IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS
BOSTON DIVISION

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-WGY

BRIEF OF THE AMERICAN COLLEGE OF OBSTETRICIANS & GYNECOLOGISTS; AMERICAN ACADEMY OF FAMILY PHYSICIANS; AMERICAN ACADEMY OF NURSING; AMERICAN COLLEGE OF CHEST PHYSICIANS; AMERICAN COLLEGE OF MEDICAL GENETICS AND GENOMICS; AMERICAN COLLEGE OF NURSE-MIDWIVES; AMERICAN GYNECOLOGICAL AND OBSTETRICAL SOCIETY; AMERICAN MEDICAL ASSOCIATION; AMERICAN MEDICAL WOMEN'S ASSOCIATION; AMERICAN SOCIETY FOR REPRODUCTIVE MEDICINE; COUNCIL OF CHAIRS OF OBSTETRICS AND GYNECOLOGY; MASSACHUSETTS MEDICAL SOCIETY; NATIONAL ASSOCIATION OF NURSE PRACTITIONERS IN WOMEN'S HEALTH; NATIONAL ASSOCIATION OF PEDIATRIC NURSE PRACTITIONERS; NORTH AMERICAN SOCIETY FOR PEDIATRIC AND ADOLESCENT GYNECOLOGY; SOCIETY FOR ADOLESCENT HEALTH AND MEDICINE; SOCIETY OF GENERAL INTERNAL MEDICINE; SOCIETY OF GYNECOLOGIC ONCOLOGY; SOCIETY OF GYNECOLOGIC SURGEONS; AND SOCIETY OF OB/GYN HOSPITALISTS AS AMICI CURIAE IN SUPPORT OF PLAINTIFFS

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INTEREST OF AMICI CURIAE

The American College of Obstetricians & Gynecologists ("ACOG"), alongside nineteen other national and state medical organizations, submits this Amici Curiae brief in support of Plaintiffs.[1]

Amici, identified in the attached Appendix, are medical organizations representing physicians, surgeons, nurse practitioners, nurses, as well as scientists, researchers, and a broad spectrum of other medical professionals. Among Amici are organizations whose members specialize in caring for pregnant people and children, the groups named in the U.S. Department of Health and Human Services ("HHS") Directive dated May 19, 2025 ("Directive") and issued by Secretary Robert F. Kennedy Jr. ordering removal of the Covid vaccination for certain cohorts from the Centers for Disease Control and Prevention ("CDC")'s Adult and Child and Adolescent Immunization Schedules. Amici organizations also represent specialists in disciplines with expertise in the study and treatment of Covid, including infectious disease and respiratory medicine.

Amici submit this brief to provide their perspective on the tangible harms caused by the Directive. Amici believe that the Directive is contrary to robust empirical evidence demonstrating the risks of Covid and the benefits of vaccination. The Directive is causing harm to vulnerable individuals, the public at large, and medical professionals, including Amici's provider members.

SUMMARY OF ARGUMENT

For decades, the American medical community and the public that it serves have relied on the federal government to provide vaccine guidance based on rigorous evaluation of scientific

[1] No party or party's counsel authored this brief in whole or in part or contributed money that was intended to fund the preparation or submission of this brief. No person, other than Amici Curiae, their members, or their counsel, contributed money intended to fund the preparation or submission of this brief.

evidence. Indeed, United States health departments and agencies exercised historic leadership—largely during the first Trump Administration—to address the country's first Covid pandemic, incentivizing and directing the development of safe and effective Covid vaccines in record time to save tens of millions of Americans from illness, hospitalization, disability, and death.[2]

Now, the Directive seeks to override HHS's rigorous, congressionally-mandated vaccine review and recommendation processes—a cornerstone of the U.S. public health system—despite their long-established use and proven track-record of success. This action controverts the medical evidence and the overwhelming consensus among the scientific and medical communities. No longer recommending the Covid vaccine on the CDC's Immunization Schedules for cohorts named in the Directive not only interferes in the essential patient-physician relationship but directly endangers the lives of pregnant patients, fetuses, infants, children, and health care providers. The Directive reflects a broader pattern of recent HHS actions that clash with scientific realities and undermine carefully-developed processes that HHS and its components have long used to carry out rigorous review of emerging data and, on that basis, issue immunization recommendations.[3]

Covid poses unique and serious risks to pregnant patients, fetuses, infants, and children, each of whom, to varying degrees, face higher rates of hospitalization, complications, and mortality from the disease without vaccination. Vaccination during pregnancy provides critical dual protection, reducing the risk of severe maternal illness and transferring protective antibodies to the fetus. These antibodies also offer an essential defense during an infant's first six months when the child is ineligible for the Covid vaccine. Pediatric vaccination after a child is older than

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[2] *See* Meagan C. Fitzpatrick et al., *Two Years of U.S. COVID-19 Vaccines Have Prevented Millions of Hospitalizations and Deaths*, The Commonwealth Fund: Blog (Dec. 13, 2022), https://tinyurl.com/3yk33tnh.

[3] *See, e.g.*, Apoorva Mandavilli et al., *Kennedy to Add New Members to Vaccine Advisory Panel*, N.Y. Times (Sept. 3, 2025), https://tinyurl.com/y53j5jue (detailing how the Secretary "fired all 17 members of the [Advisory Committee on Immunization Practices], asserting without evidence that the committee members were 'plagued with persistent conflicts of interest,' even though they had been carefully vetted for such conflicts").

six months is also crucial, mitigating the risk of severe illness or death in that population, protecting the public against the spread of infection, and increasing herd immunity.

The Directive also places medical providers—including physicians, nurse practitioners, and nurses represented by Amici—at a heightened risk of contracting, and further spreading, Covid. The Directive will limit access to the vaccine for pregnant providers while exposing them to a less vaccinated patient base more susceptible to the virus and likelier to have severe symptoms.

Extensive studies confirm that Covid vaccines are both safe and effective, with the minimal identified risks outweighed by the demonstrated benefits of protection from infection, serious illness, prolonged hospitalization, disability, and death.

The Directive's reversal of the CDC's longstanding Covid vaccine recommendations for pregnant people and healthy children communicates to the American public that the vaccine is unnecessary, unsafe, or both—directly controverting the existing scientific evidence while relying on no scientific findings itself and reflecting no consultation with the CDC. This unwarranted about-face has contributed to a nationwide epidemic of vaccine skepticism and hesitancy among patients. It has created confusion among the Amici organizations' members and interfered with their practices and the clinician-patient relationship. Decreased administration of the Covid vaccine will predictably lead to a marked increase in the number of preventable infections, hospitalizations, long-term disabilities, and deaths. We therefore urge the Court to grant Plaintiffs' requested relief and enforce the statutorily-mandated process for the provision of vaccine guidance and recommendations based on the totality of the scientific evidence.

ARGUMENT

I. COVID POSES SERIOUS RISKS TO PREGNANT INDIVIDUALS, FETUSES AND NEWBORNS, MAKING TIMELY VACCINATION CRITICAL

Although several years have passed since the Covid pandemic began, there is a continuing

need for vaccination. The CDC estimates that, between October 1, 2024 and September 20, 2025, there were between 13.8 and 20.3 million illnesses, 380,000 to 540,000 hospitalizations, and 44,000 to 63,000 deaths attributable to Covid infections.[4] From the start of the year through September 20, 2025, there have been over 15,940 Covid-related deaths.[5] In addition, the virus continues to evolve, and periodic booster shots are recommended to maintain immunity, much like the annual flu vaccine.[6] To that end, in April 2025, the CDC's Advisory Committee on Immunization Practices ("ACIP"), the federal advisory committee that develops vaccine recommendations, was in the process of drafting Covid vaccine guidance for the 2025–26 season.[7]

The past five years of scientific and medical evidence have shown that the dangers posed by Covid are heightened during pregnancy, the postpartum period, and early infancy. In these contexts, Covid is not a routine illness; it can be devastating, potentially leading to complications such as acute respiratory distress, cardiac events, or sepsis, and even causing death.[8] Vaccination offers critical protection to vulnerable populations from these well-established heightened risks.

