



Big Pharma Technocrats Use COVID Model To Push RSV Vaccines

Description

Medical Technocrats embedded in government hierarchy are running the same game plan as with COVID to mandate vaccines wherever they can direct the needle. In this case, it is for babies and toddlers and a common but mild virus known as RSV. Will they ever stop? No, not until it is unprofitable for them to continue. ? TN Editor

Southern California's Orange County Health Department this month declared a local health emergency over concerns around the rising number of pediatric cases of Respiratory Syncytial Virus (RSV).

County officials also declared a Proclamation of Local Emergency, allowing them to access state and federal resources in response to the spread of RSV.

The news came amid media warnings of a looming "triple-demic" of RSV, influenza and COVID-19 and news that Pfizer and GlaxoSmithKline (GSK) are close to securing regulatory approval for their RSV vaccine candidates — including Pfizer's RSV vaccine for pregnant women.

RSV was first identified in 1956, and frequently affects children, with a majority of childhood cases occurring before age 2. For most children, symptoms are similar to those of the common cold, according to the Centers for Disease Control and Prevention (CDC).

It can, however, cause serious symptoms in the very young and the elderly, although childhood deaths are infrequent, according to CDC data.

According to California attorney Rita Barnett-Rose, there's no evidence to support claims that Orange County hospitals are overextended, or to justify a state of emergency.

In an interview with The Defender, Barnett-Rose drew parallels between Orange County's emergency declaration for RSV and other state, local and federal emergency declarations for COVID-19:

“One of the other alarming things that happened with COVID is when [Gov. Gavin] Newsom declared the state of emergency in COVID. He also waived the 30 and 60-day review periods for all local governing boards.

“So, yeah, so that’s what everyone is concerned about, this perpetual state of emergency.

“And the other thing that it triggers is it asks, once they declare a state of emergency, aside from getting the funding, it also triggers a request to Governor Newsom to declare a statewide state of emergency and then also to have Newsom ask President Biden to declare a national state of emergency.”

That could lead to Emergency Use Authorization (EUA) of RSV vaccines, according to Barnett-Rose, who told The Defender there may be an avenue to challenge the legality of the latest Orange County emergency declaration.

Is pharma using COVID playbook to push RSV vaccines?

Dr. Regina Chinsio-Kwong, Orange County’s health officer, said in a press release county officials issued the declaration due to “rapidly spreading virus infections causing record numbers of pediatric hospitalizations and daily emergency room visits.”

The declaration will allow the county to access state and federal resources and to allow non-pediatric hospitals to offer beds to sick children, Chinsio-Kwong said.

Children’s Health Defense (CHD) California Chapter notes that this declaration was unanimously ratified “over the objections by members of the public who showed up to speak against the declarations.”

Dr. Melaine Patterson, chief nursing officer for Children’s Health Orange County, said area hospitals are seeing an “unprecedented” volume of children visiting their emergency rooms — approximately 400 per day, with wait times of “four to 12 hours.”

She also said that, as of Nov. 1, there were 285 patients in her hospital, compared to 188 on that date last year, adding that 11 of those current patients were placed in ICU as a result of RSV infections. RSV cases also are on the rise nationally.

Chinsio-Kwong advised the public to remain “up to date with other vaccinations such as flu and COVID-19” to “reduce the burden on hospitals this fall and winter.”

“Our best shot at protecting ourselves and our children from respiratory illnesses continues to be the same things we practiced throughout the pandemic including the use of masks when indoors around others and staying home when you are sick,” Chinsio-Kwong said.

However, Barnett-Rose said hospitals in Orange County may be overextended not due to an unusually high number of admissions, but due to unvaccinated staff having been let go.

She told The Defender:

"I do think that has a big role in it, and a lot of people pointed that out during the hearings and public comments were made about that.

"They were trying to claim ... there were not enough pediatric experts or pediatric-trained doctors and medical professionals, so they needed to go outside of the county. And I do think a big part of that is that they did let go of many pediatric nurses and pediatric physicians that refused to take the vaccines. So I do think that this is a crisis of their own making ... if there is even a crisis."

San Diego County also issued a warning to its residents Nov. 4 over rising RSV cases but stopped short of declaring an emergency.

CHD California questioned why Orange County would declare a "Local Health Emergency" now — even though local COVID-19 states of emergency haven't been lifted.

Despite claims that the purpose of these new declarations is exclusively meant to help county hospitals, CHD California said, "the language of the emergency Resolutions says something else entirely":

"Both the Resolution to ratify the Local Health Emergency under Health & Safety Code section 101080 and the Proclamation of a Local Emergency under Government Code section 8630 declare the need for these local emergencies not only based on the asserted need to handle allegedly rising cases of RSV — but also because of other unnamed 'other respiratory illnesses' that were not discussed during the special meeting or otherwise disclosed to the public."

