
**UNITED STATES COURT OF APPEALS
FOR THE FIRST CIRCUIT**

American Academy of Pediatrics, *et al.*,
Plaintiffs - Appellees,

v.

Robert F. Kennedy, Jr., *et al.*,
Defendants - Appellants.

On Appeal from the U.S. District Court
for the District of Massachusetts

**BRIEF OF *AMICI CURIAE* PUBLIC HEALTH GROUPS IN SUPPORT OF
THE PLAINTIFFS-APPELLEES SEEKING AFFIRMANCE**

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CORPORATE DISCLOSURE STATEMENT

Amici curiae American Cancer Society, American Cancer Society Cancer Action Network, AIDS Institute, American Lung Association, American Society of Pediatric Hematology/Oncology, Arthritis Foundation, Association of Pediatric Hematology/Oncology Nurses, Blood Cancer United, Byrd Cancer Education and Advocacy Foundation, CancerCare, Cancer Nation, Cervivor, Inc., GO2 for Lung Cancer, HealthyWomen, Hypertrophic Cardiomyopathy Association, IATVFoundation, International Foundation for Autoimmune and Autoinflammatory Arthritis, LUNGevity Foundation, National Association for the Advancement of Colored People, National Comprehensive Cancer Network, National Consumers League, National Multiple Sclerosis Society, National Patient Advocate Foundation, and Pro-Vaccine Legal Alliance at American Families for Vaccines are all groups committed to public health and improving the lives of patients. No party to this filing has a parent corporation and no publicly held corporation owns 10% or more of the stock of any of the parties to this filing.

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STATEMENT OF INTEREST OF *AMICI CURIAE*

The American Cancer Society, the American Cancer Society Cancer Action Network, the AIDS Institute, the American Lung Association, the American Society of Pediatric Hematology/Oncology, the Arthritis Foundation, the Association of Pediatric Hematology/Oncology Nurses, Blood Cancer United, the Byrd Cancer Education and Advocacy Foundation, CancerCare, Cancer Nation, Cervivor, Inc., GO2 for Lung Cancer, HealthyWomen, the Hypertrophic Cardiomyopathy Association, the IATVFoundation, the International Foundation for Autoimmune and Autoinflammatory Arthritis, the LUNGevity Foundation, the National Association for the Advancement of Colored People, the National Comprehensive Cancer Network, the National Consumers League, the National Multiple Sclerosis Society, the National Patient Advocate Foundation, and the Pro-Vaccine Legal Alliance at American Families for Vaccines (collectively, the “Public Health Groups”) are among the largest, most prominent organizations representing the interests of patients, survivors and families affected by cancer, lung disease, multiple sclerosis, arthritis, and AIDS, as well as an association of nurses who treat these patients. *Amici* are dedicated to supporting patients and their families across the United States and together represent millions of people who suffer from the various diseases to which *amici* dedicate their efforts. Patients suffering from these conditions rely on vaccines for protection against infectious

disease, and a number of these illnesses can themselves be treated or prevented with vaccines.¹

Vaccinations play a critical role in promoting public health, preventing serious illnesses and protecting millions of people with serious conditions that compromise their immune systems or otherwise put them at heightened risk for severe illness from vaccine-preventable diseases. *Amici* have strong and continuing interests in protecting access to and development of vaccines that are proven to be safe and effective, and therefore have a profound interest in maintaining the institutional integrity of the Advisory Committee on Immunization Practices (“ACIP”) and ensuring that its membership complies with applicable legal standards.²

SUMMARY OF THE APPLICABLE STATUTORY FRAMEWORK

The Federal Advisory Committee Act (“FACA”), 5 U.S.C. §§ 1001 *et seq.*, and its implementing regulations establish binding membership criteria for ACIP. *See* 5 U.S.C. §§ 1003(a), 1004(b)(2); 41 C.F.R. § 102-3.60(b). Among other requirements, ACIP membership must “be fairly balanced in terms of the points of view represented,” 5 U.S.C. § 1004(b)(2), and “should include persons with

¹ This brief is filed with the consent of all parties. No person or entity other than *amici* and their counsel authored this brief in whole or in part or contributed money intended to fund preparing or submitting this brief.

² Separate statements of interest of each of the individual *amici* are contained in the Addendum.

demonstrated professional or personal qualifications and experience relevant to the functions and tasks to be performed by the committee.” 41 C.F.R. § 102-3.60(b)(1). These “functions and tasks” include developing and recommending “updates to [Centers for Disease Control and Prevention] immunization schedules for children, adolescents, and adults.”³

