequently, off-label vaccinations by pharmacists would likely automatically lose PREP protection. Because the vaccine itself is FDA-approved, some argue that

[51] *Declaration Under the Public Readiness and Emergency Preparedness Act for Medical Countermeasures Against COVID-19*, 85 Fed. Reg. 15,198 (Mar. 17, 2020).
[52] Third Amendment to Declaration Under the Public Readiness and Emergency Preparedness Act for Medical Countermeasures Against COVID-19, 85 Fed. Reg. 52,136 (Aug. 24, 2020).
[53] Twelfth Amendment to Declaration Under the Public Readiness and Emergency Preparedness Act for Medical Countermeasures Against COVID-19, 89 Fed. Reg. 99,875 (Twelfth Amendment) (Dec. 11, 2024).
[54] *Id*.
[55] Rob Stein, *The Latest COVID Vaccines Come With New FDA Limits*, NPR (Aug. 27, 2025), https://tinyurl.com/y7vhfjkt.
[56] *Id*.

PREP protections remain for all COVID-19 vaccinations, regardless of age or health status,[57] but the issue remains unsettled. Thus, pharmacists cannot be assured of PREP's liability protections.

Indeed, even if HHS were to confirm that all COVID-19 vaccinations are "FDA authorized," PREP coverage for pharmacists still requires the second prong-compliance with CDC/ACIP guidance.[58] Under a universal recommendation, that standard was clear: pharmacists did not have to question if they were in compliance with the ACIP/CDC guidance. Under SCDM, pharmacists and other vaccine providers are now expected to engage in detailed conversations with patients and adjust their actions based on risk factors in an encounter that lasts mere minutes.[59] The parameters of that conversation are left to the discretion of the vaccine provider who now must assess complex risk across a significantly heterogenous patient population.[60] Taken together, the "recommendation" for SCDM and the need for off-label administration for many patients creates liability exposure for pharmacists who were promised immunity through 2029 as essential partners in the nation's vaccination strategy. Instead of clarity, they face risk, even as the health care system continues to rely on them to protect vulnerable populations.

The uncertainty of PREP liability protection is especially significant because SCDM exposes pharmacists to heightened liability under negligence and malpractice theories. These claims are successful when a plaintiff can show that a pharmacist breached the standard of care

[57] *See* Melissa Jenco, *AAP provides logistical guidance after CDC approves COVID vaccine use*, American Academy of Pediatrics (Oct. 6, 2025) ("Clinicians administering the COVID vaccine, even off-label, could have two layers of protection — malpractice coverage and provisions under the PREP Act. The PREP Act provides broad immunity from state and federal liability, although some court decisions have narrowed the protection, and immunity is not a guarantee.")
[58] *See* Twelfth Amendment, *supra* note 53.
[59] *See* Ram Koppaka, *When ACIP Abandons Clarity, Public Health Suffers*, Health Affairs Forefront (Nov. 17, 2025), https://tinyurl.com/mrd84dkx (noting that the SCDM shift creates a "recipe for fragmentation and confusion" and that "[c]linicians are expected to adjust the discussion based on risk factors, but with no clear standards.").
[60] *See id.* (describing the broad patient population as "strikingly heterogeneous—spanning healthy young adults, people with serious chronic illness, and pregnant individuals.")

when administering the vaccine.[61] While that standard is ultimately determined by state law, its not uncommon for litigants to cite CDC/ACIP recommendations as persuasive authority in malpractice disputes.[62] At base, the SDCM designation undermines clarity; the resulting ambiguity becomes a tool for litigation. Although malpractice suits for vaccine administration remain rare, but plaintiff firms actively market these claims, signaling recognition of new opportunities.[63]

Faced with uncertain authority and increased liability exposure, it is not difficult to imagine pharmacists retreating from their vital role in vaccination en masse. That retreat will not be felt evenly. It will fall hardest on rural and underserved communities that rely on pharmacies as primary access points—communities already facing structural barriers to care. In short, the SCDM designation does more than create legal uncertainty; it threatens the backbone of vaccine delivery for the populations least able to absorb its consequences.[64]

B. Barriers to Protection Leave Children and Pregnant Patients at Great Risk.

The downgrade of COVID-19 vaccination to shared clinical decision-making has consequences that fall hardest on those least able to absorb them. Pregnant patients and children face unique risks from infectious disease, making timely vaccination critical for their health and, in the case of pregnancy, for infant protection. Yet the shift to SCDM has introduced barriers at every level—from uncertainty in pharmacy settings to delays in longstanding programs like Vaccines for Children. These disruptions do not occur in isolation; they compound existing inequities, leaving vulnerable populations without reliable access to a vaccine that remains safe, effective, and essential for preventing severe illness.