A. Pregnant and Postpartum Individuals Face Much Higher Risks of Severe Illness and Death from Covid

Pregnancy is a confirmed risk factor for severe Covid outcomes. Indeed, just a day after the Directive's effective date, a *New England Journal of Medicine* article co-authored by the current Federal Drug Administration ("FDA") Commissioner and Director of the FDA's Center for Biologics Evaluation and Research ("CBER") endorsed the view that pregnancy is an "underlying

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[4] Centers for Disease Control and Prevention ("CDC"), *Preliminary Estimates of COVID-19 Burden for 2024-2025* (Dec. 6, 2024), https://tinyurl.com/yc7f7fxy (last visited Oct. 7, 2025).

[5] National Center for Health Statistics, CDC, *Provisional COVID-19 Mortality Surveillance: National Vital Statistics System*, https://tinyurl.com/4t987f7d (last visited Oct. 7, 2025).

[6] *See* CDC, *Stay Up to Date with COVID-19 Vaccines* (June 6, 2025), https://tinyurl.com/ywesyjze (last visited Oct. 7, 2025).

[7] *See* Advisory Comm. on Immunization Practices ("ACIP"), *Agenda of April 15–16, 2025 ACIP Meeting*, https://tinyurl.com/2w8eufj2 (last visited Oct. 7, 2025).

[8] Jaime-Dawn E. Twanow et al., *The COVID-19 Pandemic and Pregnancy: Impact on Mothers and Newborns*, 42 Seminars in Pediatric Neurology 100977 (May 21, 2022).

medical condition[] that increase[s] risk of severe Covid."[9] In particular, physiological changes during pregnancy—such as reduced lung capacity and altered immune function—make expectant and postpartum patients more susceptible to severe respiratory infections.[10]

The government's own evidence shows that pregnant people are at greater risk for severe illness and death from Covid. According to CDC data, pregnant patients who contract Covid experience severe complications at a higher rate than similarly-aged people who are not pregnant.[11] The United States has documented thousands of severe cases among pregnant patients and dozens of maternal deaths attributable to Covid.[12] In one CDC analysis of the early pandemic period, Covid contributed to *one quarter* of all maternal deaths, a striking indication of the virus's toll on maternal health.[13] As the CDC recently confirmed, pregnant individuals continue to face an increased risk of severe outcomes from Covid, including intensive care and use of ventilators.[14]

Extensive peer-reviewed studies corroborate the disproportionate impact of Covid on pregnant patients. A comprehensive April 2021 systematic review and meta-analysis concluded that Covid in pregnancy significantly increases the odds of preeclampsia, preterm birth, and other

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[9] Vinay Prasad & Martin A. Makary, *An Evidence-Based Approach to Covid-19 Vaccination*, 392 New Eng. J. Med. 2484 (May 20, 2025), fig. 2 (capitalization removed); *accord* Lakshmi Panagiotakopoulos, CDC, *Use of 2025–2026 COVID-19 Vaccines: Work Group Considerations*, slide 12 (Apr. 15, 2025), https://tinyurl.com/vc3p8c9x (identifying pregnancy and recent pregnancy as risk factors for severe COVID-19 illness on a "conclusive" basis).

[10] *See* CDC, *Respiratory Viruses and Pregnancy* (Sept. 26, 2024), https://tinyurl.com/27sbmea9 (changes in the immune system, heart, and lungs during pregnancy raise the risk of severe illness from respiratory viruses like COVID-19); Adson José Martins Vale et al., *Susceptibility to COVID-19 in Pregnancy, Labor, and Postpartum Period: Immune System, Vertical Transmission, and Breastfeeding*, 2 Frontiers Glob. Women's Health 602572 (Feb. 16, 2021).

[11] Laura D. Zambrano et al., *Update: Characteristics of Symptomatic Women of Reproductive Age with Laboratory-Confirmed SARS-CoV-2 Infection by Pregnancy Status — United States, January 22–October 3, 2020*, 69(44) Morbidity & Mortality Wkly. Rep. [hereinafter, MMWR] 1641, 1641–42 (Nov. 6, 2020) (pregnant patients had significantly higher adjusted risks of ICU admission and invasive ventilation).

[12] CDC, Health Alert Network Advisory 00453, *COVID-19 Vaccination for Pregnant People to Prevent Serious Illness, Deaths, and Adverse Pregnancy Outcomes from COVID-19* (Sept. 29, 2021), https://tinyurl.com/626ejz22 [https://tinyurl.com/su5yzy64] (last visited Oct. 7, 2025) (noting over 22,000 COVID-related hospitalizations and 161 maternal deaths in pregnant people in the U.S. as of that date).

[13] U.S. Government Accountability Off., GAO-23-105871, *Maternal Health: Outcomes Worsened and Disparities Persisted During the Pandemic*, at 2 (Oct. 2022), https://tinyurl.com/nsa8unau.

[14] CDC, *COVID-19 Vaccination for Women Who Are Pregnant or Breastfeeding* (Sept. 10, 2024), https://tinyurl.com/4jv6evws (last visited Oct. 7, 2025).

adverse outcomes.[15] Pregnant Covid patients are also more likely to require intensive care unit ("ICU") admission and mechanical ventilation than non-pregnant Covid patients.[16] One large 2023 study found that pregnant patients with Covid had a 2.6-fold higher risk of severe complications and a 14-fold higher risk of death compared to pregnant patients without Covid at the time of delivery.[17] A significant cohort of pregnant patients with severe Covid faces lasting health repercussions that can drastically affect the health of their pregnancy and could lead to death of the patient.[18]

Pregnant patients also face elevated levels of severe risk from Covid during the postpartum period. For example, one large study of Brazilian mothers analyzed data from pregnant and postpartum patients and found that both groups faced "high lethality and a high incidence of clinical and obstetric complications" associated with severe Covid.[19] The study concluded that these populations "should be considered vulnerable,"[20] consistent with broad scientific consensus and the current FDA Commissioner's and CBER Director's characterization on May 20, 2025.[21]

In addition to significant physical risks, Covid also presents psychiatric risks for pregnant and postpartum patients and their infants. A recent umbrella review of more than 300 studies found that depression and anxiety among pregnant and postpartum women significantly increased during the Covid epidemic, affecting nearly one in three women.[22] Post-birth, many hospitals also limit

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15 Shu Qin Wei et al., *The Impact of COVID-19 on Pregnancy Outcomes: A Systematic Review and Meta-Analysis*, 193(16) Canadian Med. Ass'n J. E540, E546–47 (2021).

16 *See* Zambrano et al., *supra* note 11, at 1642.

17 Koji Matsuo et al., *Severe Maternal Morbidity and Mortality of Pregnant Patients With COVID-19 Infection During the Early Pandemic Period in the US*, 6(4) JAMA Network Open e237149, at 1 (2023).

18 Jose Villar et al., *Pregnancy Outcomes and Vaccine Effectiveness during the Period of Omicron as the Variant of Concern, INTERCOVID-2022: A Multinational, Observational Study*, 401 Lancet 447 (2023).

