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November 21, 2025

Martin Kulldorff, PhD
Chair, Advisory Committee on Immunization Practices
Centers for Disease Control and Prevention
1600 Clifton Road NE
Atlanta, GA 30333

Re: Comments for the December 2025 Meeting of the Advisory Committee on Immunization Practices (Docket No. CDC-2025-0783)

Dear Dr. Kulldorff:

On behalf of the American Society of Hematology (ASH), thank you for the opportunity to provide comments in advance of the Advisory Committee on Immunization Practices' (ACIP) upcoming meeting on December 4 and 5, 2025. ASH sent the attached letter to ACIP ahead of the Committee's September 2025 meeting to urge the Committee to maintain the current child and adolescent immunization schedule. We are writing again to reinforce this message and highlight key considerations as the Committee reviews issues related to the childhood and adolescent schedule, vaccine safety, and Hepatitis B vaccines.

As we noted in the last letter, many individuals with hematologic conditions such as leukemia, lymphoma, sickle cell disease (SCD), and bone marrow failure syndromes are immunocompromised. The immune compromise can be a result of both the diseases themselves, and the treatment administered; therapies like chemotherapy, bone marrow transplant, cellular therapies, and gene therapies can cause profound immune suppression, placing patients at heightened risk of unfavorable outcomes from infectious diseases that are preventable with vaccines. What may ordinarily be a minor viral or bacterial infection for patients with normal immune systems can become life-threatening for those with compromised immune systems. Access to and administration of vaccinations to reduce the risk of life-threatening infections for such hematology patients is essential.

Vaccines are one of the most powerful tools we have to protect children, especially those with underlying hematologic conditions, from life-threatening infections. Extensive evidence shows that giving multiple vaccines simultaneously at the same visit is safe and does not increase the risk of serious adverse events. For children with conditions such as SCD, this practice is not only safe, but also essential. These children are at extremely high risk for severe infections, and any delay in vaccination leaves them vulnerable. Additionally, for children with hematologic disorders such as SCD, reducing the total number of injections or appointments needed to complete recommended vaccines is very important to achieve protective immunity as quickly as possible to pathogens to which they are uniquely susceptible. For patients with hemophilia and other inherited or acquired bleeding disorders, they face bleeding risk with each needlestick so minimizing the number of injections with combined vaccinations is crucial. Vaccines given on schedule have dramatically reduced mortality in children with SCD, particularly in the first five years of life. (I, II, III, IV)

Children with hematologic disorders face unique challenges that make timely immunization critical. Splenic dysfunction increases susceptibility to dangerous encapsulated bacteria, making pneumococcal, meningococcal, and Haemophilus influenzae type b vaccines vital for survival. Immune compromise, whether from chronic anemia, bone marrow disorders, transplant, or immunosuppressive therapy, can reduce vaccine responses, which means careful

2025

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timing and, sometimes, additional doses are required. Even in children with thrombocytopenia or coagulopathy, vaccines remain safe with proper technique. Simply put, these vaccines save lives.

The Hepatitis B vaccine is especially important for individuals with hematologic disease and disorders. Hepatitis B is often silent and can become chronic, leading to severe complications, including cancer. These complications can be particularly problematic in immunocompromised individuals. There is no effective curative treatment and treatment to suppress the virus does not work as well in immunocompromised patients. Hence, preventing infection is critical. Children with hematologic conditions frequently require transfusions and are at higher risk of exposure to bloodborne viruses, therefore preventing infection through early vaccination is critical to avoiding exposure and lifelong complications. Additionally, early vaccination is a key preventive measure, as HBV infection can also exacerbate liver-related complications in people with hematologic conditions. Furthermore, Hepatitis B infection is also a potential cause of aplastic anemia which can be prevented with vaccination.

Vaccines also prevent infections that can trigger secondary hematologic crises. Viruses such as parvovirus B19 can cause aplastic episodes, and bacterial infections can rapidly progress to sepsis in children with limited or absent splenic function. By preventing these infections, vaccines reduce both immediate dangers and long-term hematologic complications. Additionally, many children with hematologic disorders depend on herd immunity, as their immune systems may not mount full protection even after vaccination. Strong community vaccination rates safeguard these children from exposure to harmful pathogens.