In addition, Congress entrusted ACIP with the responsibility of making recommendations that have a direct and immediate impact on public health by affecting which vaccines must be covered by most public and private insurers. Most private insurers are required to provide coverage for “immunizations that have in effect a recommendation from” ACIP, 42 U.S.C. § 300gg-13(a)(2); 45 C.F.R. § 147.130(a)(1)(ii), and Medicare Part D and Medicaid plans must cover ACIP-recommended vaccines. 42 U.S.C. §§ 1395w-102(b)(8), 1396a(a)(10)(A), 1396d(a)(13)(B). The Vaccines for Children (“VFC”) program, which makes vaccines available to children who might otherwise be left without access to them, is required to provide ACIP-recommended vaccines at no cost to covered patients. 42 U.S.C. §§ 1396s(d)(1), (e). ACIP’s vaccine classifications and recommendations determine whether millions of people have access to low-cost or

³ CTRS. FOR DISEASE CONTROL & PREVENTION, *Advisory Committee on Immunization Practices Charter* at 2 (filed May 27, 2026), <https://www.cdc.gov/acip/downloads/acip-charter.pdf>.

no-cost vaccines, and—when inadequately justified or explained—can leave the public confused about vaccines’ efficacy, risk, and coverage by insurance. This confusion can, in turn, lead to a decline in vaccine uptake, with potentially dire consequences for immunocompromised patients. ACIP recommendations also serve as the clinical foundation for vaccine decisions across medical specialties, including oncology. The American Society of Clinical Oncology, the largest membership organization of oncology professionals, directly incorporates ACIP-recommended immunization schedules for immunocompromised adults into its treatment and management guidelines for adults with cancer.⁴

These high stakes illustrate the importance of placing decisions about vaccines in the hands of qualified experts—an ACIP comprised of members who meet the standards established by statute, regulation and ACIP’s own charter. To the extent there is any question as to the meaning of the statutory criteria, the Court owes no deference to the agency’s interpretation but rather “must exercise [its] independent judgment.” *See Loper-Bright Enterprises v. Raimondo*, 603 U.S. 369, 412-13 (2024).

⁴ Mini Kamboj, *et al.*, *Vaccination of Adults with Cancer: ASCO Guideline*, 42 J. Clinical Oncology 1699-1721 (Mar. 18, 2024) (DOI:10.1200/JCO.24.00032), <https://ascopubs.org/action/doSearch?ContribAuthorRaw=Kamboj%2C+Mini>.

SUMMARY OF THE ARGUMENT

Vaccines are critical to the health and welfare of people at risk for or diagnosed with cancer and other serious diseases. Vaccines serve three key purposes: preventing cancer and other conditions by targeting viruses that cause them; treating cancer and other diseases by training the immune system to target specific cells; and protecting cancer patients and individuals suffering from other chronic conditions from infectious vaccine-preventable diseases. ACIP's vaccine recommendations, which determine vaccine availability and influence vaccination rates, are particularly important to millions of patients with compromised immune systems resulting from cancer or from immunosuppressant or immunomodulating medications. These patients are especially vulnerable to infectious vaccine-preventable diseases, and they rely heavily on broad community vaccination to safely participate in daily life activities such as attending school, working outside the home, and seeking medical care.

Community benefit is one of the strongest public health justifications for vaccination. The Supreme Court has long recognized that vaccination requirements exist to protect the public as a whole, particularly those who cannot protect themselves, beginning with *Jacobson v. Massachusetts*, 197 U.S. 11 (1905) and reaffirmed in *Zucht v. King*, 260 U.S. 174 (1922). Congress relied on these precedents when it passed statutes expressly incorporating ACIP

recommendations, assuming ACIP would operate through an expert, balanced, and scientifically grounded process.

Given the implications of ACIP decisions for public health, it is critical that its recommendations be evidence-based, grounded in the latest science, and informed by the professional expertise and experience of its members. ACIP's governing statutes, regulations, and charter require as much. The recent termination and replacement of ACIP's membership, and ACIP's subsequent changes to its vaccine recommendations, represent a radical departure from those requirements and risk reducing access to and undermining confidence in vaccines. The public health consequences of these actions are grave. People with cancer and other life-altering conditions face heightened risks as community protection erodes and access to promising vaccine treatments is delayed.

ARGUMENT

I. ACIP RECOMMENDATIONS HAVE DIRECT AND FAR-REACHING CONSEQUENCES FOR PATIENTS.

ACIP plays vital and unique roles in public health: it provides expert advice to the Centers for Disease Control and Prevention ("CDC") on the use of vaccines that have been approved by the Food and Drug Administration ("FDA") as safe and effective to prevent diseases. Congress has enshrined its trust in ACIP recommendations through statutes that drive insurance coverage; and states, health care institutions, and leading medical organizations rely on its recommendations to

guide immunization policies, inform clinical practice and ensure appropriate patient care.

