Health Freedom Louisiana
3301 17th Street #7443
Metairie, LA 70010
info@healthfreedomla.org

March 21, 2023

Dr. Courtney Phillips, Secretary
Louisiana Department of Health
P.O. Box 629
Baton Rouge, LA 70821-0629
Via email: Courtney.Phillips@la.gov

Secretary Phillips,

Please be advised that due to your repeated lack of compliance with the EUA despite our requests, we have reported this incident to the FDA for the reasons detailed below.

Once again, we write regarding the Food and Drug Administration's (FDA) "Conditions of Authorization" set forth in the letters granting Emergency Use Authorization for Pfizer-BioNTech and Moderna's COVID-19 Vaccine and Bivalent COVID-19 Vaccine.[1,2] The response from a recent public records request submitted on February 27, 2023, indicates that the Louisiana Department of Health (LDH) is providing egregiously false information to Louisianans by stating emergency use authorized vaccines are FDA approved. When asked **where** and **when** FDA approved Comirnaty and Spikevax vaccines have been distributed in Louisiana, I received this response:

> **"Louisiana Immunization Program has received CDC distribution guidance regarding Comirnaty (Pfizer) and Spikevax (Moderna) vaccines, but we have not distributed the vaccines to our providers yet. Currently, in Louisiana, we have the FDA-approved (EUA) COVID-19 vaccines from Pfizer and Moderna available to providers, although they are not packaged under their respective branded names. It will take some time for the transition to the new packaging of these vaccines to reflect their product names (Pfizer-Comirnaty, Moderna-SpikeVax). Both FDA-approved vaccines are available throughout Louisiana. To get a current list of COVID-19 vaccine providers, go online to vaccines.gov."**

[1] fda.gov/media/150386/download
[2] fda.gov/media/144636/download

Vaccines cannot be both FDA-approved *and* EUA.

Section A of the Moderna and Pfizer-BioNTech EUA for the COVID-19 Vaccine and Bivalent Vaccine currently available for children ages 6 months and up and 5 years and up, respectively, requires:

> "PfizerInc. and **authorized distributor(s)** will ensure that the authorized Pfizer- BioNTech COVID‑19 Vaccine and Pfizer-BioNTech COVID‑19 Vaccine, Bivalent are distributed, as directed by the U.S. government, including CDC and/or other designee, and the authorized labeling (i.e., **Fact Sheets**) will be made available to vaccination providers, recipients, and caregivers consistent with the terms of this letter."

The respective authorized labeling, or Fact Sheet,[3] stipulates the information required to be given to patients includes:

> "FDA has authorized the emergency use of the Pfizer-BioNTech [or Moderna] COVID-19 Vaccine, *which is not an FDA-approved vaccine*."

Additionally, **Section Y** states:

> **All descriptive printed matter, advertising, and promotional material** relating to the use of the Pfizer-BioNTech [or Moderna] COVID-19 Vaccine or Pfizer-BioNTech [or Moderna] COVID‑19 Vaccine, Bivalent **clearly and conspicuously shall state, as applicable,** that:
>
> - The Pfizer-BioNTech [or Moderna] COVID‑19 Vaccine has not been approved or licensed by FDA, but has been authorized for emergency use by FDA, under an EUA to prevent Coronavirus Disease 2019 (COVID-19) for use in individuals 12 years of age and older, in individuals 5 through 11 years of age, or in individuals 6 months through 4 years of age as appropriate [for Moderna 12 years of age and older, 6 years through 11 years of age, or 6 months through 5 years of age as appropriate]; or
> - The Pfizer-BioNTech [or Moderna] COVID‑19 Vaccine, Bivalent has not been approved or licensed by FDA, but has been authorized for emergency use by FDA, under an EUA to prevent Coronavirus Disease 2019 (COVID-19) for use in individuals 5 years of age and older [for Moderna 6 years of age and older]; and
> - The emergency use of this product is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of the medical product under Section 564(b)(1) of the FD&C Act unless the declaration is terminated or authorization revoked sooner.

In clear violation of these stipulations established under federal law,[4] LDH states in the public records request response, an example of **descriptive printed matter**, that the Emergency Use Authorized (EUA) products are FDA approved.