19 Isabel Cristina Melo Mendes et al., *Severe Covid-19 in Pregnant and Postpartum Women Admitted to an Intensive Care Unit: A Retrospective Cohort Study*, 18(2) PLoS ONE e0295444 (Dec. 2023).

20 *Id.*

21 *See* Prasad & Makary, *supra* note 9.

22 Nicholas Adrianto et al., *Depression in Pregnant and Postpartum Women during COVID-19 Pandemic: Systematic Review and Meta-Analysis*, 65(4) Obstetrics & Gynecology Sci. 287 (2022).

patients' contact with their infants if the patient is infected with Covid.[23] Such limited contact can interfere with the patient's ability to bond with the baby—a crucial factor in both patient and infant psychological health—and may further limit the ability to breastfeed, which both strengthens the bonding process and provides additional immunological protection to the infant against Covid.[24]

B. Covid Disproportionately Harms Newborns Who Cannot Be Vaccinated

Because newborns and infants in the first six months of life have immature immune systems and are not eligible for Covid vaccination, they also face exceptional risks from Covid infection.[25] These risks mainly derive from two sources: Infants can be harmed if their parent contracts Covid prior to delivery and can themselves be infected after birth.

Sobering data on infant Covid outcomes illustrate those risks. CDC data showed that infants under six months old have the highest Covid hospitalization rate of any pediatric age group.[26] In fact, during an Omicron variant wave in 2022, infants under 6 months experienced Covid hospitalization at rates comparable to 65-to-74-year-olds, a group disproportionately susceptible to the disease.[27] Between April 2024 and April 2025, Covid infections led to the hospitalization of thousands of U.S. infants under one year of age.[28] At an April 2025 ACIP meeting, officials reported that, in the previous year, Covid had led to the hospitalization of approximately 9,000-15,000 U.S. children, about 20 percent of whom required ICU care.[29] Further

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[23] Georgie Dowse et al., *Born into an Isolating World: Family-centred Care for Babies Born to Mothers with COVID-19*, 56 Lancet: eClinicalMedicine 101822 (2023).

[24] *See* Gus A. Mayopoulos et al., *COVID-19 Positivity Associated with Traumatic Stress Response to Childbirth and No Visitors and Infant Separation in the Hospital*, 11 Scientific Reports 13535 (2021).

[25] CDC, *Protecting Infants and Children from COVID-19–Associated Hospitalization* (Oct. 2, 2024), https://tinyurl.com/yc3whujd (last visited Oct. 7, 2025).

[26] Sarah Hamid et al., *COVID-19–Associated Hospitalizations Among U.S. Infants Aged <6 Months — COVID-NET, 13 States, June 2021–August 2022*, 71(45) MMWR 1442 at Figure 1 (2022).

[27] *Id.*

[28] *See* Alexandra B. Yonts et al., *April 2025 ACIP Meeting Update: Influenza, COVID-19, HPV, RSV and Other Immunizations*, 156(3) Pediatrics e2025072444 (2025); Fiona P. Havers, CDC, *COVID-19–Associated Hospitalizations — COVID-NET, April 2025 Update*, slides 10-11 (Apr. 15, 2025), https://tinyurl.com/2ywyj3bb.

[29] *See* Havers, *supra* note 28, at slide 17.

CDC research establishes that more than 95 percent of hospitalized infants' mothers had not been vaccinated during pregnancy, underscoring that non-immunization renders infants defenseless.[30] Rigorous peer-reviewed research provides further confirmation of Covid's risks for infants. A 2024 study that examined data from over one million children's visits to a large hospital system in California concluded that infants under six months had the highest rate of hospitalization.[31]

Fetuses and infants also face unique risks when pregnant individuals contract Covid. Covid infection during pregnancy is associated with higher stillbirth rates.[32] Studies also show that infants born to mothers with Covid during pregnancy are at increased risk of premature birth or low birth weight; in rare cases, the virus may transmit to the fetus.[33] Maternal Covid infection is also correlated with neonatal Respiratory Distress Syndrome.[34] These findings reinforce the intimate link between a pregnant person's health and that of fetuses and infants: When the pregnant person becomes seriously ill with Covid, the fetus or infant's health is also seriously jeopardized.

II. COVID VACCINES ARE SAFE AND EFFECTIVE FOR PREGNANT INDIVIDUALS, FETUSES, AND INFANTS

Since their development, Covid vaccines have been extensively studied by scientists across the globe using a wide variety of methodologies. Volumes of resulting clinical and real-world evidence show that vaccination helps prevent severe Covid and is safe for pregnant individuals, fetuses, and infants. The Secretary's Directive ignores the proven safety and effectiveness of

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[30] *See* ACOG et al., *Open Letter Urging COVID-19 Vaccination Coverage in Pregnancy* (June 11, 2025), https://tinyurl.com/3wbv3jsw; Fiona P. Havers et al., *COVID-19-Associated Hospitalizations and Maternal Vaccination Among Infants Aged <6 Months - COVID-NET, 12 States, October 2022-April 2024*, 73(38) MMWR 830 (2024).

[31] Ousseny Zerbo et al., *Incidence and Risk of Coronavirus Disease 2019 Hospitalization Among Unvaccinated Children*, 18 Influenza & Other Respiratory Viruses e70022 (2024).

[32] *See* Carla L. DeSisto et al., *Risk for Stillbirth Among Women With and Without COVID-19 at Delivery Hospitalization — United States, March 2020–September 2021*, 70(47) MMWR 1640, 1640–41 (Nov. 26, 2021).

[33] *See, e.g.*, John Allotey et al., *Clinical Manifestations, Risk Factors, and Maternal and Perinatal Outcomes of Coronavirus Disease 2019 in Pregnancy: Living Systematic Review and Meta-Analysis*, 370 BMJ m3320 (2020).

[34] Olivia M. Man et al., *Respiratory Distress in SARS-CoV-2 Exposed Uninfected Neonates Followed in the COVID Outcomes in Mother-Infant Pairs (COMP) Study*, 15 Nature Commc'ns 399 (2024).

Covid vaccines in these categories of patients, needlessly placing them at greater risk of facing the severe adverse outcomes described above. In turn, these risks have cascading negative effects on a patient's loved ones, communities, and providers.

A. Covid Vaccination During Pregnancy Effectively Protects the Pregnant Individual, Fetus, and Infant

Numerous large studies confirm that vaccinated pregnant individuals have far lower rates of Covid infection, hospitalization, and death than their unvaccinated counterparts.[35] For example, an international study during the Omicron wave found that unvaccinated pregnant people were at far greater risk of developing and dying from severe Covid than vaccinated pregnant people.[36] The study reported that unvaccinated pregnant patients experienced surges in ICU admissions and maternal deaths, evidence that vaccine-induced immunity is life-saving.[37] Data from the United States are similarly compelling. Numerous studies, including CDC surveillance reports, have found that Covid vaccination increases protection against serious illness, death, and birth complications. By late 2022, with the virus still circulating, the Covid mortality rate among pregnant people had dropped from its early-pandemic peak,[38] very likely due to vaccinations.

Vaccination against Covid during pregnancy yields a three-fold benefit: It helps safeguard the pregnant individual from severe disease, protects the fetus in-utero through the transmission of antibodies, and protects the infant post-birth from potential exposure to the virus from the patient.[39] In addition, antibodies transferred through the placenta can persist in an infant's bloodstream for

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35 Greg Marchand et al., *Maternal and Neonatal Outcomes of COVID-19 Vaccination During Pregnancy, a Systematic Review and Meta-Analysis*, 8 NPJ Vaccines 103 (2023).