For example, federal law requires most commercial insurers and Medicaid and Medicare Part D plans to cover ACIP-recommended vaccines. *See* 42 U.S.C. § 300gg-13(a)(2); 45 C.F.R. § 147.130(a)(1)(ii); 42 U.S.C. §§ 1395w-102(b)(8), 1396a(a)(10)(A), 1396d(a)(13)(B). The VFC program likewise relies on ACIP recommendations to determine which vaccines to make available at no-cost to children who are uninsured, underinsured, eligible for Medicaid, or American Indian or Alaska Native. 42 U.S.C. §§ 1396s(d)(1), (e). With roughly half of U.S. children receiving their vaccines at no cost through the VFC program, many millions of children depend on ACIP's recommendations for protection from vaccine-preventable diseases.⁵

Because private health insurance, Medicaid, Medicare Part D and VFC program coverage of vaccine costs is tied to ACIP's vaccine recommendations, a seemingly minor change in an ACIP recommendation can lead to the reduction or elimination of coverage for a particular vaccine, driving up the vaccine's cost for

⁵ *See* CTRS. FOR DISEASE CONTROL & PREVENTION, *Transcript for Vital Signs Telebriefing: Vaccines for Children Program celebrates 30 years of providing lifesaving vaccinations to children at no cost* (Aug. 13, 2024), <https://www.cdc.gov/media/releases/2024/t0814-vs-vaccines-children-program.html>.

patients. Even what might appear to be small shifts in the costs of medical care, such as a one or five dollar co-payment for a vaccine, can result in significantly lower vaccination rates.⁶ Additionally, many states and municipalities rely on ACIP recommendations and CDC guidance as the basis for their local vaccine policies. States implement ACIP and CDC recommendations by establishing school and childcare vaccination requirements, defining allowable vaccination exemptions, determining coverage for state-regulated insurance plans, and issuing clinical and public health guidance to providers and local health departments. A recent analysis examined 14 states and found that more than half directly tie vaccination requirements for healthcare workers and hospital patients to ACIP recommendations.⁷ The report cautioned that changes to these recommendations could leave vulnerable populations, including immunocompromised patients, less protected against vaccine-preventable diseases.

ACIP's pervasive influence on Americans' access to vaccines—and thus on the protection of immunocompromised individuals—demands scientific rigor and

⁶ See S. Artiga, et al., *The effects of premiums and cost sharing on low-income populations: Updated review of research findings*, KAISER FAMILY FOUNDATION (June 1, 2017), <https://www.kff.org/medicaid/the-effects-of-premiums-and-cost-sharing-on-low-income-populations-updated-review-of-research-findings/>.

⁷ AMERICAN FAMILIES FOR VACCINES, *Vaccine Policy Atlas: State laws that reference the Advisory Committee on Immunization Practices (ACIP)* (Jan. 2026), <https://static1.squarespace.com/static/688baf8af1d98541f68b14a7/t/699f036d5f4681445e323867/1772028781279/Vaccine+Policy+Atlas-January+2026.pdf>.

specialized expertise across multiple scientific disciplines, including immunology, epidemiology and clinical research. ACIP members must have the background and expertise required to develop recommendations grounded in an independent, evidence-based, scientific process. They must also be capable of communicating clear guidance to healthcare professionals, parents and rate payers regarding vaccine policies. In short, ACIP members must have the qualifications set forth in ACIP's controlling statute, regulation and charter.

II. VACCINATIONS ARE ESSENTIAL ACROSS THE HEALTH SPECTRUM.

A. Vaccines Can Prevent Cancer and Other Illnesses.

1. Prevention of Cancer.

The human papillomavirus ("HPV") and the hepatitis B ("HepB") vaccines illustrate the important and evolving role vaccines play in cancer prevention: both have protected generations of people from cancer caused by the viruses they target.

HPV infections are responsible for 37,000 cancers in the U.S. every year, including virtually all cervical cancers, 90% of anal cancers, and 60-70% of oropharyngeal, vaginal, vulvar, and penile cancers.⁸ In 2026 alone, an estimated 13,490 people are expected to be diagnosed with cervical cancer, and 4,200 will

⁸ AMERICAN CANCER SOCIETY, *Cancers Linked with HPV* (Mar. 19, 2026), <https://www.cancer.org/cancer/risk-prevention/hpv/hpv-and-cancer-info.html>.

die from the disease.⁹ An estimated 60,480 people in the U.S. are expected to be diagnosed with oropharyngeal and oral cavity cancers in 2026.¹⁰ Since the mid-2000s, incidence rates for oral cavity and oropharyngeal cancer have increased by 1% per year, mostly because of a rise in cancers linked with HPV infection.¹¹

Though significant, these numbers conceal a positive trend. A 2026 study found a sharp decline in cervical cancer incidence beginning with the generation of women born in 1988—the first generation eligible for the HPV vaccination.¹² Women born during the 1990s had roughly half the cervical cancer incidence of women born during the 1970s, and the downward trend has continued.¹³ Between 2016 and 2021, the incidence of cervical cancer among women aged 20 to 31 was 27% lower than in 2000-2005, a decrease that correlated with the increasing availability of the HPV vaccine.¹⁴ A similar phenomenon has been observed

⁹ AMERICAN CANCER SOCIETY, *Cancer Facts and Figures 2026* at 25 (2026), <https://www.cancer.org/content/dam/cancer-org/research/cancer-facts-and-statistics/annual-cancer-facts-and-figures/2026/2026-cancer-facts-and-figures.pdf>.