Barnett-Rose provided insights into the legal meaning underlying these declarations. She told The Defender:

"There's a local health emergency, which is declared by the public health officer as opposed to the [county] board ... and that is when the health officer says ... 'I've been talking to the hospitals and we've done some assessments and there's an increasing rate of respiratory illnesses and the children's hospitals, and so, because of this, I am asking to declare a local health emergency.' ...

"But her authority to declare a local health emergency only lasts for seven days unless it's ratified by our board of supervisors. And so, on Nov. 2, our board ratified that, which means now it's in place and it needs to be renewed or looked at every 30 days, unless Governor Newsom waives that condition."

CHD California argued that the "overly broad language used in these emergency declarations should be deeply concerning to anyone wary of a repeat of the "public health" measures ordered under COVID-19," noting that adding the vague statement referring to "other respiratory viruses" creates "plenty of room for further abuse."

Barnett-Rose told The Defender that, during the Nov. 2 meeting, Chinsio-Kwong said, "No restrictions are currently [emphasis added] in place," a statement that "caused ... a little bit of an uproar during the hearing because of her wording, which suggests that indeed they may end up rolling out mask mandates or some other mandates."

Under this type of “slippery language,” argued CHD California, even the common cold could be used to issue an emergency declaration.

Barnett-Rose agreed:

“How do you measure that? How do you dispute it? How do you examine it? How do you end it?

“If you’re going by one infectious disease, at least you can try to find some data on hospitalizations or cases or deaths or ICU beds. But when it’s everything, it can still include COVID, flu, cold, COPD, a whole bunch of things that would qualify as respiratory illnesses.”

Barnett-Rose said that attempts will be made to legally challenge these declarations as “overbroad,” noting, however, that while case law precedent exists to challenge overbroad legislation, there is no such precedent in place for states of emergency.

Barnett-Rose she’s looking into whether there’s some way to litigate against these broad states of emergency.

When statutes are overbroad, she said, sometimes you can challenge them for being overly broad or too vague, but she’s not sure if there’s a similar precedent for challenging an overly broad state of emergency.

Declaring a local state of emergency at the county level could trigger a chain of events leading all the way to a national declaration of emergency, according to CHD California:

“By ratifying and/or declaring these local emergencies, the Board has now triggered an official request to Governor Newsom that he also declare a state-wide state of emergency on the same overly broad basis — and to ask the President of the United States to declare a national state of emergency.”

“A nationally declared state of emergency may trigger all of the same measures that have already deeply divided our country: masks on airplanes, business and school closures, and coercive school and employee mandates for experimental ‘vaccines’ offered as the ‘only solution’ back to Freedom,” CHD California argued.

Barnett-Rose said the emergency declaration in Orange County may be tied to the fact that there are multiple RSV vaccines already in the pipeline:

“The reason this is becoming really huge news is because this is what happened with the COVID state of emergency, too, it kind of went like that in dominoes.

“Once Biden declares a national state of emergency, then that triggers all of the emergency use authorizations that allowed the so-called vaccines for COVID. And I’m sure you already know that there’s vaccines in the works now for RSV that they’re floating out there in the news as well.”

Recounting events that occurred in relation to COVID-19, Barnett-Rose told The Defender that Orange County and some other counties in California declared a state of emergency, “then it went to the state, then it went national, and then, of course, once there’s a national emergency, you can go into Iowa.”

“So I do think that this is very suspicious timing, the articles that we are seeing in the news about being close to this RSV vaccine,” Barnett-Rose said. “And so, I do think that they’re trying to repeat the same playbook.”

Up to 30 RSV vaccine candidates already in pipeline

Pharmaceutical industry publication FiercePharma reported that Pfizer and GSK “moved closer to regulatory approvals” in the past week, and “could each see the first-ever approvals for an RSV vaccine in 2023.”

GSK’s candidate will be reviewed May 3, 2023, while Pfizer is “eyeing an approval filing by year-end.”

In all, up to 30 RSV candidate vaccines have been identified by the National Institutes of Health (NIH).

GSK has secured priority review status for its RSV vaccine following the submission of data from its AReSVi-006 phase 3 trial. The candidate vaccine exclusively targets adults 60 and older, and the data reportedly “showed high overall vaccine efficacy against RSV lower respiratory disease” at a rate of 82.6%, Fierce Biotech reported.

GSK initially intended to develop an RSV vaccine for older adults and for infants, but plans for the latter were shelved due to a “safety concern.” Nevertheless, GSK CEO Emma Walmsley in a call last week with investors described GSK’s new vaccine as “a very significant scientific achievement.”

Previous efforts to develop an RSV vaccine have failed because they “had a persistent tendency to cause worse disease,” due to “a phenomenon known as antibody-dependent enhancement (ADE).”

Dr. Ruth Karron, a pediatrician and professor of international health at the Johns Hopkins Bloomberg School of Public Health, said, “The difference this year is the general public for the first time is probably eagerly awaiting an RSV vaccine, because they’re seeing firsthand just how much of a problem RSV can be,” in a statement drawing a clear connection with the reported increase in RSV cases this year.