36 Villar et al., *supra* note 18.

37 *Id.*; *see also* Martina L. Badell et al., *Covid-19 Vaccination in Pregnancy*, 378 BMJ e069741 (2022).

38 *See* Latoya Hill et al., *Racial Disparities in Maternal and Infant Health: Current Status and Efforts to Address Them*, Kaiser Fam. Found. (Nov. 4, 2024), https://tinyurl.com/a4f4wfc7 (maternal mortality declined in 2022 after the significant increase in 2020-21 due to COVID-19).

39 Jean L. Devera et al., *A Narrative Review of COVID-19 Vaccination in Pregnancy and Breastfeeding*, 44 J. Perinatology 12 (2024).

months post-birth.[40] Hospital data show the vast majority of infants under six months hospitalized with Covid were born to unvaccinated patients and that use of invasive mechanical ventilation on infants with Covid was *nine times more common* than for infants born to vaccinated patients.[41] In fact, it is exceedingly rare for infants born to vaccinated mothers to suffer from severe Covid, a testament to the meaningful in-utero protection conferred before birth.[42] Vaccination during pregnancy is also associated with lower rates of preterm birth, given that severe illness can result in early labor, emergency delivery, and post-birth complications in the infant.[43] Vaccinated patients likewise have lower rates of stillbirth and neonatal ICU admission than unvaccinated patients.[44]

Tangible benefits of vaccinating pregnant patients continue in the postpartum phase. Antibodies in a mother's milk can provide the baby with passive immunity, adding a further layer of protection against infection and disease.[45] A 2023 review of dozens of studies confirmed that breast milk of vaccinated mothers contains robust virus-fighting antibodies.[46] Researchers have detected no meaningful amount of vaccine mRNA in breast milk—only proactive antibodies.[47]

Simply put, vaccinating pregnant individuals is one of the most effective measures available to prevent Covid from harming pregnant people and their infants. In light of the

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[40] *See, e.g.*, Lydia L. Shook et al., *Durability of Anti–Spike Antibodies in Infants After Maternal COVID-19 Vaccination or Natural Infection*, 327(11) JAMA 1087 (2022).

[41] Regina M. Simeone et al., *Effectiveness of Maternal mRNA COVID-19 Vaccination During Pregnancy Against COVID-19–Associated Hospitalizations in Infants <6 Months During SARS-CoV-2 Omicron Predominance – 20 States, March 9, 2022–May 31, 2023*, 72(39) MMWR 1057 (2023).

[42] Hamid et al., *supra* note 26, at 1444-45.

[43] Marchand et al., *supra* note 35, at 103.

[44] Badell et al., *supra* note 37.

[45] *See* Margarita Dimitroglou et al., *Anti-SARS-CoV-2 Immunoglobulins in Human Milk After Coronavirus Disease or Vaccination — Time Frame and Duration of Detection in Human Milk Factors That Affect Their Titers: A Systematic Review*, 15 Nutrients 1905 (2023) (confirming that breast milk from vaccinated or previously infected mothers contains antibodies with neutralizing capability).

[46] *See* Yan-Fei He et al., *Breastfeeding vs. Breast Milk Transmission During COVID-19 Pandemic, Which Is More Important?*, 11 Frontiers Pediatrics 1253333 (2023) (finding direct breastfeeding did not pose additional risk of infant infection, and noting zero COVID-19 deaths among over 1,300 infants of vaccinated/infected mothers).

[47] *See id.* at 1; *see also* Nazeeh Hanna et al., *Detection of Messenger RNA COVID-19 Vaccines in Human Breast Milk*, 176(12) JAMA Pediatrics 1268 (2021) (finding no vaccine mRNA in any breast milk samples post-vaccination).

substantial benefits to the patient, fetus, and infant, the CDC and medical experts, including Amici, have overwhelmingly endorsed vaccination as an important strategy to prevent Covid during and after pregnancy.[48] The Directive contradicts and ignores these recommendations despite extensive scientific evidence to the contrary.[49]

B. Covid Vaccines Are Safe During Pregnancy, with No Evidence of Fertility Issues, Pregnancy Loss, or Fetal Harm

Covid vaccination, which confers significant benefits to the pregnant patient, fetus, and newborn child for the reasons given above, also carries minimal risks during pregnancy. There is no credible scientific evidence that the vaccine poses a significant risk of harm to the pregnant person, fetus, or infant.[50] In fact, numerous studies have proven the vaccine's safety.[51]

Since the vaccine rollouts in late 2020, health agencies worldwide have closely monitored vaccinated pregnant people for adverse outcomes. Nearly five years later, and across multiple independent analyses of this data, scientists have found *no credible evidence* of any correlation between the vaccine and any significant safety concerns.[52] One comprehensive review from March 2022 examining data from over 70,000 vaccinated pregnant people concluded that it could "rule out any adverse effect in [pregnant patients] and their infants" from the Covid vaccine.[53] Another study similarly compared unvaccinated patients to patients who had been vaccinated during pregnancy and after pregnancy and concluded that vaccination during pregnancy "was not

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48 *See* ACOG, *Practice Advisory: COVID-19 Vaccination Considerations for Obstetric–Gynecologic Care* (Sept. 2025), https://tinyurl.com/v7z5hhwz; *see also* Neil Murthy et al., *Advisory Committee on Immunization Practices Recommended Immunization Schedule for Adults Aged 19 Years or Older – United States, 2023*, 72(6) MMWR 141 (Feb. 10, 2023).

49 *See, e.g.*, ACOG, *Practice Advisory*, *supra* note 48.

50 *See* CDC, *COVID-19 Vaccination for Women Who Are Pregnant or Breastfeeding*, *supra* note 14 (stating that studies worldwide show vaccination is safe in pregnancy for mother and baby).

51 *See* Agustín Ciapponi et al., *Safety of COVID-19 Vaccines During Pregnancy: A Systematic Review and Meta-Analysis*, 41 Vaccine 3688 (2023) (finding no safety concerns for COVID-19 vaccines in pregnancy).

52 *See id.* at 3688; Prasad & Makary, *supra* note 9, at 2484.

53 *See* Domenico U. De Rose et al., *SARS-CoV-2 Vaccines During Pregnancy and Breastfeeding: A Systematic Review of Maternal and Neonatal Outcomes*, 14(3) Viruses 539 (2022).

significantly associated with increased risk of peripartum outcomes."[54] In short, getting a Covid shot is just as safe for a pregnant person as for other eligible individuals.

The scientific evidence also clearly establishes that Covid vaccines have no negative effect on reproductive fertility—an unfounded rumor debunked by years of data.[55] As early as 2021, the CDC, FDA, and other federal and state health agencies ruled out any link between Covid vaccines and infertility,[56] a conclusion borne out by later research.[57] Furthermore, studies have found no connection between Covid vaccination and other pregnancy- or birth-related complications. Large-scale studies show no links between Covid vaccination and miscarriage or stillbirth. For example, one study found that vaccination rates were the same among those who miscarried and those who did not.[58] If anything, Covid vaccination reduces the risk of stillbirth by protecting the mother from severe illness that can endanger the fetus.[59] A 2022 *JAMA Pediatrics* review reported that vaccination did not increase risks of preterm birth; small-for-gestational-age infants; Cesarean delivery; or low Apgar scores at birth.[60] In fact, the review noted that infants born to vaccinated patients had lower rates of NICU care and a lower incidence of fetal death.[61] Finally, there is no evidence that Covid vaccination during pregnancy negatively affects infant health immediately

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[54] *See* Deshayne B. Fell et al., *Association of COVID-19 Vaccination in Pregnancy With Adverse Peripartum Outcomes*, 327(15) JAMA 1478 (2022) (finding vaccination during pregnancy not associated with increased risk of adverse outcomes).

