## Mission:

To protect, promote & improve the health of all people in Florida through integrated state, county & community efforts.



Joseph A. Ladapo, MD, PhD State Surgeon General

Vision: To be the Healthiest State in the Nation

June 29, 2022

The Honorable James E. Clyburn Chairman, Select Subcommittee on the Coronavirus Crisis 2157 Rayburn House Office Building Washington, DC 20515

Dear Chairman Clyburn:

While we were initially pleased with the opportunity to meet on June 28, 2022, with staff of the House Committee on Oversight and Reform, and the House Select Subcommittee on the Coronavirus Crisis, we have become aware of the blatantly false statements perpetuated by a misleading press release issued by your office. It is unfortunate that staff used this educational meeting as a launching pad for politically charged attacks. The purpose of the meeting was to discuss:

- 1) Misinformation regarding ordering versus pre-ordering in Florida,
- Ability for private providers to order the COVID-19 vaccine for children as young as six months,
- 3) Pediatric COVID-19 guidance,
- 4) Vaccine availability and access.

Information regarding the meeting released to media outlets earlier today mischaracterizes the conversation and we welcome the opportunity to clarify.

## **Vaccine Ordering**

At no point did the Florida Department of Health limit vaccine access in Florida. While responding to COVID-19 for over two years, Florida determined the following:

- 1) Pre-ordering is an unnecessary relic and was implemented when supply was low and demand was high among high-risk populations, including those 65 and older. There continues to be a low demand for pediatric COVID-19 vaccines.
- 2) Inefficiencies were observed by the Department during pre-ordering of previous vaccine authorizations, and the Department determined that the process is cumbersome and no longer needed.
- 3) By simply allowing providers to determine their individual needs, rather than assuming demand, direct ordering allows for more efficient resource management and distribution.

The Department permitted private providers to order the vaccine as soon as the Emergency Use Authorization (EUA) was issued on June 17, 2022. In fact, some pediatricians ordered vaccines on that day. While the Department chose not to engage in the pre-ordering process, providers were never restricted from ordering. Moreover, they cannot order any vaccines from the Centers for Disease Control and Prevention (CDC) that have not been authorized or approved.



Providers started receiving orders as early as June 21, 2022, which is further evidence for why the pre-ordering process is not needed. States that pre-ordered this vaccine will likely be left holding a significant amount of product due to the lack of demand.

## Pediatric COVID-19 Vaccine Guidance

Separate from ordering, I recommended against pediatric COVID-19 vaccines for children under 5. There are <u>no data</u> that prove this vaccine is <u>more effective than the placebo</u> in reducing severe illness and other clinically meaningful outcomes in this age group. There is also inadequate data regarding the safety of the COVID-19 vaccine. A <u>recent pre-print study</u> shows a higher risk of serious adverse events of special interest in the treatment group versus the placebo group in adults, for example. Additionally, since the release of the COVID-19 vaccines, studies continue to show a risk of myocarditis and pericarditis across several age groups, especially in <u>adolescents and young men</u>.

To <u>receive an EUA</u>, a manufacturer must show that a product "may be effective" at preventing a disease or condition, and the FDA must determine that the benefits outweigh the risks. The manufacturers failed to meet this burden of proof, especially for those ages 6 months through 4 years. The burden of proof for vaccine efficacy and safety does not fall on the Florida Department of Health. This burden falls squarely on drug manufacturers. It is the responsibility of the U.S. Food and Drug Administration (FDA) and CDC to review a manufacturer's data, and the Department disagrees with their recommendation.

## Data

Florida has always ensured COVID-19 vaccines and treatments are widely available, but never mandated. The FloridaHealthCOVID19.gov website provides the public with:

- 1) Reports including county-level data and vaccination rates.
- 2) Vaccine, treatment, and testing locators.

As to your inquiry about data on pediatric COVID-19 uptake, these data can be seen in the reports on this website. You can find data we referenced that show the low demand for pediatric vaccines <a href="here">here</a>. Additionally, page 21 of the <a href="Kaiser survey shows">Kaiser survey shows</a> that demand dropped significantly from 31% in January 2022 to 18% in April 2022. This drop may be attributed to a loss in confidence after the original application for <a href="EUA was withdrawn">EUA was withdrawn</a>.

Last year, the State of Florida transitioned from an emergency COVID-19 response to an endemic phase which shifts health care back to private providers and the normal stream of health care. We expect health care providers to manage COVID-19 care, especially when caring for young patients, through prevention and treatment, on a case-by-case basis.

It is unfortunate that the information you released is perpetuating confusion among the public. Parents are in the best position to make these decisions for their children. Florida remains committed to making recommendations and decisions based on data and science – not ideology.

Sincerely

Joseph A. Ladapo, MD, PhD State Surgeon General