



Health Freedom Louisiana
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March 21, 2023

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Dear Dr. Marks and Dr. Stockbridge,

Please see the attached letters addressed to the Louisiana Department of Health (LDH) regarding repeated and egregious violations of the “Conditions of Authorizations” stipulated in the letters granting emergency use for the COVID-19 vaccines. We have attempted to resolve this issue with LDH directly, but they have repeatedly ignored us. Please accept this notice as our formal complaint of the same to the FDA and our request that you investigate this matter immediately.

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



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Metairie, LA 70010
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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](https://www.fda.gov/media/150386/download)

² [fda.gov/media/144636/download](https://www.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](https://www.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=%7CZ3JhbnVsZWlkOIVTQy1wcmVsaW0tdGl0bGUyMS1zZW50aW9uMzYwYmJiLTNh%7C%7C%7C0%7Cfalse%7Cprelim](https://www.uscode.house.gov/view.xhtml?hl=false&edition=prelim&req=granuleid%3AUSC-prelim-title21-section360bbb-3&num=0&saved=%7CZ3JhbnVsZWlkOIVTQy1wcmVsaW0tdGl0bGUyMS1zZW50aW9uMzYwYmJiLTNh%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 Program⁸ (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](https://www.fda.gov/media/150386/download) pg 20

⁶ [fda.gov/media/144636/download](https://www.fda.gov/media/144636/download) pg 19

⁷ [fda.gov/patients/learn-about-expanded-access-and-treatment-options/understanding-investigational-drugs](https://www.fda.gov/patients/learn-about-expanded-access-and-treatment-options/understanding-investigational-drugs)

⁸ healthfreedomla.org/reporting-vaccine-reactions-injuries/

⁹ hsra.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

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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

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 Pfizer¹ and Moderna² 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

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

² <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/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

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.

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

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, featuring a red outline of the state of Louisiana, is positioned to the left of the man.

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?
5-11 years old*	Pfizer-BioNTech vaccine	2 doses given 3 weeks apart	Booster shot is authorized by the FDA and recommended by the CDC
12-17 years old**	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 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.

SLEEVES UP

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





HealthFreedomLA.org

November 12, 2021

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

RE: False and Misleading Messaging to Parents about the COVID-19 Vaccine for 5-11 Year Olds

Dear Dr. Phillips,

I am concerned that a lot of the messaging on the Louisiana Department of Health's flyers and social media posts, included at the end of this letter, is misleading and in some instances outright false. This prevents parents from making an accurate, informed decision and as a result obtaining informed consent is not possible.

False Claim #1 - COVID-19 Vaccines are Safe for Kids

The following statements are taken from two separate flyers from LDH: "The COVID-19 vaccines are safe and effective. All studies done show that COVID-19 vaccines are safe for kids. This vaccine for children has passed rigorous clinical trials and is safe – just like the other common vaccines we recommend our children receive. These vaccines are as safe and as effective as any vaccines we've ever had for any disease. The vaccine is so safe that the CDC and American Academy of Pediatrics (AAP) urge all eligible people to get the COVID-19 vaccine as soon as it is available to them."

In stark contrast, Pfizer admits¹:

"In countries where the vaccine has not been approved by the relevant regulatory authority, it is an investigational drug, and its safety and efficacy have not been established."

While the FDA granted Emergency Use Authorization for the Pfizer vaccine for children 5-11 years old, it has not been fully approved and as such has made no determination of its safety or efficacy in that age group. To discount the experimental nature of this drug is incredibly misleading and deceiving to parents and providers. Indeed, as defined by the FDA², products granted EUA by definition are investigational and experimental.

¹ [cvdvaccine.com](https://www.cvdvaccine.com)

² [fda.gov/drugs/types-applications/investigational-new-drug-ind-application](https://www.fda.gov/drugs/types-applications/investigational-new-drug-ind-application),
[fda.gov/patients/learn-about-expanded-access-and-other-treatment-options/understanding-investigational-drugs](https://www.fda.gov/patients/learn-about-expanded-access-and-other-treatment-options/understanding-investigational-drugs)

False Claim #2 - All Possible Side Effects are Known and Mild

In one of the LDH flyers, the only possible side effects listed as an answer to the question “Are there any side effects from the COVID-19 vaccine?” were “mild, short-term side effects, like a sore arm, body aches, headache, a fever, or tiredness for a day or two.” It goes on to say “The shot makes them stronger and better able to fight off the virus if they come in contact with it.”

These statements go against the actual study data³ which showed much higher incidences of systemic adverse reactions in the study group versus the control group, including fever, fatigue, and headache. Further, the messaging on the flyer directly contradicts information found in the [Fact Sheet for Providers](#)³ for the Pfizer COVID-19 vaccine for children ages 5-11:

“Additional adverse reactions, some of which may be serious, may become apparent with more widespread use of the Pfizer-BioNTech COVID-19 Vaccine.”