[55] *See* Drieda Zace et al., *The Impact of COVID-19 Vaccines on Fertility: A Systematic Review and Meta-Analysis*, 40(42) Vaccine 6023 (2022) (finding no evidence that vaccination affects female or male fertility).

[56] *See* CDC, *COVID-19 Vaccination for People Who Would Like to Have a Baby* (Sept. 10, 2024), https://tinyurl.com/yzfuuf27 (last visited Oct. 7, 2025).

[57] *See* De Rose et al., *supra* note 53, at 539; Alice Lu-Culligan et al., *No Evidence of Fetal Defects or Anti-syncytin-1 Antibody Induction following COVID-19 mRNA Vaccination*, 20(5) PLoS Biology e3001506 (2022); Adi Anis Heusler et al., *The Influence of SARS-CoV-2 Vaccination on in vitro Fertilization Outcomes*, 21 Hum. Vaccines & Immunotherapeutics 2541495 (2025).

[58] *See* Elyse O. Kharbanda et al., *Spontaneous Abortion Following COVID-19 Vaccination During Pregnancy*, 326(16) JAMA 1629 (2021).

[59] *See* Smriti Prasad et al., *Systematic Review and Meta-Analysis of the Effectiveness and Perinatal Outcomes of COVID-19 Vaccination in Pregnancy*, 13 Nature Commc'ns 2414 (2022) (vaccination in pregnancy associated with 15% lower probability of stillbirth).

[60] *See* Atsuyuki Watanabe et al., *Peripartum Outcomes Associated With COVID-19 Vaccination During Pregnancy: A Systematic Review and Meta-Analysis*, 176(11) JAMA Pediatrics 1098 (2022).

[61] *Id.*

after birth.[62] As discussed above, infants born to vaccinated patients are typically healthier.[63]

III. PEDIATRIC VACCINATION IS SAFE, EFFECTIVE, AND IMPORTANT TO PROTECT AGAINST BOTH SEVERE INDIVIDUAL DISEASE AND INCREASED DISEASE TRANSMISSION

In addition to withdrawing the Covid vaccine recommendation for pregnant people, the Directive ordered the CDC to remove the recommendation for healthy children from six months to 18 years of age.[64] This decision, too, ignored the overwhelming weight of scientific evidence showing that pediatric Covid vaccines are safe and provide substantial protections. In particular, the Covid vaccine both reduces the rate of complications in children and protects the public from increased disease transmission. And, as is true for pregnant people, the evidence shows that the Covid vaccine poses minimal safety risks and is effective for children.

A. Pediatric Vaccination Protects Children, Their Peers, and the Public

Although healthy children generally do not face the same heightened Covid risks as pregnant people or young infants, vaccination still confers important benefits. It protects children themselves, guarding against rare but serious complications. It also protects their peers, families, and communities by reducing transmission and contributing to herd immunity.

Vaccinating healthy children helps guard against severe Covid infection. Although serious illness or death from Covid is less common in healthy children than in other groups, vaccination has been proven significantly to reduce both the rate and severity of infection. For example, a

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62 Sarah C.J. Jorgensen et al., *Newborn and Early Infant Outcomes Following Maternal COVID-19 Vaccination During Pregnancy*, 177(12) JAMA Pediatrics 1314, 1320 (2023).

63 *Id.*; *see also supra* pp. 9-11.

64 Although the Directive ordered the CDC to "remove COVID-19 vaccines from the recommended Child and Adolescent Immunization Schedule by Age and recommended vaccines during pregnancy," ECF No. 75-6 at 1, ACIP has, as of September 19, 2025, recommended that the Covid vaccine be based on Shared Clinical Decision-Making (SCDM) for all individuals between 6 months and 65 years of age. CDC, *ACIP Recommends COVID-19 Immunization Based on Individual Decision-making* (Sep. 19, 2025), https://tinyurl.com/zxvt5w55 (last visited Oct. 7, 2025). As the Plaintiffs' brief in support of a preliminary injunction notes, ECF No. 74 at 3-4, and Amici's experience confirms, whether the CDC rescinds its recommendation or downgrades it to SCDM, the resulting harm will be similar. Fewer patients will receive a beneficial vaccine to protect against a potentially serious infection, and clinicians will face conflicting guidance that does not comport with the scientific evidence. *See infra* Section IV.

recent study of 275 hospitals found that as many as 41 percent of children hospitalized with acute Covid between October 2022 and April 2024 had *no* underlying health conditions and, among those hospitalized, over ninety-six percent did not have up-to-date Covid vaccinations.[65] These findings demonstrate that even children without risk factors can experience serious illness that vaccination could have mitigated or prevented altogether. That is why all twenty Amici have recommended, and continue to recommend, vaccinations and boosters for healthy children.

Vaccinating healthy children also has a significant public health benefit. Children often play a significant role in spreading illness within their families, communities, and the public at large. As with other illnesses, children are significant vectors of Covid transmission both within their families and among the public.[66] Indeed, there is "unequivocal evidence that children play an important role in the transmission of SARS-CoV-2, particularly within school and household settings."[67] One meta-analysis found that, as the virus evolved, children's role in household spread increased, underscoring the importance of vaccinating children to mitigate transmission of Covid variants.[68] Vaccinating children against Covid thus provides benefits for, and far beyond, the child.

B. Covid Vaccines Are Safe and Effective for Children over Six Months Old

Scientific and medical evidence shows that Covid vaccines are safe and effective for children over six months old and that any health risks are far outweighed by the vaccine's benefits.

Numerous studies in the United States and other countries have concluded that the Covid

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65 *See* Rebecca J. Free et al., *Hospitalization for COVID-19 and Risk Factors for Severe Disease Among Children: 2022–2024*, 156(3) Pediatrics e2025072788 (2025).

66 *See, e.g.*, Anna Funk et al., *Household Transmission Dynamics of Asymptomatic SARS-CoV-2–Infected Children: A Multinational, Controlled Case-Ascertained Prospective Study*, 78(6) Clinical Infectious Diseases 1522 (2024); Yi-Ju Tseng et al., *Smart Thermometer–Based Participatory Surveillance to Discern the Role of Children in Household Viral Transmission During the COVID-19 Pandemic*, 6(6) JAMA Network Open e2316190 (2023).

67 Deepti Gurdasani & Christina Pagel, *What is the Role of Children in Transmission of SARS-CoV-2?*, 377(6611) Science 1147 (2022); *see also* Rebecca K. Borchering et al., *Impact of SARS-CoV-2 Vaccination of Children Ages 5–11 Years on COVID-19 Disease Burden and Resilience to New Variants in the United States, November 2021–March 2022: A Multi-model Study*, 17 Lancet Regional Health - Americas 100398 (2023).