¹⁰ *Id.* at 19.

¹¹ AMERICAN CANCER SOCIETY, *Key Statistics for Oral Cavity and Oropharyngeal Cancers* (March 23, 2026), <https://www.cancer.org/cancer/types/oral-cavity-and-oropharyngeal-cancer/key-statistics.html>.

¹² Chenxi Jiang, et al., *Cervical cancer incidence rates by birth cohort against the backdrop of human papillomavirus vaccination in the United States*, J. Nat'l Cancer Inst. (Jan. 7, 2026) (DOI:10.1093), <https://academic.oup.com/jnci/advance-article-abstract/doi/10.1093/jnci/djaf374/8416735?redirectedFrom=fulltext>.

¹³ *Id.*

¹⁴ *Id.*

among men, with evidence of a decreasing risk of HPV-related head and neck cancer and other HPV-associated cancers.¹⁵

The HepB vaccine has had similar success in reducing cancer rates. Hepatitis B infections among children and adolescents have declined, lowering the risk of chronic infection and HBV-related liver cancer later in life.¹⁶ If begun at birth, the HepB vaccine series can reduce a person's risk of developing liver cancer by 84%.¹⁷

The dramatic success of the HPV and HepB vaccines in reducing rates of HPV- and HBV-related cancers points to the effectiveness of vaccines in preventing and potentially eliminating certain cancers altogether. Absent coherent, scientific, evidence-based recommendations from ACIP, access to these and other vaccines may be curtailed, usage rates can be expected to decline, and the promise of future cancer-preventing vaccines will dim.

¹⁵ Jefferson DeKloe, et al., *Effects of HPV vaccination on the development of HPV-related cancers: A retrospective analysis of a United States-based cohort*, 42 J. Clinical Oncology (May 29, 2024) (DOI:10.1200/JCO.2024.42.16), https://ascopubs.org/doi/10.1200/JCO.2024.42.16_suppl.10507.

¹⁶ Danae Bixler, et al., *Progress and Unfinished Business: Hepatitis B in the United States, 1980-2019*, Pub. Health Rep. (June 2023) (DOI:10.1177/00333549231175548), <https://pubmed.ncbi.nlm.nih.gov/37300309/>.

¹⁷ Chunfeng Qu, et al., *Efficacy of Neonatal HBV Vaccination on Liver Cancer and Other Liver Diseases over 30-year Follow-up of the Qidong Hepatitis B Intervention Study: A Cluster Randomized Controlled Trial*, PLoS Med. (Dec. 2014) (DOI:10.1371/journal.pmed.1001774), <https://pubmed.ncbi.nlm.nih.gov/25549238/>.

2. Prevention of Lung Disease.

Each year, vaccines prevent severe respiratory illnesses that impose significant costs on the national healthcare system and damage patients' health. During the 2024-2025 flu season, for instance, flu vaccination is estimated to have prevented up to 360,000 hospitalizations and 39,000 deaths.¹⁸ Adults who were hospitalized with the flu despite being vaccinated still benefited from vaccination: they were less likely to face severe in-hospital outcomes, such as admission to the intensive care unit, invasive mechanical ventilation, or organ support.¹⁹ Likewise, children who received an annual flu vaccine were 58% less likely to require a flu-related emergency department or urgent care visit than their unvaccinated peers.²⁰ Unvaccinated children, meanwhile, accounted for 85% of the 174 reported

¹⁸ CTRS. FOR DISEASE CONTROL & PREVENTION, *Influenza Activity in the United States during the 2024-25 Season and Composition of the 2025-26 Influenza Vaccine* (Sept. 26, 2025), <https://www.cdc.gov/flu/whats-new/2025-2026-influenza-activity.html>.

¹⁹ Nathaniel Lewis, et al., *Vaccine Effectiveness Against Influenza A – Associated Hospitalization, Organ Failure, and Death: United States, 2022-2023*, 78 *Clinical Infectious Diseases* (Apr. 2024) (DOI:10.1093/cid/ciad677), <https://pubmed.ncbi.nlm.nih.gov/38051664/>.

²⁰ Mark Tenforde, et al., *Influenza Vaccine Effectiveness Against Hospitalizations and Emergency Department or Urgent Care Encounters for Children, Adolescents, and Adults During the 2023-2024 Season, United States*, *Clinical Infectious Diseases* (Oct. 2025) (DOI:10.1093/cid/ciae597), <https://pubmed.ncbi.nlm.nih.gov/39656838/>.

influenza-associated pediatric deaths during the 2025-26 flu season.²¹ The economic cost of the flu season has reached nearly \$29 billion in lost productivity and medical expenses, a number that would doubtless be higher without the flu vaccine.²²

The Respiratory Syncytial Virus (“RSV”) vaccine, which first became available during the 2024-25 RSV season, has seen similar success. Widespread availability of maternal and infant RSV immunizations has been associated with falling RSV-related hospitalization rates among infants, which are now lower than pre-pandemic levels.²³

Vaccines targeting respiratory illnesses indirectly prevent other serious conditions. Flu infections can trigger asthma attacks and aggravate chronic obstructive pulmonary disease (“COPD”) or other lung disease symptoms. By reducing the risk of contracting the flu, vaccination can reduce the risk of these flu-

²¹ CTRS. FOR DISEASE CONTROL & PREVENTION, *Weekly US Influenza Surveillance Report: Key Updates for Week 20, ending May 23, 2026* (May 29, 2026), <https://www.cdc.gov/fluview/surveillance/2026-week-20.html>.

