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VIA FEDEX AND EMAIL

Rochelle Walensky
Director at CDC
Office of the Director
Centers for Disease Control and Prevention
1600 Clifton Rd
Atlanta, GA 30329
Aux7@cdc.gov

RE: Increased rate of Respiratory Syncytial Virus (RSV) in Children Who Received Covid-19 Vaccine

Dear Director Walensky:

On behalf of our client, Informed Consent Action Network (“**ICAN**”), we write regarding the increase in RSV cases currently being observed in the United States.¹

In the clinical trial for Moderna’s pediatric Covid-19 vaccine (mRNA-1273), it found an increased rate of RSV and upper respiratory infection among children that received the vaccine. As provided in the FDA’s review memorandum for this vaccine:

- **For 6 to 23-month-olds:** “Within 28 days after vaccination, some respiratory tract-related infections were reported with greater frequency in the mRNA-1273 group compared to the placebo group, including croup, respiratory syncytial virus (RSV), and pneumonia. Events of croup were reported by 1.3% of mRNA-1273 recipients and 0.3% of placebo recipients, RSV by 0.8% of mRNA-1273 recipients and 0.5% of placebo recipients, and pneumonia by 0.2% of mRNA-1273 recipients and no placebo recipients.”²

¹ See, e.g., <https://www.nytimes.com/2022/10/23/health/flu-covid-risk.html>; <https://www.cbsnews.com/news/what-is-rsv-children-cases-rising/>; <https://www.abc27.com/local-news/rsv-cases-on-the-rise-among-midstate-kids/>; <https://www.wjbf.com/csra-news/rsv-cases-on-the-rise/>; <https://fox8.com/news/rsv-cases-on-the-rise-in-children-what-parents-should-know/>.

² <https://www.fda.gov/media/159611/download> at 161.

- **For 2 to 5-year-olds:** “Within 28 days after vaccination, some respiratory tract-related infections were reported with greater frequency in the mRNA-1273 group than in the placebo group. Events of pneumonia were reported by 0.3% and 0% of mRNA-1273 and placebo recipients, respectively. Respiratory syncytial virus (RSV) infection was reported by 0.4% and <0.1% of mRNA-1273 and placebo recipients, respectively.”³
- **For 6 to 11-year-olds:** “Within 28 days after vaccination, some respiratory tract infection-related PTs were reported more frequently in the vaccine group compared to the placebo group, such as Respiratory syncytial virus infection (0.3% vs 0%) and Upper respiratory tract infection (3.9% vs 2.5%). An analysis including all respiratory-tract infection related PTs, except COVID-19, showed a small imbalance of 5.9% in the vaccine group compared to 4.4% in the placebo group.”⁴

In discussing these data, FDA’s VRBPAC committee “stressed the importance of continued post-authorization safety surveillance, in particular for myocarditis/pericarditis and for certain respiratory infections (RSV and pneumonia) in the youngest age group, for which imbalances of uncertain clinical significance were observed in the clinical trial.”⁵

In the clinical trial for Pfizer’s pediatric Covid-19 vaccine (BNT162b2), serious adverse events “reported in the BNT162b2 group included RSV bronchiolitis (5 participants), pneumonia (2 participants), gastroenteritis (2 participants), lower respiratory tract infection (2 participants).”⁶

We commend the CDC for the meticulous level of data it collects regarding RSV cases across the country, as detailed here <https://www.cdc.gov/surveillance/nrevss/rsv/index.html>. The CDC provides surveillance reports dating back to 1984 and offers state, HHS regional, census region and division, and national trends related to RSV.

Given the CDC’s robust and ongoing data collection among those tested for and positive for RSV, **please let us know the percent of children who have tested positive for RSV who had received a Covid-19 vaccine prior to their RSV diagnosis.**

Very truly yours,



Aaron Siri, Esq.

Elizabeth A. Brehm, Esq.

³ *Id.* at 126.

⁴ *Id.* at 81.

⁵ *Id.* at 181.

⁶ <https://www.fda.gov/media/159393/download> at 52.