

October 23, 2024

Dear Ms. Pajer,

Thank you for contacting my office regarding vaccine and immunization information the Tennessee Department of Health provided recently to health and medical professionals in our state. Please know we share your interests and values in making sure the practice of health and medical care in Tennessee is safe and effective and leads to the best possible outcomes for patients.

The Department takes its responsibility in the service of patients seriously when providing best practice recommendations to Tennessee's health and medical professionals. Ultimately, the Department seeks to support the dialogue between patients and providers so providers can make informed care recommendations to their patients, and patients can make the best possible decisions about their individual care from among all available options.

The following responses reflect my sincere attempt to answer your questions as thoroughly as possible, based on the best information available to the Department, noting much of the information on vaccine safety and research is available from federal sources.

1. All clinical trials on which your claims of safety are based for the co-administering of RSV, COVID-19, and influenza products to babies, pregnant women, and others.

2. For each trial:

- Whether or not the trial included enough participants to be considered sufficiently powered to reveal severe adverse reactions;*
- Whether or not the trial lasted long enough to inform about long-term safety issues;*
- The exclusion criteria and how those exclusions may impact trial results and whether the results can be generalized to the public.*

RSV, Flu, and COVID vaccine safety information is available at the following CDC sources: COVID, <https://bit.ly/4fg3nwU>; Influenza, <https://bit.ly/4eTxnyS>; and, RSV, <https://bit.ly/48pMptF>. Additional information on vaccine safety and effectiveness during pregnancy is available from the CDC for COVID, <http://bit.ly/4eSb4cB>, and for Influenza, <https://bit.ly/3BRcRAM>. Information on the co-administration of the Influenza vaccine with other recommended vaccines is available at <https://bit.ly/3NyG5q6>.

3. A summary of types and numbers of adverse reactions reported to the Vaccine Adverse Event Reporting Systems (VAERS) and MedWatch for:

- Individually administered RSV, COVID-19, and influenza products.*
- Co-administered RSV, COVID-19, and influenza products.*

VAERS data can be downloaded directly from <https://bit.ly/3BYhIVN>, and the FDA Adverse Event Reporting System (FAERS) has MedWatch data available at <https://bit.ly/3Y9bHaM>.

4. The states in the United States and the countries which no longer recommend COVID-19 vaccines for children, adolescents, young adults, pregnant women, or for anyone.

A comprehensive report of states and countries and their individual decisions on vaccines is not available from the Department, and we are not aware of an external source with a summary of this information. We welcome sources to be shared where this data and information might be available.

5. Guidance for reporting adverse reactions and filing for compensation for injuries or death due to co-administration when each product has a different legal liability status for manufacturers and healthcare providers who administer them.

Multiple reporting systems monitor adverse vaccine events to ensure the safety of products. As previously noted, VAERS can be used to report adverse events in adults related to COVID, Influenza, and RSV vaccines, <https://bit.ly/3NxsvU2>. Adverse events related to Nirsevimab, the RSV immunization available for infants, should be reported to MedWatch/FAERS, <https://bit.ly/3Y9bHaM> since it is considered an immunization or medication and not vaccine. Patients experiencing adverse reactions after receiving Nirsevimab with any non-Nirsevimab vaccine can report the incident to MedWatch/FAERS and to VAERS. Additionally, the CDC's Vaccine Safety Monitoring Program is available at <https://bit.ly/3Yyoyob>.

Individuals who believe they have been injured from receiving an Influenza vaccine or a COVID vaccine may file petitions with the National Vaccine Injury Compensation Program, <https://bit.ly/4eTEoiW>, and also with the Countermeasures Injury Compensation Program, <https://bit.ly/4hiV05m>. Please see the table on the following webpage, <https://bit.ly/3AaDD62>, for a comparison of the two injury compensation programs.

We appreciate your concerns. Thank you for considering the interests of all Tennesseans and their public health outcomes.

Sincerely,

Caitlin Newhouse, MD MPH

Medical Director
Vaccine-Preventable Diseases & Immunization Program