68 Borchering et al., *supra* note 67.

vaccine is safe for children between the ages of 6 months and 18 years old. A 2025 study of four large administrative claims databases containing data on 13.9 million Americans ages 6 months and older who received a bivalent Covid vaccine found *no* statistical signals of serious medical health outcomes like anaphylaxis or myocarditis among the 642,142 vaccinated children ages 6 months to 17 years.[69] The study concluded that its "[r]esults were consistent with published COVID-19 vaccine safety studies and support the safety profile of bivalent COVID-19 mRNA vaccines."[70] Similarly, a 2022 study found that, among nearly 50,000 cases reviewed of children ages 5 to 11 who received a Covid vaccine, "most reported reactions were mild-to-moderate" and "97% were nonserious."[71] The study concluded that "no safety signals were detected in weekly sequential monitoring after administration of 726,820 doses" of the vaccine.[72] An English study analyzing data from more than 5 million children vaccinated against Covid found no increased risks of adverse events, such as hospitalization or aggravation of existing health conditions, and reported a "favo[]rable safety profile of COVID-19 vaccination in under-18s."[73]

These and other studies have also found that the Covid vaccine is highly effective in preventing severe health outcomes among children. A 2023 study examined a broad range of data from January 2020 to December 2022, including (1) peer-reviewed studies published on PubMed and Medline, (2) study data from the FDA website used in decision memoranda for vaccine authorizations in the pediatric population, and (3) post-authorization data regarding pediatric

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69 Patricia C. Lloyd et al., *Safety Monitoring of Bivalent COVID-19 mRNA Vaccines Among Recipients 6 Months and Older in the United States*, 34(5) Pharmacoepidemiology & Drug Safety e70151 (May 2025).

70 *Id.*

71 Anne M. Hause et al., *Safety of COVID-19 Vaccination in United States Children Ages 5 to 11 Years*, 150(2) Pediatrics e2022057313 (2022).

72 *Id.*

73 Emma Copland et al., *Safety Outcomes Following COVID-19 Vaccination and Infection in 5.1 Million Children in England*, 15 Nature Commc'ns 3822, at Abstract (2024).

Covid vaccinations from the CDC website.[74] In assessing the safety and efficacy of Covid vaccines in pediatric patients, the study concluded, "[t]here is sufficient and continually growing safety and efficacy data available to recommend COVID-19 vaccinations for children ≥6 months of age."[75]

IV. THE DIRECTIVE WILL CAUSE LASTING HARM TO PREGNANT PATIENTS, FETUSES, INFANTS, AND CHILDREN BY DISCOURAGING VACCINATION AGAINST COVID

As Amici's members have witnessed firsthand, the Directive has already caused serious harm in health care settings across the country, which will worsen the longer the Directive remains in effect. Covid vaccinations still prevent illness and death. By reversing the CDC's immunization recommendations for Covid, the Directive has disrupted the robust, proven vaccine framework that patients, providers, and health systems have relied on for decades. It has also undermined patient trust in vaccines, which will discourage uptake and lead to increased infection and illness.

Although the pandemic has ended, vaccination remains important. Data show that immunity from an initial vaccine series diminishes after roughly six months, and booster doses provide added protection—even for those previously infected.[76] Boosters in pregnant patients, children, and adults help reduce the risk of long Covid and other post-Covid complications.[77] In short, the scientific evidence is conclusive that maintaining current Covid vaccination status remains critically important to guard against the virus's severe and potentially long-lasting effects. The threat is not theoretical: As of August 7, 2025, Covid diagnoses accounted for over two percent of emergency room visits for children up to age 11, "the largest jump of any age group."[78]

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[74] Jeremy S. Stultz & Lea S. Eiland, *A Review of the Data Supporting Use of COVID-19 Vaccinations in the Pediatric Population*, 57(11) Annals Pharmacotherapy 1328 (2023).

[75] *Id.* at Abstract.

[76] *See, e.g.*, Daniel Feikin et al., *Duration of effectiveness of vaccines against SARS-CoV-2 infection and COVID-19 disease: results of a systematic review and meta-regression*, 399(10328) The Lancet 024 (2022).

[77] *See* Alexandre R. Marra et al., *The Effectiveness of COVID-19 Vaccine in the Prevention of Post-COVID Conditions: A Systematic Literature Review and Meta-Analysis of the Latest Research*, 3 Antimicrobial Stewardship & Healthcare Epidemiology e168 (2023).

[78] Sabrina Malhi, *Covid is Rising. New Vaccines May Not be Ready Until mid-September*, Wash. Post (Aug. 16, 2025), https://tinyurl.com/3mf88ejs.

The CDC's immunization schedule has been the gold standard of preventive care, relied on by both providers and patients to assess which vaccines are safe, effective, and necessary to protect the health of patients, their children, and their surrounding communities.[79] The sudden removal of a vaccine from that schedule delivers an unmistakable message that the vaccine is no longer safe, effective, or needed—contrary to the established medical evidence.[80] Furthermore, the removal of the Covid vaccine from the list will not go under the radar. In fact, it has already been broadly communicated through social media,[81] sowing confusion and fear in patients, contributing to mistrust in vaccine safety and efficacy generally, and forcing medical providers to choose between their training and established scientific evidence and the edicts of the Directive.[82]

When (not if) vaccination rates drop as a result of the Directive, the outcome is predictable: more pregnant patients, fetuses, infants, children, and their communities will be left vulnerable to Covid and will suffer preventable illness that will lead to severe health outcomes in a portion of those patients, including loss of viable pregnancies, more newborns hospitalized with Covid in their first weeks of life,[83] disability, and death.[84] These are not hypothetical concerns; CDC data showed that hospital admissions for those 17 years of age or younger were more than three times

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79 *See* Jason L. Schwartz, Perspective, *Revised Recommendations for Covid-19 Vaccines — U.S. Vaccination Policy under Threat*, 393(5) New Eng. J. Med. 417 (June 18, 2025); Press Release, American Medical Association ("AMA"), *AMA Statement on Removal of COVID-19 Vaccine from CDC Immunization Schedule* (June 9, 2025), https://tinyurl.com/a42jdfry.

80 *See supra* pp. 8-16; *see also* Press Release, American Academy of Pediatrics, *AAP Statement Opposing Removal of COVID-19 Vaccine Recommendation for Children and Pregnant Individuals* (May 27, 2025).

81 *See., e.g.*, Melissa Rudy, *CDC removes COVID vaccine recommendation for healthy children and pregnant women*, Fox News (May 27, 2025), https://tinyurl.com/2fxzne6c; Rob Stein & Michel Martin, *COVID Shots No Longer Recommended for Kids and Pregnant Women, RFK, Jr. Says*, NPR: Morning Edition (May 28, 2025), https://tinyurl.com/32vbcref.

82 *See* ACOG, Committee on Ethics, Committee Opinion No. 829, *Ethical Issues with Vaccination in Obstetrics and Gynecology* (July 2021), https://tinyurl.com/2pt6n8s7; Kai Ruggeri et al., *Behavioural Interventions to Reduce Vaccine Hesitancy Driven by Misinformation on Social Media*, 384 BMJ e076542 (2024); Flinta Rodrigues et al., *The Impact of Social Media on Vaccination: A Narrative Review*, 38(40) J. Korean Med. Sci. e326 (2023).

83 *See* John Parkinson, *CDC Pulls COVID-19 Vaccine From Immunization Schedule for Pregnant Women, Healthy Children*, Contagion Live (May 27, 2025), https://tinyurl.com/2trhbs5r (quoting Tina Tan, president of the Infectious Diseases Society of America); N.B. Halasa et al., *Maternal Vaccination and Risk of Hospitalization for Covid-19 among Infants*, 387 New Eng. J. Med. 109 (2022).

84 *See supra* pp. 7-8.

higher in states with the lowest versus higher vaccination rates in August 2021.[85] By intentionally discouraging vaccination in defiance of the scientific evidence, the Directive threatens to undo the hard-won progress in protecting vulnerable groups as the fall respiratory virus season approaches.