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[61] Pharmacist Malpractice: Trial and Litigation Strategy, 78 Am. Jur. Trials 407, § 4 (Laura Smalley ed., updated Dec. 2025).

[62] *See e.g., Matthews v. Aganad*, 394 Ill.App.3d 591, 333 Ill.Dec. 421, 914 N.E.2d; *Van Horn v. Hornbeak*, 2010 WL 599885, at *5 (E.D. Cal. Feb. 18, 2010).

[63] Pharmacy Error Injury Lawyer, *Liability for COVID-19 and Flu Vaccine Errors*, Pharmacy Error Injury Lawyer Blog (Dec. 16, 2021), https://tinyurl.com/yc7ybd3b.

[64] *See supra* Section IV.A.1.

Infectious disease can pose unique risks to pregnant people and children, qualifying them as distinctly vulnerable populations.[65] The American College of Obstetricians, the leading professional membership organization for obstetricians and gynecologists comprised of over 60,000 health professionals in the field, made clear in their October 2025 guidance that specific vaccines, including the COVID-19 vaccine, are "an essential part of prenatal care."[66] Vaccination is known to reduce COVID-19 risk among pregnant people and to provide passive immunity to infants.[67] The COVID-19 vaccine is further known to be safe for pregnant people, having no association with major congenital malformation, pregnancy loss, or stillbirth.[68] Obstetrician-gynecologists are not known to routinely administer vaccines outside of influenza and Tdap themselves, leaving other vital vaccines to be procured elsewhere.[69] The COVID-19 vaccine is likewise effective and safe for children. The vaccine mitigates risk of long-COVID and reduces the emergency department utilization and hospitalization rate of young children.[70] Rates of serious

[65] *E.g.*, Ctrs. for Disease Control & Prevention, *About Infectious Agents and Reproductive Health* (Jul. 22, 2024), https://tinyurl.com/57psn3jc; Rachel Zahn, M.D., *Children and infectious disease***,** EBSCO (2023), https://tinyurl.com/54uy7zmv.

[66] Am. Coll. of Obstetricians & Gynecologists, *Immunization for Pregnant Women: A Call to Action*, ACOG, https://tinyurl.com/ytrntfkr (last visited Dec. 11, 2025).

[67] Natasha B. Halasa et al., *Effectiveness of Maternal Vaccination with mRNA COVID-19 Vaccine During Pregnancy Against COVID-19–Associated Hospitalization in Infants Aged <6 Months — 17 States, July 2021–January 2022*, 71 Morbidity & Mortality Wkly. Rep., 7, 264–67 (2022).

[68] Jake Scott et al., *Updated Evidence for Covid-19, RSV, and Influenza Vaccines for 2025–2026*, 393 N. Engl. J. Med. 1123 (2025), ("Across seven observational studies, Covid-19 vaccination was not significantly associated with the risk of miscarriage, stillbirth, congenital anomalies, or small-for-gestational-age measure."); Clément Bernard et al., *First-Trimester mRNA COVID-19 Vaccination and Risk of Major Congenital Anomalies*, JAMA Netw. Open, 8(10): e2840133, 1 (2025); Stacey L. Rowe et al., *COVID-19 Vaccination During Pregnancy & Major Structural Birth Defects*, 155 Pediatrics e2024069778, 1, 13 (2025), https://doi.org/10.1542/peds.2024-069778; A.J. Sharma et al., *COVID-19 Vaccination During Pregnancy & Birth Defects: Results From the CDC COVID-19 Vaccine Pregnancy Registry, United States 2021–2022*, 117 Birth Defects Res. e2474, 1, 4–7 (2025), https://doi.org/10.1002/bdr2.2474; Elyse O. Kharbanda et al., *Spontaneous Abortion Following COVID-19 Vaccination During Pregnancy*, 326 JAMA 1629 (2021), https://doi.org/10.1001/jama.2021.15494; Naomi R. Greene et al., *COVID-19 Vaccination During Pregnancy and Risk of Stillbirth: A Nationwide Cohort Study*, 179 JAMA Pediatr.3, 210–218 (2025), https://jamanetwork.com/journals/jamapediatrics/fullarticle/2810937.

[69] Sean T O'Leary et. al., *Immunization Practices of US Obstetrician/Gynecologists for Pregnant Patients*, 54 Am. J. Prev. Med. 2015 (2017), https://doi.org/10.1016/j.amepre.2017.10.016.

