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February 22, 2023

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

Secretary Phillips:

We write regarding the COVID-19 vaccine and Bivalent COVID-19 vaccine “**descriptive printed matter, advertising, and promotional material**” on the Louisiana Department of Health (LDH) website and social media platforms, including those facilitated under separate names such as Bring Back Louisiana and Sleeves Up Louisiana, which are in violation of both the Pfizer<sup>1</sup> and Moderna<sup>2</sup> emergency use authorizations (EUAs). The descriptive printed matter, advertising, and promotional material in question fail to meet the Food and Drug Administration's required “**Conditions Related to Printed Matter, Advertising, and Promotion**” as stated in the respective EUAs.

The Moderna and Pfizer-BioNTech EUAs for the COVID-19 Vaccine and the Bivalent COVID-19 Vaccine currently available for children ages 6 months and up and 5 years and up respectively require:

**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

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<sup>1</sup> <https://www.fda.gov/media/150386/download> pages 28-29

<sup>2</sup> <https://www.fda.gov/media/144636/download> pages 26-27

- 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.

Material in violation of the EUAs include, *but are not limited to*, the following (images in Appendix A):

COVID-19 Information and all attached toolkit material:

- [TOOLKIT: Digital Media Toolkit for Parents](#)
- [TOOLKIT: Digital Media Toolkit for Partners](#)
- [NEW POSTER for Healthcare Providers](#)
- [NEW POSTER for Pharmacies](#)
- [POSTER for Healthcare Providers](#)
- [NEW Q&A ONE PAGER: LDH Guidance for Children Ages 6 months and up](#)

COVID-19 Vaccine: Frequently Asked Questions

- [https://ldh.la.gov/assets/oph/Coronavirus/Vaccine/OPH\\_21\\_0002\\_Flyer.pdf](https://ldh.la.gov/assets/oph/Coronavirus/Vaccine/OPH_21_0002_Flyer.pdf)
- <https://ldh.la.gov/covidvaccine/>
- <https://ldh.la.gov/assets/oph/Coronavirus/marketingmaterials/booster/COVIDnewboosterguidance.png>
- [https://ldh.la.gov/assets/oph/Coronavirus/Vaccine/resources/LDH\\_ChildrenVaccines\\_FactSheet\\_2022\\_HiRes.pdf](https://ldh.la.gov/assets/oph/Coronavirus/Vaccine/resources/LDH_ChildrenVaccines_FactSheet_2022_HiRes.pdf)

Because the Moderna and Pfizer-BioNTech COVID-19 Vaccine and Bivalent COVID-19 Vaccine “**printed matter, advertising, and promotional material**” on LDH’s website and social media platforms lack the language required by each of the FDA’s EUAs conditions for them, **we request their immediate removal.**

We further request that you, as the Secretary of the Louisiana Department of Health, send notices to the appropriate hospitals, schools, and other facilities utilizing LDH’s descriptive or promotional material for both the COVID-19 Vaccine and Bivalent COVID-19 Vaccine, informing them to immediately remove such material as it does not comply with FDA regulations and violates the terms of the EUAs. As the material provided by LDH has been in violation of the EUAs while it was posted, distributed, and visible to the public for more than two years, an official announcement from LDH to the public is in order and we request that it be made immediately. Not providing this information is not only a breach of trust, unethical, and a violation of informed consent, but it is illegal as well. If LDH refuses to assume responsibility and take the necessary actions to (1) remove all material in violation, (2) inform all third-party providers, educational institutions, and facilities that use LDH’s material, and (3) announce to the public the error, then we reserve the right to seek any and all remedies under the law.

If you would like to discuss this or have any questions regarding the matter, please feel free to reach us at [info@healthfreedomla.org](mailto:info@healthfreedomla.org).

Regards,

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

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

## APPENDIX A

Examples of “descriptive printed matter, advertising, and promotional material” found on the Louisiana Department of Health website that violate the Food and Drug Administration’s requirements of the Pfizer-BioNTech and Moderna COVID-19 Vaccine or Pfizer-BioNTech and Moderna COVID-19 Vaccine, Bivalent EUAs.



### GET THE VACCINE

- ➔ Find a Vaccine Provider
- ➔ Get In-Home Vaccination
- ➔ Children 6 months and up now eligible
- ➔ Learn More About Boosters and Third Doses
- ➔ Find a Vaccine Event Near You
- ➔ Schedule an on-site vaccination clinic
- ➔ Need Help? Call the Vaccine Hotline at 1-855-453-0774.

Spanish | Vietnamese

An advertisement featuring a man with dark hair wearing a blue button-down shirt and a light blue surgical mask. He has a blue bandage on his right upper arm. The background is a soft-focus indoor scene. The "BRING BACK LOUISIANA" logo with a red outline of the state of Louisiana is overlaid on the left side of the image.