²² Robert Popovian, Wayne Winegarden, *Influenza’s Economic Burden and the Impact of Adult Vaccination*, (Dec. 30, 2025), <https://adultvaccinesnow.org/wp-content/uploads/2026/02/2025.12.23.25342685v1.full.pdf>.

²³ Monica Patton, *Interim Evaluation of Respiratory Syncytial Virus Hospitalization Rates Among Infants and Young Children After Introduction of Respiratory Syncytial Virus Prevention Produces – United States, October 2024 – February 2025*, 74 Ctrs. for Disease Control & Prevention Morbidity and Mortality Weekly Report 273-281 (May 8, 2025), <https://www.cdc.gov/mmwr/volumes/74/wr/mm7416a1.htm>.

related exacerbations of chronic health conditions. Indeed, flu vaccination is associated with an 80% decrease in congestive heart failure and COPD exacerbations.²⁴ By preventing flu infections in the first place, the flu vaccine also helps prevent heart attacks, which are six times more likely to occur during the week following a flu infection.²⁵

B. Vaccines Treat Cancer By Boosting The Immune System.

Cancer vaccine treatments improve the lives of cancer patients by prompting the immune system to fight tumor cells. These therapeutic cancer vaccines differ from vaccines that target viruses. The latter train the immune system to recognize and attack a particular virus, while the former trigger the immune system to mount an attack against cancer cells in the body. Rather than prevent disease, therapeutic cancer vaccines treat a disease that is already present.

²⁴ Ashley Tippet, et al., *Influenza Vaccine Effectiveness Pre-Pandemic Among Adults Hospitalized with Congestive Heart Failure or Chronic Obstructive Pulmonary Disease and Older Adults*, 78 Clinical Infectious Diseases 1065-1072 (Apr. 15, 2024) (DOI:10.1093/cid/ciad679), <https://pubmed.ncbi.nlm.nih.gov/37946601/>.

²⁵ Jeffrey Kwong, et al., *Acute Myocardial Infarction after Laboratory-Confirmed Influenza Infection*, 378 New England J. Med. 345-353 (Jan. 24, 2018) (DOI:10.1056/NEJMoa1702090), https://www.nejm.org/doi/full/10.1056/NEJMoa1702090?query=featured_home&cf_chl_f_tk=N.5v9nL2yc03Nw9go.1zJQ_.ReAkSCPv8VY5bXQao.M-1782851859-1.0.1.1-IT9b8RHLzjFiHA5vTCKXNnVmuRMdYluJjoyxmqa3Ap0.

Several of these promising vaccines have already been approved by the FDA, including vaccines for certain prostate and bladder cancers.²⁶ More are being researched, and the science is changing quickly.²⁷ Researchers are looking for ways to combine therapeutic cancer vaccines with other forms of cancer treatments, including another type of immunotherapy called checkpoint inhibitor therapy, to help improve the immune system.²⁸ While early results are promising, more research is necessary. Expert, evidence-based vaccine policies are needed to guide cancer vaccine development and ensure people with cancer have access to new vaccines as they become available.

C. Vaccines Protect People With Cancer and Other Serious Health Conditions From Vaccine-Preventable Diseases.

Vaccinated individuals are protected from debilitating and potentially deadly diseases, but the benefits of vaccines go beyond the individual. High vaccination rates protect entire communities by reducing the spread of infectious diseases.²⁹ This widespread protection is essential to safeguard the health of people whose

²⁶ AMERICAN CANCER SOCIETY, *Cancer Vaccines and Their Side Effects* (Jul. 7, 2025), <https://www.cancer.org/cancer/managing-cancer/treatment-types/immunotherapy/cancer-vaccines.html>.

²⁷ *Id.*

²⁸ *Id.*

²⁹ AMERICAN CANCER SOCIETY, *Cancer Facts & Figures 2026* (2026), <https://www.cancer.org/content/dam/cancer-org/research/cancer-facts-and-statistics/annual-cancer-facts-and-figures/2026/2026-cancer-facts-and-figures.pdf>.

immune systems are compromised by chronic disease. Many cancer patients have a weakened immune system due to their illness or treatment. Some are unable to receive vaccinations, while for others, vaccines may be less effective. This is especially true of patients with blood cancers, such as leukemia or lymphoma, or patients undergoing chemotherapy, long courses of corticosteroids, certain types of immunotherapies, or a stem cell or bone marrow transplant.³⁰ Individuals with chronic lung disease, heart disease, diabetes, or chronic kidney disease are also at increased risk for severe illness from respiratory viruses and thus benefit from wide community vaccination.³¹ The same is true for people living with other immune-mediated conditions such as multiple sclerosis (“MS”). Many individuals with MS receive immunosuppressive or immunomodulating therapies that increase their susceptibility to vaccine-preventable diseases.