Pfizer announced Nov. 1 that its own candidate RSV vaccine wrapped up its phase 3 trial for efficacy early. Unlike GSK’s candidate vaccine, Pfizer’s vaccine targets pregnant women. The vaccine is designed to be administered early in the third trimester with the intent that the vaccine-induced antibodies be passed from the mother to her newborn.

Pfizer, in its Nov. 1 announcement, claimed that its bivalent RSV prefusion vaccine candidate RSVpreF, also known as PF-06928316, delivered “broadly positive” results — namely, a significant reduction in the rate of respiratory illness in newborns and their mothers.

Pfizer claimed 81.8% efficacy against severe cases of RSV for babies up to three months, and 69.4% efficacy after six months.

Pfizer’s MATISSE (MATernal Immunization Study for Safety and Efficacy) trial involved 7,400 pregnant women and their newborns, tracking the infants for one year following birth, and some for two years. It was conducted in 18 countries beginning in June 2020.

Pfizer’s vaccine trial did not deliver statistically significant results regarding the prevention of infant

medical visits caused by RSV, including for non-severe cases.

Nevertheless, Pfizer said there are “no major safety concerns” with its product, adding:

“At the recommendation of the DMC [Data Monitoring Committee], and in consultation with the U.S. Food and Drug Administration (FDA), Pfizer has stopped enrollment in the study.

“Based on these positive results Pfizer plans to submit a Biologics License Application (BLA) to the FDA by the end of 2022 for the vaccine candidate followed by other regulatory authorities in the coming months.”

Pfizer’s phase 3 trial data has not yet been vetted by independent experts, and has not been peer-reviewed or published.

On March 2, 2022, Pfizer’s candidate vaccine received a Breakthrough Therapy Designation from the FDA, while previously, in November 2018, the FDA granted it Fast-Track status, according to the Pfizer release.

“Pfizer’s investigational RSV vaccine candidate builds on foundational basic science discoveries including those made at the National Institutes of Health (NIH),” the vaccine maker said in its press release.

The NIH research in question also was “key to the hugely successful COVID-19 vaccines,” according to ABC 7 Los Angeles.

Others looking to develop an RSV vaccine include Moderna and AstraZeneca and Sanofi, in a joint initiative. Moderna received fast-track designation from the FDA on Aug. 3, 2021, for its mRNA-1345 RSV vaccine for older adults, while AstraZeneca and Sanofi are developing a viral vector RSV vaccine by the name of “nirsevimab.”

An August 2021 article in The Defender predicted that RSV would represent the “new frontier for vaccine development,” as pharmaceutical companies would be “lured by the prospect of a large untapped global RSV vaccine market,” leading to a vaccine development “gold rush.”

Media tout benefits, ignore safety concerns

Online news portal Vox described the development of new RSV vaccines as “very, very good news” in a recent article.

Coupled with media coverage about “rising” RSV cases nationwide, it appears the stage is being set to create an emergency in the public consciousness, which could lead to EUAs being granted to the new vaccines and a rush to get the public vaccinated.

Blogger James Roguski, however, called into question the results of the Pfizer phase 3 trial, raising many safety concerns that are indicated in the company’s own data but were downplayed by Pfizer in its public proclamations. In a recent post, he wrote:

“In the Phase II study, researchers found that women who received RSVpreF vaccine containing aluminum hydroxide had a higher incidence of local reactions than those who received

RSVpreF vaccine without aluminum hydroxide.

“It seems like 1 of the 117 infants in the placebo group suffered fetal death and 6 infants in the ‘vaccinated’ group are unaccounted for.”

Roguski also highlighted the many adverse events that were recorded for both infants and pregnant mothers who participated in the study, none of which were recorded for the placebo group.

For infants, some of these adverse events included acute respiratory failure, bronchiolitis, cardiac murmur, chordee (bent penis), conjunctival hemorrhage, hypoglycemia, jaundice, low birth weight, neonatal hypoxia, neonatal respiratory failure, seizure, sepsis, upper respiratory tract infection and vascular malformation.

Pregnant women, in turn, experienced adverse events including fetal growth restriction, fetal tachycardia, gestational diabetes, nonreassuring fetal heart rate pattern, premature labor, premature separation of placenta, vaginal hemorrhage and thrombocytopenia.

For some, these safety concerns are conjuring up memories of previously failed attempts to develop an RSV vaccine.

A vaccine tested in 1966 led to the deaths of two toddlers as a result of “enhanced disease symptoms,” while many infants “suffered worse symptoms than usual, and needed to be hospitalized.”

As previously reported by The Defender, RSV itself originated in monkeys housed in a Maryland facility where they were used to conduct polio vaccine research. Remarking on this and the connection to RSV vaccine development today, Brian Hooker, CHD’s chief scientific officer, told The Defender, “It is incredible that the vaccine industry can create a disease — RSV from the polio vaccine — and then create another vaccine to ‘prevent’ that disease. Talk about a business proposition!”

by Michael Nevradakis, Ph.D.,

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