The potentially life-threatening impact on infants under six months is especially concerning because those infants primarily depend on vaccination during pregnancy for protection. If the Directive's chilling effect on vaccination results in fewer pregnant individuals choosing (and being able) to get vaccinated, more newborns will be hospitalized with Covid in their first weeks of life.

V. THE DIRECTIVE HAS HARMED AND WILL CONTINUE TO HARM AMICI'S MEMBERS

The Directive also poses concrete, continuing harm to Amici's members, many of whom are medical providers who have reported that greater obstacles to vaccine access are undermining their relationships with patients, disrupting their clinical practices, and putting their health at risk.

First, the Directive exposes pregnant providers to the risk of contracting the virus by preventing, or creating obstacles to, receiving the vaccine and by increasing the likelihood of exposure to unvaccinated patients. Physicians[86] and other healthcare providers[87] have ethical obligations to treat patients regardless of immunization status. In the early epidemic period, when vaccines were not widely available to doctors or patients, frontline health care workers had a nearly 12-times higher risk of testing positive for Covid compared to the general community.[88]

Second, members report that the Directive has led to increased time spent counseling

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85 *See, e.g.*, Stephanie Soucheray, *Child COVID Hospital Cases Up in Low-Vaccination States*, CIDRAP News (Sept. 3, 2021), https://tinyurl.com/4ckyhtyj (citing evidence that, during the Delta and Omicron surges, U.S. regions with low vaccination uptake reported significantly higher rates of children and adolescents with severe outcomes).

86 *See, e.g.*, AMA, *Code of Medical Ethics*, *Opinion 8.3*: *Physicians' Responsibilities in Disaster Response & Preparedness*, https://tinyurl.com/5n8rpw7v (last visited Oct. 7, 2025); AMA, *Can Physicians Decline Unvaccinated Patients?* (Sept. 15, 2021), https://tinyurl.com/4e893xs4.

87 *See* Epiphany Cruz-Maxwell et al., *Vaccination Discrimination Goes Against Nursing Ethics*, The Hastings Center for Bioethics (Dec. 17, 2021), https://tinyurl.com/2bsu52hu.

88 Long H. Nguyen et al., *Risk of COVID-19 Among Front-line Health-Care Workers and the General Community: A Prospective Cohort Study*, 5(9) Lancet Public Health e475 (2020).

confused and skeptical patients. Others report that the sudden vaccine recommendation reversal has caused rifts with vaccine-skeptical patients, undermining trust and potentially affecting the sustainability of their practices.[89] Vaccine skepticism is already widespread in the United States, particularly as to the Covid vaccine.[90] Hesitancy may also have spillover effects for other critical vaccines long recommended by the CDC during a major measles outbreak.[91] As vaccine hesitancy grows, providers must devote more time to educating patients regarding the scientific evidence about vaccines and potential adverse consequences of non-vaccination, straining their practices and leaving less time for other patients and other clinical and public-health responsibilities.

Third, many of Amici's member providers now face a difficult—and wholly unnecessary—professional and ethical conflict: whether to follow the Directive or, instead, the weight of medical evidence and their clinical judgment to recommend vaccination. Providers now suddenly feel compelled to make immunization recommendations at odds with those of the U.S. federal government, which is a historically atypical and damaging position to be in that can erode patient trust. The Directive also exposes providers to professional and legal repercussions, including professional discipline, licensing sanctions, or medical malpractice liability, for recommending vaccination on the basis of the clear weight of evidence and their clinical judgment. After Plaintiff American Academy Pediatrics ("AAP") put out its own Covid vaccine guidance in early August 2025, recommending that children be vaccinated, Secretary Kennedy posted on the social media

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[89] *Cf.* Roy H. Perlis, *Trust in Physicians and Hospitals During the COVID-19 Pandemic in a 50-State Survey of US Adults*, 7(7) JAMA Network Open e2424984, at 1 (July 1, 2024) ("This survey study of US adults suggests that trust in physicians and hospitals decreased during the COVID-19 pandemic.").

[90] *See* Muhammad Ittefaq et al., *Analysis of Public Opinion Polls About COVID-19 Vaccines: Theoretical and Policy Implications for Vaccine Communication and Campaigns to Address Vaccine Hesitancy*, 20(1) Hum. Vaccines & Immunotherapeutics 2437921 (2024); Panagiotakopoulos, *supra* note 9, at slides 44-50.

[91] *See* M. Lelinneth B. Novilla et al., *Why Parents Say No to Having Their Children Vaccinated against Measles: A Systematic Review of the Social Determinants of Parental Perceptions on MMR Vaccine Hesitancy*, 11(5) Vaccines (Basel) 926 (May 2, 2023); *see also U.S. Measles Cases Hit Highest Level Since Declared Eliminated in 2000*, Johns Hopkins Bloomberg Sch. Pub. Health (July 7, 2025), https://tinyurl.com/ye26a5pv.

site X: "AAP should … be candid with doctors and hospitals that recommendations that diverge from the CDC's official list are not shielded from liability under the 1986 Vaccine Injury Act."[92] As a further example, during a September 4, 2025, hearing before the Senate Finance Committee where Secretary Kennedy testified, Senator Bill Cassidy (R-LA), a physician, read a constituent letter from a fellow physician stating that his practice was "confused and concerned" about vaccine eligibility and was seeking legal advice regarding vaccine eligibility due to liability concerns.[93] That experience and those sentiments reflect those of many of Amici's provider members.

The Directive also creates ethical challenges for medical providers who determine that their patients should get the vaccine for any number of reasons (including underlying health conditions) but who cannot afford, or whose insurance no longer covers, the vaccine. In sum, Amici's members now face clinically unfounded conflicts regarding their ethical responsibilities and professional risks on a key public health issue because of an HHS directive that clashes with the scientific evidence and general clinical consensus on Covid vaccinations.

Fourth, these professional and ethical conflicts, increased risks of harm to patients, a reduced ability to protect the most vulnerable, and difficulties in managing patient loads have created emotional and psychological burdens for many of Amici's members who are clinicians and providers in diverse settings—from private hospitals and clinics to public and non-profit medical centers that serve vulnerable populations and underprivileged communities across the country.[94]

CONCLUSION

Amici respectfully request that Plaintiffs' requested relief be granted.

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[92] Secretary Robert F. Kennedy, Jr. (@SecKennedy), X.com (Aug. 19, 2025, 5:17 PM), https://tinyurl.com/4fh4prht (last visited Oct. 7, 2025).

[93] *The President's 2026 Health Care Agenda: Hearing Before the S. Comm. on Fin.*, 119th Cong. (Sept. 4, 2025), https://tinyurl.com/34h3b8pz (questioning by Sen. Bill Cassidy, at 1:42:10-1:42:35).

[94] *See* Christine A. Sinsky et al., *Politicization of Medical Care, Burnout, and Professionally Conflicting Emotions Among Physicians During COVID-19*, 98(11) Mayo Clinic Proceedings 1613-1628 (Nov. 2023).

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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 October 9, 2025.

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APPENDIX

LIST OF AMICI CURIAE

1. **American College of Obstetricians & Gynecologists (ACOG)** is the premier professional membership organization for obstetrician–gynecologists. The College produces practice guidelines for health care professionals and educational materials for patients, provides practice management and career support, facilitates programs and initiatives to improve women's health, and advocates for members and patients. There are over 62,000 ACOG members spanning a wide geography and across the career life cycle.