These patients rely on broad community-wide vaccination in order to safely participate in everyday activities. High vaccination rates ensure they remain protected from vaccine-preventable diseases even if they themselves cannot receive vaccinations. Household contacts of cancer patients are often vectors for

³⁰ AMERICAN CANCER SOCIETY, *Vaccinations and Flu Shots for People with Cancer* (Mar. 26, 2026), <https://www.cancer.org/cancer/side-effects/infections/vaccination-during-cancer-treatment.html>.

³¹ CTRS. FOR DISEASE CONTROL & PREVENTION, *People at Increased Risk for Severe Respiratory Illnesses* (Aug. 18, 2025), <https://www.cdc.gov/respiratory-viruses/risk-factors/index.html>.

the spread of vaccine-preventable infections, and one in four cancer patients is a parent of a child under the age of 18.³² Thus, broad protective coverage boosted through high childhood vaccination rates is critical to allow immunocompromised cancer patients to safely interact with their loved ones.³³

High vaccination rates limit how widely infectious diseases circulate, reducing the number of people exposed. Without adequate community vaccination coverage, people with cancer, cancer survivors, people at increased risk of severe illness from respiratory viruses and other conditions, and their families, risk preventable morbidity and mortality simply by participating in everyday activities or interacting with family. High vaccination rates ensure that these individuals remain protected and allow them to actively participate in daily life.

III. RECENT DEPARTURES FROM ESTABLISHED ACIP NORMS HARM PATIENTS.

ACIP is not currently constituted as required by FACA, applicable regulations, or its own charter. The newly constituted ACIP has veered from its established practice and recommended changes to the vaccine schedule that were

³² Yusuf Hasiya, Kumar Abhishek, *The current state and future direction of childcare for cancer patients: a narrative review*, Support Care Cancer (Jan. 2025) (DOI:10.1007/s00520-025-09174-6), <https://pubmed.ncbi.nlm.nih.gov/39883180/>.

³³ Sandra E. Talbird, et al, *Impact of Routine Childhood Immunization in Reducing Vaccine-Preventable Diseases in the United States* 150 Pediatrics (Sep. 2022) (DOI:10.1542/peds.2021-056013), <https://pubmed.ncbi.nlm.nih.gov/35821599/>.

not triggered by new evidence regarding vaccine safety or effectiveness and did not involve a careful review of scientific evidence and public discussion. Rather than having members “with demonstrated professional or personal qualifications and experience relevant” to ACIP’s duties, 41 C.F.R. § 102-3.60(b)(1), ACIP now consists of members who lack expertise in reviewing, understanding, and making recommendations on the basis of scientific evidence.

The newly constituted ACIP’s redesignation of vaccines previously recommended for routine use among all children to “shared clinical decision-making” (“SCDM”)³⁴ illustrates the risks associated with decisions that are not based on new evidence or public comment. SCDM has long been a facet of discussions between parents and healthcare providers. Such discussions work best when guided by clear recommendations from trusted public health authorities. However, when an FDA-approved vaccine previously recommended for routine use is reclassified as SCDM, the change can signal the vaccine is neither necessary nor broadly recommended despite having proven safe and effective, leading to confusion among caregivers, parents and patients, particularly in rural and other

³⁴ U.S. DEPT. OF HEALTH AND HUMAN SERVICES, Decision Memo: Adopting Revised Childhood and Adolescent Immunization Schedule (Jan. 5, 2026), <https://www.hhs.gov/sites/default/files/decision-memo-adopting-revised-childhood-adolescent-immunization-schedule.pdf>.

underserved communities.³⁵ Furthermore, many states base school entry vaccination requirements on ACIP's recommendations for routine use, meaning that a change in vaccine designation to SCDM can be expected to result in the elimination of the vaccine from school entry requirements, reducing vaccination coverage in school settings and weakening community-wide immunity.³⁶

A decline in childhood vaccination coverage poses a direct risk to cancer and other patients, many of whom are immunocompromised and rely on high vaccination coverage in their communities for protection. A recent study shows that at current vaccination levels, measles could once again spread continuously within the U.S. in as little as two decades, leading to 851,300 cases over 25 years.³⁷ The same study projected that significant reductions in coverage across childhood

³⁵ See ANNENBERG PUB. POL'Y CTR., U. PENNSYLVANIA, *CDC Urges 'Shared Decision-Making' on Some Childhood Vaccines; Many Unclear About What That Means* (Jan. 5, 2026), <https://www.annenbergpublicpolicycenter.org/cdc-urges-shared-decision-making-on-some-childhood-vaccines-many-unclear-about-what-that-means/>; Manali Desai, et al., *Healthcare Professionals' Awareness of and Barriers to Shared-Clinical-Decision-Making for HPV Vaccination among Adults 27-45 years* (Sep. 2025) (DOI:10.1080/21645515.2025.2560061), <https://pmc.ncbi.nlm.nih.gov/articles/PMC12452441/>.