[70] Atsuyuki Watanabe et al., *Assessment of Efficacy and Safety of mRNA COVID-19 Vaccines in Children Aged 5 to 11 Years: A Systematic Review and Meta-analysis*, 177 JAMA Pediatr. 384 (2023), https://doi.org/10.1001/jamapediatrics.2022.6243; Ruth Link-Gelles et al., *Effectiveness of Monovalent and Bivalent mRNA Vaccines in Preventing COVID-19–Associated Emergency Department and Urgent Care Encounters Among*

side effects are low with myocarditis incidence in adolescents ranging between 1.3-3.1 per 100,000 doses, and lower for very young children.[71]

Instilling apprehension and forcing pharmacists to act defensively undermines the goal of a robust public health system—one that depends on high vaccination rates, particularly among vulnerable populations. This is especially harmful when an overwhelming majority of practitioners agree that the COVID-19 vaccine is safe and effective.[72] With high vaccination rates, thousands of hospitalizations can be avoided.[73] With their legal authority uncertain and their liability for administering COVID-19 vaccines likely increased, pharmacists face unnecessary challenges to vaccinate patients when it is a public health imperative to do so. Given their heightened vulnerability to infectious disease, pregnant people and children will be disproportionately harmed.

C. SCDM Already Thwarted Efforts to Vaccinate Vulnerable Children.

The shift to SCDM produced immediate, tangible barriers to care. In October 2025, millions of children anticipating COVID-19 vaccination through the long-standing VFC Program were left without access to COVID-19 vaccines.[74] The VFC Program provides free vaccines to

Children Aged 6 Months–5 Years — VISION Network, United States, July 2022–June 2023, 72 Morbidity & Mortality Wkly. Rep. 886, 887 (2023).

[71] *See* Jake Scott M.D. et al., *Updated Evidence for Covid-19, RSV, and Influenza Vaccines for 2025*-2026, 393 N Engl J. Med. 2221, 2221, 2226, 2237 (2025); Kristin Goddard et al., *Safety of COVID-19 mRNA Vaccination Among Young Children in the Vaccine Safety Datalink*, 152 Pediatrics 1, 2 (2023).

[72] *See* Am. Coll. of Physicians et al., *Joint Statement on COVID-19 Vaccines*, ACP, https://tinyurl.com/23zpfbya (last visited Dec. 11, 2025).

[73] *See* Silvia Fernández-García et al., *Effectiveness and Safety of COVID-19 Vaccines on Maternal and Perinatal Outcomes: A Systematic Review and Meta-Analysis*, 9 BMJ Glob. Health e014247, 9 (2024); Am. Acad. of Pediatrics, *Meta-Analysis: COVID-19 Vaccination During Pregnancy Is Safe and Beneficial for Mother and Infant*, AAP (Sept. 26, 2025), https://tinyurl.com/3bz2h9wt.

[74] *See* Melissa Jenco, *Pediatricians Express Frustrations Over Delay in COVID Vaccines for Children in Federal Program*, AAP News (Oct. 2, 2025), https://tinyurl.com/hzevhj93. The Vaccines for Children (VFC) Program was created by § 13631 of the Omnibus Budget Reconciliation Act of 1993, Pub. L. No. 103-66, § 13631, 107 Stat. 312 (Aug. 10, 1993), and codified at 42 U.S.C. § 1396s(b) (VFC as part of the Social Security Act). The program is implemented through a state-federal partnership, with federal vaccine purchases and state-run distribution via enrolled providers. States manage enrollment and administration, while the CDC purchases ACIP-recommended vaccines and ships them directly to providers at no cost. *See* Ctrs. for Disease Control & Prevention, Vaccines for Children (VFC) Program Operations Guide, CDC at 14–15 (July 23, 2025), https://tinyurl.com/yd49y8sj.

children who might not otherwise be vaccinated because of cost.[75] Its reach is vast: roughly half of U.S. children receive vaccines through VFC.[76] The children covered by this program—those who are uninsured, Medicaid-eligible, American Indian or Alaska Native, or underinsured—are among the most vulnerable.[77]

Two weeks after ACIP's downgrade, the CDC's acting director chose to delay necessary authorizations to release COVID-19 vaccines through the VFC.[78] Without these authorizations, distributors were unable to ship VCF vaccines to healthcare providers.[79] As a result, the children who rely on VCF were left without any meaningful access to the vaccine for weeks.[80] This caused just one pediatric practice in Michigan to have to turn away 59 children, including a toddler, a child in foster care, and a teenager on the autism spectrum.[81] The disruption fell hardest on families already facing barriers such as transportation challenges and parents' work obligations.[82]

Physicians had no answers for their patients, and CDC offered no updates. In these critical weeks, children covered by VFC faced uncertainty and delay, while those with private insurance were largely unaffected. For disadvantaged families, the downgrade closed the door to the vaccine.