2. **American Academy of Family Physicians (AAFP)**, founded in 1947, is one of the largest national medical organizations, representing nearly 130,000 family physicians and medical students nationwide. AAFP seeks to improve the health of patients, families, and communities by advocating for the health of the public and by supporting its members in providing continuous comprehensive health care to all.

3. **American Academy of Nursing (AAN)** serves the public by advancing health policy through the generation, synthesis, and dissemination of nursing knowledge. Academy Fellows are inducted into the organization for their extraordinary contributions to improve health locally and globally. With more than 3,200 Fellows, the Academy represents nursing's most accomplished leaders in policy, research, administration, practice, and academia.

4. **American College of Chest Physicians (CHEST)** is comprised of more than 18,000 physicians, advance practice providers, respiratory therapists, and other front line health care professionals who provide patient care in pulmonary, critical care, and sleep medicine. CHEST serves as an important connection to clinical knowledge, research,

and resources, including through its highly respected peer reviewed journal, clinical practice guidelines, and consensus statements. CHEST is interested in providing evidence-based guidance on respiratory disease-related public health issues and advocating for best practices in patient care.

5. **American College of Medical Genetics and Genomics (ACMG)** is the only nationally recognized medical professional organization solely dedicated to improving health through the practice of medical genetics and genomics, and the only medical specialty society in the United States that represents the full spectrum of medical genetics disciplines in a single organization. The ACMG is dedicated to improving health through the clinical and laboratory practice of medical genetics and to guiding the safe and effective integration of genetics and genomics into all of medicine and healthcare, resulting in improved personal and public health.

6. **American College of Nurse-Midwives (ACNM)** is the professional association that represents certified nurse-midwives and certified midwives in the United States. ACNM sets the standard for excellence in midwifery education and practice in the United States and strengthens the capacity of midwives in developing countries. Members of ACNM are primary care providers for women throughout their lifespans, with a special emphasis on pregnancy, childbirth, and gynecologic and reproductive health. ACNM's mission is to support midwives, advance the practice of midwifery, and achieve optimal, equitable health outcomes for the people and communities midwives serve through inclusion, advocacy, education, leadership development, and research.

7. **American Gynecological and Obstetrical Society (AGOS)** is composed of

individuals attaining national prominence in scholarship and leadership in the discipline of Obstetrics, Gynecology and Women's Health. AGOS's mission is to promote excellence in women's health care through advocacy for research and clinical training and the development of academic leaders in obstetrics and gynecology. AGOS is committed to enhancing diversity and inclusion across the organization.

8. **American Medical Association (AMA)** is the largest professional association of physicians, residents, and medical students in the United States. Additionally, through state and specialty medical societies and other physician groups seated in its House of Delegates, substantially all physicians, residents, and medical students in the United States are represented in the AMA's policy-making process. The AMA was founded in 1847 to promote the art and science of medicine and the betterment of public health, and these remain its core purposes. AMA members practice in every medical specialty and in every state.

9. **American Medical Women's Association (AMWA)** is the oldest multi-specialty organization for women in medicine. Its mission is to advance women physicians and improve the health of women. AMWA achieves this by providing and developing programs in advocacy, leadership, education, and mentoring—and through strategic alliances. For more than a century, AMWA has represented the vision and voice of women in medicine.

10. **American Society for Reproductive Medicine (ASRM)** is dedicated to the advancement of the science and practice of reproductive medicine. Its members include approximately 8,000 professionals.

11. **Council of Chairs of Obstetrics and Gynecology (CUCOG)** is an association

promoting excellence in medical education in the fields of obstetrics and gynecology. Its members represent the departments of obstetrics and gynecology of schools of medicine across the country.

12. **Massachusetts Medical Society (MMS)** is the largest professional association for physicians and medical students in Massachusetts, with over 23,000 members. The MMS advocates on behalf of physicians and patients to help inform and shape health-related policy at the state and federal levels, to promote public health, and to advance health equity. The MMS is committed to advancing evidence-based medical knowledge and promoting patient safety and quality care.

13. **National Association of Nurse Practitioners in Women's Health (NPWH)** is the national professional association representing more than 13,500 board certified women's health nurse practitioners and advanced practice registered nurses who provide women's and gender-related healthcare. NPWH sets a standard of excellence by translating and promoting the latest women's healthcare research and evidence-based clinical guidance, providing high quality continuing education, and advocating for patients, providers, and the women's health nurse practitioner profession. NPWH's mission includes protecting and promoting women's and all individuals' rights to make their own choices regarding their health and well-being within the context of their lived experience and their personal, religious, cultural, and family beliefs.

14. **National Association of Pediatric Nurse Practitioners (NAPNAP)** is the professional membership association for pediatric nurse practitioners and all pediatric-focused advanced practice registered nurses. With over 8,000 members, it is the only national organization dedicated to both advancing the APRN role and improving the

quality of health care for infants, children and adolescents. NAPNAP members include national child health experts, respected authors, distinguished faculty and practicing clinicians who represent many facets of pediatric health care delivery.

15. **North American Society for Pediatric and Adolescent Gynecology (NASPAG)** is a voluntary, non-profit organization devoted to conducting, encouraging, and supporting programs of medical education, research and professional training in the field of pediatric and adolescent gynecology ("PAG"). NASPAG members are pediatric and gynecologic providers who reside in North America. Its focus is to serve and be recognized as the lead provider in PAG education, research, and clinical care; conduct and encourage multidisciplinary and inter-professional programs of medical education and research in the field of PAG; and advocate for the reproductive well-being of children and adolescents and the provision of unrestricted, unbiased, and evidence-based practice of PAG.

16. **Society for Adolescent Health and Medicine (SAHM)** is a multidisciplinary organization committed to the promotion of optimal health and well-being for all adolescents and young adults by supporting adolescent health and medicine professionals through the advancement of clinical practice, care delivery, research, advocacy, and professional development.

17. **Society of General Internal Medicine (SGIM)** is a member-based internal medical association of over 3,300 of the world's leading general internists, who are dedicated to improving access to care for all populations, eliminating health care disparities, and enhancing medical education. SGIM's mission is to cultivate innovative educators, researchers, and clinicians in general internal medicine, leading the way to better health

for everyone. SGIM members advance the practice of medicine through their commitment to providing comprehensive, coordinated, and cost-effective care to adults; educating the next generation of outstanding physicians; and conducting cutting-edge research to improve quality of care and clinical outcomes of all patients.

18. **Society of Gynecologic Oncology (SGO)** is the premier medical specialty society for health care professionals trained in the comprehensive management of gynecologic cancers. As a 501(c)(6) organization, SGO contributes to the advancement of women's cancer care by encouraging research, providing education, raising standards of practice, advocating for patients and members, and collaborating with other domestic and international organizations.

19. **Society of Gynecologic Surgeons (SGS)** is a select member group of over 500 physicians representing both private practice and academic faculty who are all involved in teaching and the practice of advanced gynecologic surgery. SGS promotes excellence in gynecologic surgery through acquisition of knowledge and improvement of skills, advancement of basic and clinical research, and professional and public education.

20. **Society of OB/GYN Hospitalists (SOGH)** is a rapidly growing group of physicians, midwives, nurses, physician assistants, and other individuals in the health care field who support the OB/GYN Hospitalist model. SOGH is dedicated to improving outcomes for hospitalized women and supporting those who share this mission. SOGH's vision is to shape the future of OB/GYN by establishing the Hospitalist model as the care standard. SOGH values excellence, collaboration, leadership, quality, and community.