

Duckworth Demands Answers From Manufacturers Of Pediatric RSV Immunization Regarding Shortage Supply

November 18 2023 10:34 AM



WASHINGTON, D.C. – As parents across the nation continue to be frustrated by a short supply of a new FDA- and CDC-backed immunization that can be used to prevent

severe disease from respiratory syncytial virus (RSV) in babies, U.S. Senator Tammy Duckworth (D-IL) is demanding answers from two major pharmaceutical manufacturers. Sanofi and AstraZeneca, who manufacture the immunization known as nirsevimab (Beyfortus), seem to have vastly underestimated the amount of vaccine needed to help protect lives this RSV season. In a letter sent today, Duckworth pushed the two pharmaceutical companies for transparency and to provide a briefing on the current amount of nirsevimab, how these supply issues came to be as well as how we can prevent such a shortage from happening again in the future so we can be better prepared in the years ahead.

“This supply shortage is impacting large hospitals and small health clinics alike, which highlights a concern for equitable care and access,” Duckworth wrote. “It leaves parents searching for this immunization and desperate for an option to reduce risk of illness and save children’s lives. We must prioritize safeguarding our most vulnerable neonates, infants and children this RSV season.”

In the letter, Duckworth asks for answers from Sanofi and AstraZeneca on the following questions by November 30th, 2023:

1. On what date did Sanofi and AstraZeneca become aware internally of this shortage in North America?
2. On what date did Sanofi and AstraZeneca provide voluntary notice to FDA on this shortage?
3. What are the barriers to scaling up nirsevimab production and distribution to meet demand in the United States?
4. Given that we know last RSV season was so severe, we were surprised to hear about the disparity between the estimated and actual demand for nirsevimab this year. What factors led to the significant underestimation of demand for the product and what actions will you take to adjust these estimates going forward?
5. What mitigating factors have you put in place to address the demand today?
6. How are you communicating with providers and healthcare systems regarding supply and mitigating strategies?
7. How are you prioritizing where and who receives the current supply? How are you ensuring distribution and access that prioritizes typically underserved communities?
8. Can you assure us that the 50mg doses will remain available during the 23-24 RSV season?
9. Why has Sanofi chosen to charge the same amount of \$495 for both the 50 mg and 100 mg 5-pack of one dose syringes?

Along with Duckworth, the letter is co-signed by U.S. Senators Kirsten Gillibrand (D-NY), Ron Wyden (D-OR), Ed Markey (D-MA), Richard Blumenthal (D-CT), Jon Ossoff (D-GA) and Elizabeth Warren (D-MA).

Full text of the letter can be found on the [Senator's website](#).