D. Access Gaps Strain Hospitals and the Broader Health Care System.

The consequences of ACIP/CDC's abrupt shift to SCDM extend far beyond a single profession or patient population—they reverberate through the entire health care system.

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[75] *Id*. at 17.
[76] *See* ABC News, *CDC Drops Universal COVID Vaccine Recommendations, Suggests Separate Guidance*, ABC News (Dec. 5, 2025), https://tinyurl.com/337kww4v.
[77] Ctrs. for Disease Control & Prevention, *Vaccines for Children (VFC) Program Eligibility*, CDC (Sept. 30, 2025), https://tinyurl.com/w8rsek8e.
[78] Anil Oza and Chelsea Cirruzzo, *Low-income children lack access to Covid vaccines because of approval delay*, StatNews (Sept. 30, 2025), https://tinyurl.com/zn65wmpc.
[79] Melody Schreiber, *CDC Drops Universal COVID Vaccine Recommendations Amid Misinformation and Access Issues*, The Guardian (Oct. 7, 2025), https://tinyurl.com/2x84wd6c.
[80] *See* Melissa Jenco, *Pediatricians express frustrations over delay in COVID vaccines for children in federal program*, AAP News (Oct. 2, 2025), https://tinyurl.com/hzevhj93.
[81] *See id*.
[82] *See id*.

Vaccination policy is not merely a matter of personal protection; it is a critical tool for preserving hospital capacity, preventing hospital-acquired infections, and stabilizing the health care workforce. When vaccination rates decline, predictable system-level harms follow: emergency department visits increase,[83] patients "boarded" for hours or days awaiting beds,[84] and hospitals lose the capacity to respond to urgent conditions, such as cardiac events stroke.[85] Additionally, unvaccinated patients are particularly vulnerable to nosocomial COVID-19 transmission.[86] In fact, one analysis of hospital outbreaks found that unvaccinated individuals were disproportionately implicated in transmission chains and associated with severe outcomes, including death.[87] These cascading effects compromise patient safety, erode staff morale, and strain resources—harms that are neither speculative nor remote, but measurable and immediate.

U.S. hospital occupancy has settled into a post-emergency steady state of approximately 75%—eleven percentage points higher than the pre-pandemic baseline.[88] When hospitals operate near capacity, admitted patients often remain in the emergency department ("ED"). This practice, known as "boarding," occurs when no inpatient bed is available, forcing admitted patients to wait in the ED for hours or days.[89] This bottleneck worsens crowding, delays care for new emergencies, and increases complications and mortality for all patients.[90]

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[83] H. Du, S. Saiyed & L.M. Gardner, *Association Between Vaccination Rates & COVID-19 Health Outcomes in the United States: A Population-Level Statistical Analysis*, 24 BMC Pub. Health 220 (2024).
[84] Alexander T. Janke, Edward R. Melnick & Arjun K. Venkatesh, *Hospital Occupancy and Emergency Department Boarding During the COVID-19 Pandemic*, 5 JAMA Network Open e2233964, 2 (2022).
[85] *See* J.E. Siegler et al., *Influence of the COVID-19 Pandemic on Treatment Times for Acute Ischemic Stroke: The Society of Vascular and Interventional Neurology Multicenter Collaboration*, 52 Stroke 40, 41 (2021); P.S. Chan et al., *In-Hospital Cardiac Arrest Survival in the United States During & After the Initial Novel Coronavirus Disease 2019 Pandemic Surge*, 15 Circ. Cardiovasc. Qual. Outcomes e008420, 151, 154–55 (2022).
[86] S.H. Kim et al., *Clinical Outcome and Prognosis of a Nosocomial Outbreak of COVID-19*, 12 J. Clinical Med. 2279, 1, 10 (2023).
[87] *Id.*
[88] Richard K. Leuchter et al., *Health Care Staffing Shortages and Potential National Hospital Bed Shortage*, JAMA Netw. Open (Feb. 19, 2025).
[89] M. Kennedy, T. Rosen & K. Biese, *Addressing the Hospital Boarding Crisis in the US—Time to Act*, 185 JAMA Intern. Med. 1038, 1038 (2025).
[90] *Id.* at 1038–39.

