Introductory Remarks for Hepatitis B Infant Schedule at September 2025 Advisory Committee on Immunization Practices (ACIP) Meeting

Thank you, Dr. Kulldorff and ACIP members, for the opportunity to address the committee. I am Dr. Ayman Chit, and I am the Head of Medical Affairs for Sanofi Vaccines, North America.

Sanofi shares a commitment to prioritize public health and evidence-based medicine. Our top priority remains ensuring access and availability of safe and effective vaccines.

The hepatitis B birth dose and vaccination early in life remain the most effective option for preventing hepatitis B infection in infants and children.

Scientific evidence overwhelmingly supports the safety of hepatitis B vaccines, as well as combination vaccines that include hepatitis B. Before and after approval, these vaccines are continuously monitored by manufacturers, as well as public health agencies and regulators.

In contemplating changes to the hepatitis B infant schedule or any changes to the vaccination schedule, impact on implementation is an important factor of consideration. Combination vaccines, for example, have the benefit of reducing the number of injections infants receive, improving workflow in healthcare provider offices, and limiting opportunities for administration errors. If a change is made to the recommendation for one of the included vaccine components, the benefits afforded by the combination will not be realized. Providers would need to stock single antigen components – and possibly combination products – which would pose challenges with ensuring adequate stock and supply at the provider level, storage and handling, administration, and documentation, all of which are critical components of ensuring vaccines are administered safely.

All of these challenges can limit patient access to recommended childhood vaccines and the freedom for personalized decision-making by parents and patients.

Delaying hepatitis B vaccination puts infants and children at risk for hepatitis B infection, reduces options for families to choose combination vaccines that include hepatitis B, and will cause significant supply disruptions for a year or longer as production of vaccines is adjusted given the long lead times required. These supply challenges would extend beyond combination vaccines to include stand-alone DTap, Hib, and polio vaccines.

In closing, we encourage ACIP to maintain the current recommendations for hepatitis B vaccine so that (1) infants continue to be protected early in life and high-risk infants do not fall through the cracks, (2) combination vaccines that include hepatitis B are widely

accessible, and (3) parents continue to have the choice to protect their infants from vaccine-preventable diseases.

Thank you again for the opportunity for us to speak with you today.

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