Many ASH members continue to share powerful accounts of how vaccines have protected the many children that they care for with hematologic conditions. This included the impactful feedback from one ASH member noting that "Before the pneumococcal conjugate vaccine (PCV) was introduced for children with SCD, our clinic saw 3–5 cases of pneumococcal sepsis each year. After PCV-13 and then PCV-20, this dropped to about one case every five years. We cannot return to a time when young children with SCD face sepsis, meningitis, and death from a nearly preventable infection. Additionally, before my career, Haemophilus influenzae type b (Hib) commonly caused severe, sometimes fatal infections in children with SCD and other blood disorders. I have never seen Hib infection in a vaccinated child, but I have cared for an unvaccinated child who nearly died of Hib sepsis during leukemia treatment. These infections may be rare now, but they can quickly resurface if herd or individual immunity declines."

For all these reasons, administering vaccines according to the standard, evidence-based schedule, and allowing concurrent vaccination, remains critical. Any delay or restriction would expose vulnerable children to preventable, potentially fatal infections. Vaccines are not just preventive for many children, especially those with hematologic diseases and disorder, but also lifesaving. Maintaining robust immunization practices protects their health, preserves their futures, and upholds our collective responsibility to safeguard those most at risk. Therefore, ASH urges ACIP not to amend the child and adolescent vaccine schedule, resulting in restricting access for Americans who choose to vaccinate their children. The Society also encourages ACIP to not make any changes to the protocol for Hepatitis B vaccines.

Thank you again for the opportunity to share this critical feedback. Should you have any questions or require additional information, please contact ASH Director of Government Relations and Public Health Stephanie Kaplan (<u>skaplan@bematology.org</u> or 202-776-0544).

Sincerely,

Yourda S. avalor, MD

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- I. Quinn CT, Rogers ZR, McCavit TL, Buchanan GR. Improved survival of children and adolescents with sickle cell disease. Blood. 2010 Apr 29;115(17):3447-52. doi: 10.1182/blood-2009-07-233700. Epub 2010 Mar 1. PMID: 20194891; PMCID: PMC2867259.
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September 11, 2025

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Re: Comments for the September 2025 Meeting of the Advisory Committee on Immunization Practices (Docket No. CDC-2025-0454)

Dear Dr. Kulldorff:

On behalf of the American Society of Hematology (ASH), thank you for the opportunity to provide comments in advance of the Advisory Committee on Immunization Practices' (ACIP) upcoming meeting during which the child and adolescent vaccine schedule will be discussed.

ASH represents more than 18,000 clinicians and scientists who are committed to the study and treatment of blood and blood-related diseases. These disorders encompass malignant hematologic disorders such as leukemia, lymphoma, and multiple myeloma, as well as non-malignant conditions such as sickle cell anemia, thalassemia, bone marrow failure, venous thromboembolism, and hemophilia. In addition, hematologists are pioneers in demonstrating the potential of treating various hematologic diseases and continue to be innovators in the field of stem cell biology, regenerative medicine, transfusion medicine, and gene therapy. Our mission is to foster high-quality care, transformative research, and innovative education to improve the lives of patients with blood and bone marrow disorders.

ASH urges ACIP to maintain the current child and adolescent vaccine schedule. Many individuals with hematologic conditions such as leukemia, lymphoma, sickle cell disease (SCD), and bone marrow failure syndromes are immunocompromised. The immune compromise can be a result of both the diseases themselves and the treatment administered; therapies like chemotherapy, bone marrow transplant, cellular therapies, and gene therapies can cause profound immune suppression, placing patients at heightened risk of unfavorable outcomes from infectious diseases that are preventable with vaccines. What may ordinarily be a minor viral or bacterial infection for patients with normal immune systems can become life-threatening for those with compromised immune systems. Access to and administration of vaccinations to reduce the risk of life-threatening infections for such hematology patients is essential. In addition, herd immunity from vaccination of as many members of society as possible protects the health of the American people.