³⁶ Elizabeth Williams, Clea Bell, *A Look at Recent Changes to State Vaccine Requirements for School Children*, KAISER FAMILY FOUNDATION (Sept. 12, 2025), <https://www.kff.org/state-health-policy-data/a-look-at-recent-changes-to-state-vaccine-requirements-for-school-children/>.

³⁷ Mathew Kiang, et al., *Modeling Reemergence of Vaccine-Eliminated Infectious Diseases under Declining Vaccination in the U.S.*, 333 J. Am. Med. Ass'n (Apr. 24, 2025) (DOI:10.1001/jama.2025.6495), <https://jamanetwork.com/journals/jama/fullarticle/2833361>.

vaccines would lead to millions of additional cases of measles, rubella, poliomyelitis and diphtheria, with broad public health implications for U.S. children, their families and anyone who is immunocompromised.³⁸

Patients often receive care and vaccinations from multiple specialists, pharmacists, and primary care clinicians over many years. Consistent communication across providers depends on clear, nationally recognized and trusted vaccination recommendations. When those vaccination recommendations become uncertain or appear to be inconsistent, people are less likely to receive timely vaccinations. This has immediate, potentially deadly consequences for immunocompromised patients because it reduces community immunity. According to a recent survey of cancer survivors, roughly one in six respondents reported skipping or delaying receiving necessary vaccines due to confusion,³⁹ with dire consequences for their health and cancer treatment.

ACIP's changes to vaccine recommendations have a sweeping impact on American public health generally and on the health of patients with cancer and other chronic conditions in particular. Any changes must therefore be well-

³⁸ *Id.*

³⁹ AMERICAN CANCER SOCIETY CANCER ACTION NETWORK, *Survivor Views on Vaccines: February 2026* (Feb. 2026), https://www.fightcancer.org/sites/default/files/national_documents/overwhelming_support_community_immunization.pdf.

considered, evidence-based and made by qualified experts in the field. The Department of Health and Human Services cannot ignore the ACIP membership criteria established by statute, regulation, and the ACIP charter.

CONCLUSION

For these reasons, and in the interests of patient care, the Court should deny the Appellants' requested relief and affirm the stay of the disputed appointments to ACIP.

Respectfully submitted,

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July 17, 2026

ADDENDUM WITH INDIVIDUAL ORGANIZATIONAL STATEMENTS OF INTEREST

The American Cancer Society's mission is to improve the lives of people with cancer and their families through advocacy, research, and patient support, to ensure everyone has an opportunity to prevent, detect, treat, and survive cancer.

The American Cancer Society Cancer Action Network empowers advocates across the country to make their voices heard and influence evidence-based public policy change as well as legislative and regulatory solutions that will reduce the cancer burden.

The AIDS Institute is a national non-partisan, nonprofit organization working to end the HIV and viral hepatitis epidemics by increasing access to health care for people living with and at risk of these conditions.

The American Lung Association is the nation's oldest voluntary health organization, representing millions of people with or at risk for lung disease in the United States. The Lung Association is committed to raising public awareness of infectious respiratory diseases and immunization through education that counters misinformation and supports informed health decisions, as well as advocacy for policies that protect cost-free coverage of vaccines, remove barriers to vaccination and improve immunization rates.

The mission of the American Society of Pediatric Hematology/Oncology ("ASPHO") is to support and empower the pediatric hematology and oncology

medical and scientific community. ASPHO's 2022-2025 Strategic Plan also formalized an organizational vision, of 'improved health and a better future for children, adolescents, and young adults with cancer and blood disorders' based on foundational values of collaboration, compassion, diversity and inclusion, health equity, and innovation.

The Arthritis Foundation is the leading nonprofit organization dedicated to the fight against arthritis – the nation's #1 cause of disability. Through groundbreaking scientific research, patient-centered programs, advocacy at all levels of government and robust community engagement, the Foundation empowers people to live their best lives while relentlessly pursuing a cure. With a presence in communities nationwide, the Arthritis Foundation amplifies the voices of those affected and works to drive lasting change.

The Association of Pediatric Hematology/Oncology Nurses supports and advances nurses in optimizing outcomes for children, adolescents, young adults, and their families throughout the continuum of care for their blood disorders and cancers.

Blood Cancer United, founded in 1949 and known until 2025 as The Leukemia & Lymphoma Society, is the largest global nonprofit focused on blood cancer patient support, research, and advocacy. Its mission is to cure blood cancer and improve the quality of life of patients and their families affected by more than

100 types of blood cancer. Blood Cancer United brings together researchers, healthcare professionals, volunteers, and advocates to help patients access the care they need.