This is not a mere hypothetical. For instance, Massachusetts, among many other states, already struggles with persistent boarding and longer lengths of stay: closures removed 129 staffed beds in 2024, and long-stay admissions (30+ days) more than doubled from 2016 to 2023.[91] Boarding rates have also risen in Massachusetts: by early 2024, nearly half of behavioral-health ED visits exceeded twelve hours, and overall twelve-hour-plus ED stays climbed from 6.6% in 2020 to roughly 9.9% in January through May 2024.[92] Boarding imposes well-documented harms and delays for older adults and medically fragile patients.[93] Against that backdrop, reducing vaccine uptake via SCDM risks raising COVID-19 ED visits and admissions, tightening ICU and inpatient bed supply and crowding out care for trauma, stroke, cardiac, and pediatric patients.[94]

Reduced vaccination also increases nosocomial COVID-19 infections, hospital-acquired infections that endanger vulnerable patients and prolong inpatient stays.[95] These infections are not only clinically devastating but operationally costly, consuming isolation rooms, PPE, and staff time.[96] Even worse, an increase in nosocomial infections increases the care needs and length of stay of patients, further stretching critical hospital resources.[97]

Finally, health care workers face elevated exposure to COVID-19 simply because of the nature of their work. Vaccination significantly reduces the likelihood of symptomatic infection

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[91] Mass. Health Policy Comm'n, *Behavioral Health ED Boarding in Massachusetts* (Feb. 27, 2025), https://tinyurl.com/mr347kke.
[92] *Id.*
[93] M. Kennedy, T. Rosen & K. Biese, *supra* note 89, at 1038–39.
[94] *See* Du et al., *supra* note 83; Alexander T. Janke, Edward R. Melnick & Arjun K. Venkatesh, *supra* note 84; Siegler et al., *supra* note 85; Chan et al., *supra* note 85.
[95] *See* Kim et al., *supra* note 86; A.E. Pop-Vicas et al., *A Severe Acute Respiratory Coronavirus Virus 2 (SARS-CoV-2) Nosocomial Cluster With Inter-Facility Spread: Lessons Learned*, 45 Infect. Control & Hosp. Epidemiol. 635, 635, 641–42 (2024), https://doi.org/10.1017/ice.2023.172.
[96] *See, e.g.*, Samantha N. Piekos et al., *Effect of COVID-19 Vaccination & Booster on Maternal–Fetal Outcomes: A Retrospective Cohort Study*, 5 Lancet Digit. Health e594 (2023), https://doi.org/10.1016/S2589-7500(23)00145-2 (finding vaccination decreased the need for supplemental oxygen and vasopressors among pregnant people); Pop-Vicas, *supra* note 95 (finding that nosocomial infection control required increased use of, among other things, isolation rooms).
[97] See Pop-Vicas et al., *supra* note 95.

and severe illness at the individual level, helping maintain staffing stability.[98] Additionally, vaccine protects populations—including clinically vulnerable patients—by lowering the overall prevalence of COVID-19 in clinical settings, which reduces the frequency and intensity of exposure for all individuals present.[99] When infections do occur—among vaccinated or unvaccinated workers—the result is absenteeism that forces hospitals to divert resources, cancel elective procedures, and increase overtime.[100] These measures accelerate burnout and erode morale, creating cascading effects on patient safety and quality of care.[101]

In a system operating near capacity, universal vaccination policy is critical: it lowers preventable COVID-19 admissions, reduces ICU utilization, and frees resources for treatment of emergent issues. The SCDM reclassification disregards these system-level consequences. On balance, the public-interest is best served by restoring clear, universal vaccination guidance.

V. CONCLUSION

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

[98] *See, e.g.*, Helena C. Maltezou et al., *COVID-19 Vaccination Significantly Reduces Morbidity and Absenteeism Among Healthcare Personnel: A Prospective Multicenter Study*, 39 Vaccine 7021, 7021–7023, 7025–7027 (2021), Pop-Vicas et al., *supra* note 95.
[99] Kim et al., *supra* note 86.
[100] Maltezou et al., *supra* note 98; Pop-Vicas et al., *supra* note 95 (noting that infected healthcare works were sent home with 10-days paid leave).
[101] *E.g.*, Xiangdan Piao, Jun Xie & Shunsuke Managi, *Continuous Worsening of Population Emotional Stress Globally: Universality and Variations*, 24 BMC Pub. Health 3576, 3 (2024).

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