---

[3] fda.gov/media/153713/download

[4] uscode.house.gov/view.xhtml?hl=false&edition=prelim&req=granuleid%3AUSC-prelim-title21-section360bbb-3&num=0&saved=%7CZ3JhbnVsZWlkOlVTQy1wcmVsaW0tdGl0bGUyMS1zZWN0aW9uMzYwYmJiLTNh%7C%7C%7C0%7Cfalse%7Cprelim

Moreover, according to the EUAs, the two products are **"legally distinct,"**[5,6] which has significance in regards to the experimental nature of EUA products and the means by which compensation is sought for injuries that result from their use.

- Section G of the EUA specifies that Pfizer-BioNTech and Moderna are still reporting findings to the FDA via an Investigational New Drug application. According to the FDA, "an investigational drug can also be called an experimental drug and is being studied to see if your disease or medical condition improves while taking it."[7]

- Unlike typical FDA-approved or licensed drugs, emergency use authorized COVID-19 Vaccines are indemnified under the PREP Act, meaning the manufacturer has no liability for any harm that may result from the use of their product, effectively removing Seventh Amendment protections and the right to seek recourse in a civil court. Instead, recipients must file for compensation through a government program called the Countermeasures Injury Compensation Program[8] (CICP) within a year of receipt of the drug. To date, of the 543 COVID-19 vaccine claims reviewed by CICP, nineteen have been determined to be eligible for compensation yet no compensation amount has been determined or distributed, with 10,653 claims pending review.[9]

Again, misrepresenting an EUA COVID-19 vaccine product as FDA-approved, as LDH has done, violates the respective EUA "Conditions of Authorizations," which were established under federal law as a means of informed consent for experimental drugs that lack full FDA-approval.

Moreover, this is not the first time LDH has provided the same misinformation. In March of 2022, the same question was submitted to LDH with this response:

> "**At this time, Louisiana has not received any shipments of the Pfizer COVID-19 vaccine packaged under its brand name, Comirnaty. We have also not received any shipments of the Moderna COVID-19 vaccine packaged under its new brand name, SpikeVax. CDC has not stated when these two vaccines, packaged to reflect their branded names, will be available to us. In Louisiana, we have the FDA-approved COVID-19 vaccines from Pfizer and Moderna available to providers, although they are not packaged under their respective branded names. It will take some time for the transition to the new packaging of these vaccines to reflect their product names (Pfizer-Comirnaty, Moderna-SpikeVax). CDC has not given us the timelines on when the newly branded/packaged vaccines will be available for distribution. Both FDA-approved vaccines are available throughout Louisiana. To get a current list of COVID-19 vaccine providers, go online to vaccines.gov**."[10]

[5] fda.gov/media/150386/download pg 20
[6] fda.gov/media/144636/download pg 19
[7] fda.gov/patients/learn-about-expanded-access-and-other-treatment-options/understanding-investigational-drugs
[8] healthfreedomla.org/reporting-vaccine-reactions-injuries/
[9] hrsa.gov/cicp/cicp-data
[10] healthfreedomla.org/wp-content/uploads/2022/08/Public-Records-Request-LDH-Covid-Vaccines.jpg

The Louisiana Department of Health provides guidance on COVID-19 vaccines products to countless people, health systems, state agencies, and the legislature. The number of people provided with this blatantly false information is so significant that action must be taken to correct it. We demand a public acknowledgement that the COVID-19 vaccine products available in Louisiana to date are not FDA approved. Louisianans, health systems, medical professionals, and state agencies including the legislature, must be made aware that LDH has been providing information that violates FDA's "Conditions of Authorization" set forth in the EUA.

Regards,
Jill Hines, Ashley Houston, Fiorella Trapani
Co-Directors
Health Freedom Louisiana

cc: Governor John Bel Edwards, Tina.Vanichchagorn@la.gov
Louisiana State Senator Fred Mills, FMills@legis.la.gov
Louisiana State Representative Larry Bagley, LBagley@legis.la.gov
Superintendent Cade Brumley, Cade.Brumley@la.gov
Attorney General Jeff Landry, LandryJ@ag.louisiana.gov