Vaccines are also critical for individuals living with SCD. Affecting approximately 100,000 Americans, SCD is an inherited, lifelong disorder, which results in patients' red blood cells becoming rigid and sickle shaped. Sickle cells can get stuck in blood vessels and block blood flow, causing pain and organ infarctions. Complications of SCD include stroke, acute chest syndrome (a condition that lowers the level of oxygen in the blood), organ damage, chronic pain, other disabilities, and premature death. Immunization is crucial to mitigate infection-related complications in these individuals, and they require a comprehensive immunization strategy that includes both standard and additional vaccines. Vital vaccines

include pneumococcal conjugate, pneumococcal polysaccharide, meningococcal conjugate, serogroup B meningococcal, Hib, annual influenza, hepatitis A and B, and HPV, many of which are included in the current child and adolescent vaccine schedule. Because immune responses vary in this population, booster doses and additional vaccinations are required to ensure optimal protection. Any barriers to access to vaccines has the potential to undermine the health of this already vulnerable population.

Another group of hematology patients that benefits immensely from vaccinations are those who have undergone surgical removal of the spleen, or splenectomy, for any reason. Splenectomy is occasionally performed for reasons like trauma to the spleen, autoimmune disorders, or hereditary disorders where the spleen is causing problems. Patients who have undergone splenectomy are at risk for life-threatening bacterial infectionsⁱⁱ. Vaccination of such patients is critical to reduce the morbidity and mortality that can occur in patients who have had splenectomy.

Additionally, those who are immunocompromised cannot safely receive certain live vaccines including the combined vaccine for measles, mumps, and rubella (MMR), and varicella. Immunocompromised individuals depend on the protection they receive from the vaccines that are safe for them to receive and the general population's immunity resulting from widespread vaccination. Should ACIP recommend changes to the child and adolescent vaccine schedule, immunocompromised individuals will be placed at greater risk of vaccine-preventable illnesses because of declining vaccination rates in the general population. This will result in more severe illnesses in this group, hospitalization, and potentially even death. The current vaccine schedule is a critical public health safeguard for those who rely most on community protection.

Specifically, ASH wishes to address the COVID-19 vaccines and their availability for the patients our members treat. We stand with our colleagues at the American Academy of Pediatrics (AAP) and the American Academy of Family Physicians (AAFP), who have recently issued statements recommending COVID-19 vaccination for nearly all individuals—not only those with high-risk conditions. Individuals with blood disorders - both who are and are not immunocompromised - are a higher risk for severe COVID-19 and may not be able to clear the virus quickly and efficiently. Vaccinations are a fundamental prevention strategy in hematologic patients with booster doses recommended for these individuals. ASH is very concerned about the Food and Drug Administration's (FDA) new recommendations for the latest COVID-19 boosters, which narrowed their use for younger adults and children to those with at least one high-risk condition. Additionally, the FDA removed one of the two vaccines available for young children. Individuals with blood cancers or those who are taking immunosuppressive drugs will continue to be eligible for boosters under this new approval. However, this recommendation has already resulted in many individuals unable to receive the vaccine due to the new qualifications. ASH is extremely concerned about the implications for patients with hematologic conditions and urges ACIP to not further restrict their access for Americans. All Americans should have the opportunity to evaluate their risk and the risk to their loved ones and have the choice to receive these vaccines without additional access and financial barriers.

Vaccinations are also important for family members and close contacts of individuals with blood disorders because they provide an additional layer of protection for the immunocompromised individual who may have a diminished immune response. By staying up to date with recommended vaccines, family members help reduce the risk of introducing infectious diseases into the home. This approach creates a safeguard around the immunocompromised person, lowering their risk of exposure and serious illness.

The protection afforded by vaccines is particularly important to individuals with hematologic disorders. Therefore, ASH urges ACIP not to amend the child and adolescent vaccine schedule, resulting in restricting access for Americans who choose to vaccinate their children. Should you have any questions or require

additional information, please contact ASH Director of Government Relations and Public Health Stephanie Kaplan (<u>skaplan@hematology.org</u> or 202-776-0544).

Sincerely,

Belinda Avalos, MD

ASH President

ⁱ Obeagu EI, Obeagu GU. Immunization strategies for individuals with sickle cell anemia: A narrative review. Medicine (Baltimore). 2024 Sep 20;103(38):e39756. doi: 10.1097/MD.0000000000039756. PMID: 39312357; PMCID: PMC11419550.

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