The Byrd Cancer Education and Advocacy Foundation's mission is to effectively assist individuals battling cancer by connecting them to support and resources, and to ensure that all relevant information reaches those in need, guiding them towards the resources necessary to fight their battle against cancer.

CancerCare is a national non-profit organization that provides free counseling, resource navigation, support groups, educational resources, advocacy and direct financial assistance to people impacted by cancer.

Cancer Nation's mission is to advocate for quality cancer care for all people touched by cancer.

Cervivor, Inc.'s mission is to eradicate cervical cancer by empowering patients, survivors, and caregivers. Cervivor aims to achieve this by fostering a global community through peer support, storytelling, and advocacy, and by ensuring equitable access to vital healthcare resources like screening, vaccination, and treatment.

GO2 for Lung Cancer is dedicated to improving survival and quality of life for all those at risk for, diagnosed with, and living with lung cancer.

HealthyWomen is dedicated to educating women in the middle — ages 35 to 64 — so they can make informed health decisions, advocate for themselves and prioritize their health and wellness.

The Hypertrophic Cardiomyopathy Association offers Support, Education, and Advocacy for Hypertrophic Cardiomyopathy (HCM) - Empowering patients and advancing research for a brighter future.

The IATVFoundation's mission is to increase access to quality education and support vulnerable communities affected by social issues.

The International Foundation for Autoimmune and Autoinflammatory Arthritis (“AiArthritis”) are leaders in advancing education, advocacy, and research for patients impacted by nearly two dozen types of autoimmune or autoimmune arthritis diseases. These include widely known conditions like rheumatoid arthritis and lupus, as well as ultra-rare conditions like Behcet's Disease or Sjogren's Syndrome. These conditions and/or medications to treat them often weaken patient immune systems and ability to fight infectious diseases, ensuring patients have coverage and access to any and all FDA-approved immunizations recommended by their medical providers is a top policy priority for AiArthritis.

The LUNGeity Foundation is a non-profit organization that envisions a world where no one dies of lung cancer. LUNGeity is firmly committed to

making an immediate impact on increasing quality of life and survivorship of all people diagnosed with lung cancer by accelerating research into early detection and more effective treatments; providing community, support, and education for everyone impacted by lung cancer; and advocating for full access to optimal care.

The National Association for the Advancement of Colored People (“NAACP”) is the oldest and largest civil rights organization in the United States. It is committed to ending racial health disparities. Its aim is not simply disease prevention, but to create an inclusive culture of healthy people and communities. The NAACP's mandate is to drive equitable health outcomes and transform healthcare systems through a comprehensive socioeconomic approach valuing the whole person. The NAACP collaborates with communities through coordinated action to tackle the social determinants of health — racism, poverty, exclusion, inferior schools, unsafe housing, poor nutrition, and toxic environments. Vaccines, accurate information, and evidence-based policies are vital to the NAACP's goal of health equity.

The National Comprehensive Cancer Network is dedicated to defining and advancing quality, effective, equitable, and accessible cancer care and prevention so all people can live better lives.

The National Consumers League is America's oldest consumer advocacy organization, dedicated to protecting and promoting social and economic justice for consumers and workers since 1899.

The National Multiple Sclerosis Society's mission is to cure MS while empowering people affected by MS to live their best lives.

National Patient Advocate Foundation is a national nonprofit organization and policy affiliate of the Patient Advocate Foundation working at the system level to influence public policy and drive change in healthcare with the mission of making the healthcare system work for all of us.

The Pro-Vaccine Legal Alliance at American Families for Vaccines defends the science, laws, and people that keep our communities healthy. The organization mobilizes the pro-vaccine majority to advocate for science-based public health laws, promote accurate information, and support vaccine confidence and access in legislatures, courts, and communities nationwide. The organization launches and supports state-based Families for Vaccines chapters, empowering local advocates to lead the charge for stronger immunization laws. And from the grassroots to the grassstops, the organization works hand in hand with partners, experts, and organizations to go the final mile in pro-vaccine advocacy—ensuring that decisions about health are grounded in evidence and guided by the common good.

CERTIFICATE OF COMPLIANCE

This brief complies with the type-volume limitation of Fed. R. App. P. 29(a)(5) and 32(a)(7)(B) because the brief contains 5,219 words, excluding the parts of the brief exempted by Fed. R. App. P. 32(f).

This brief complies with the typeface requirements of Fed. R. App. P. 32(a)(5) and the type-style requirements of Fed. R. App. P. 32(a)(6) because it has been prepared in a proportionally spaced typeface using Microsoft Office 365 in 14-point Times New Roman font.

July 17, 2026

/s/ Scott P. Lewis
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CERTIFICATE OF SERVICE

I hereby certify that I electronically filed the foregoing with the Clerk of the Court for the United States Court of Appeals for the First Circuit by using the appellate CM/ECF system on July 17, 2026.

I hereby certify that participants in the case are represented by registered CM/ECF users, and service will be accomplished by the appellate CM/ECF system.

July 17, 2026

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