## OFFICE OF PUBLIC HEALTH OFFICIAL GUIDANCE ON HOW FAMILIES CAN KEEP THEIR CHILDREN SAFE FROM COVID-19

Updated May 18, 2022

The U.S. Centers for Disease Control and Prevention (CDC), the American Academy of Pediatrics (AAP) and the Louisiana Department of Health's official recommendation is clear: vaccinating your children ages 5-17 is the best way to protect them against COVID-19.

### VACCINE & BOOSTER RECOMMENDATIONS FOR CHILDREN

| IF YOUR CHILD IS...      | THEY CAN RECEIVE THE... | THEY SHOULD RECEIVE THE VACCINE... | SHOULD MY CHILD GET A BOOSTER?   |
|--------------------------|-------------------------|------------------------------------|--|
| <b>5-11 years old*</b>   | Pfizer-BioNTech vaccine | 2 doses given 3 weeks apart        | Booster shot is authorized by the FDA and recommended by the CDC   |
| <b>12-17 years old**</b> | Pfizer-BioNTech vaccine | 2 doses given 3-8 weeks apart      | 1 booster of Pfizer-BioNTech vaccine is recommended at least 5 months after the final dose in the primary series |

\*Vaccines for ages 5-15 are under emergency use authorization (EUA). For ages 16-18, the vaccines have received full approval.

\*\*First booster shots for 12-17 year olds are under emergency use authorization (EUA).

### WHY IS IT IMPORTANT TO GET YOUR CHILD VACCINATED NOW?

Unfortunately, COVID-19 continues to spread in Louisiana. The COVID-19 lull we enjoyed following the Omicron surge earlier this year is starting to reverse itself. While hospitalizations remain low at this time, cases, percent positivity, and emergency department visits for COVID-like illness are all increasing statewide.

According to the latest data from the Kaiser Family Foundation, COVID-19 was the fourth leading cause of death among children ages 5-14 and young people ages 15-24 in January 2022.

**Having your child vaccinated against the virus will strengthen their immune system, help prevent them from getting severe COVID-19 symptoms, and could keep them out of the hospital.**

### WHAT SHOULD I DO IF MY CHILD IS GOING TO SUMMER CAMP OR STARTING SCHOOL IN THE FALL?

You should not wait – make sure your child is up to date on their COVID-19 vaccinations now, given the recent increases in COVID-19 cases throughout Louisiana.

### WHAT CAN FAMILIES DO TO KEEP CHILDREN UNDER 5 HEALTHY UNTIL THEY ARE ELIGIBLE FOR THE COVID-19 VACCINE?

We know many families are anxiously awaiting the anticipated announcement that the COVID-19 vaccine is available for children under 5, and we have been actively planning for it. In the meantime, families can:

- **Focus on preventative care and wellness.** Keep up with regular pediatric visits and wellness checks.
- **Talk to your pediatrician.** They have the most accurate information about COVID-19 vaccines and when they will be available. It is also important to check on other routine vaccinations.
- **Assess the risk of activities.** Remember: outdoor activities are safer than indoor activities. When in doubt, masking and/or rapid testing can decrease uncertainty. Stay vigilant if your child is immunocompromised or another family member is vulnerable to severe illness.

The federal government is providing free COVID-19 at-home tests. You can order yours at [covidtests.gov](https://covidtests.gov) or call **1-800-232-0233 (TTY 1-888-720-7489)**.

### WHAT IF I STILL HAVE QUESTIONS?

That's normal! Talk to your or your child's doctor about what is right for your family. You can also call our **COVID-19 Support Hotline at 1-855-453-0774** to get your questions answered, speak directly with a medical professional, find a vaccine provider or therapeutics near you, and schedule a vaccine appointment or homebound vaccination.

# SLEEVESUP

to help end the pandemic



SLEEVES UP - to help end the pandemic

## The COVID-19 Vaccine Is Here.

Nearly 95% Effective | FDA Authorized | Available At No Cost

Click or call to find out when and where you can get vaccinated.



COVIDVACCINE.LA.GOV



211



LOUISIANA  
DEPARTMENT OF HEALTH





## UPDATED COVID-19 BOOSTERS

CDC endorses updated COVID-19 boosters

### Get the facts:

- These updated boosters are formulated to offer continued protection against the original strain, while also offering better protection against the two lineages of the Omicron variant, BA.4 and BA.5, which represent over 90% of currently circulating virus
- “Mix and matching” of the new bivalent booster dose is allowed

### Who is eligible?

- **Moderna:** individuals 18 years of age and older
- **Pfizer:** individuals 12 years of age and older