“The significant known and potential risks and benefits of Pfizer-BioNTech COVID-19 Vaccine, and the extent to which such risks and benefits are unknown.”

Additionally, the [Fact Sheet for Providers](#)³ specifically warns of two known serious side effects, listed under WARNINGS AND PRECAUTIONS, but have no mention anywhere on LDH’s communications:

“Postmarketing data demonstrate increased risks of myocarditis and pericarditis, particularly within 7 days following the second dose.”

False Claim #3 - Co-Administration of COVID-19 Vaccine with Other Vaccines is Safe

On the flyer, the answer to the question “Can kids get the COVID vaccine at the same time as their annual immunizations?” was “Yes. In fact, the American Academy of Pediatrics (AAP) supports kids getting routine immunizations at the same time they get a COVID-19 vaccine, including the flu shot.” Then you have a social media post on LD’s page which shows a young boy with a bandaid on his arm and it states: “There were no tears...when he bravely got his COVID-19 and flu vaccines at the same time.”

There is NO DATA to support this recommendation. Further, to tell parents to do so without a clear warning that it has never been studied and the risks of doing such is completely unknown is blatant negligence. The [Fact Sheet for Providers](#)³ clearly states:

“There is no information on the co-administration of the Pfizer-BioNTech COVID-19 Vaccine with other vaccines.”

While the American Academy of Pediatrics may ignore the lack of studies and safety data, the agency charged with the health and welfare of Louisiana citizens may not.

False Claim #4 - The COVID-19 Vaccine Protects Others

One social media post on the LD’s page states: “Olivia (age 9) was thrilled to find out she could now protect herself, her friends, and her school! ... got her COVID19 vaccine.”

³ [fda.gov/media/153714/download](https://www.fda.gov/media/153714/download)

It is now well established that this product has not been able to prevent transmission nor infection in other age groups⁴, especially in regards to the Delta variant, so the assumption that it somehow will in this age group is not supported and not based on any existing science. Again, we point to Pfizer's own admission⁵:

"In countries where the vaccine has not been approved by the relevant regulatory authority, it is an investigational drug, and its safety and efficacy have not been established."

Providers are Legally Required to Adequately Inform Vaccine Recipients & Caregivers

As stated on the [Fact Sheet for Providers](#)⁶:

"As the vaccination provider, you must communicate to the recipient or their caregiver, information consistent with the "Vaccine Information Fact Sheet for Recipients and Caregivers" (and provide a copy or direct the individual to the website www.cvdvaccine.com to obtain the Vaccine Information Fact Sheet) prior to the individual receiving each dose of Pfizer-BioNTech COVID-19 Vaccine, including: ...

The significant known and potential risks and benefits of Pfizer-BioNTech COVID-19 Vaccine, and the extent to which such risks and benefits are unknown."

LDH is intentionally omitting critical information and misleading parents into having an inaccurate representation of the COVID-19 vaccine for 5-11 year olds. A false representation of downplaying the investigational/experimental nature of this product and its side effects, while exaggerating its safety and benefits.

It is imperative that parents and medical professionals are not misled by the messaging from your agency as the shots are rolled out in this age group. These drugs must be given their due respect as experimental and true informed consent must be given by parents, which is impossible if the information being presented to them is inaccurate.

Regards,
Jill Hines, Fiorella Trapani, et al
Co-Director
Health Freedom Louisiana

CC: Matthew Block, Executive Counsel
Members of the Louisiana State Legislature
Elizabeth Murrill, Solicitor General

⁴ medrxiv.org/content/10.1101/2021.09.28.21264262v1, bit.ly/cdcsldesdelta, [thelancet.com/journals/lancet/article/PIIS0140-6736\(21\)02183-8/fulltext](https://thelancet.com/journals/lancet/article/PIIS0140-6736(21)02183-8/fulltext), bit.ly/studywaningimmunitycovidvaccines, brownstone.org/articles/79-research-studies-affirm-naturally-acquired-immunity-to-covid-19-documented-linked-and-quoted/

⁵ cvdvaccine.com

⁶ fda.gov/media/153714/download

THE COVID-19 VACCINE IS NOW RECOMMENDED FOR CHILDREN AGES 5 AND UP

The FDA has authorized and the CDC now recommends the COVID vaccine for emergency use in children ages 5-11, following a rigorous review of the data.

YOU'VE PROBABLY GOT A LOT OF QUESTIONS. WE'RE HERE TO HELP.

Our most recent COVID surge was fueled by the highly transmissible Delta variant and had a devastating impact on Louisianans, including children.

Q: Should kids get a COVID-19 vaccine?

A: Yes. The COVID-19 vaccines are safe and effective. Getting vaccinated is the best way to protect kids from getting infected with COVID-19.

Q: Are COVID-19 vaccines safe for kids?

A: All studies done show that COVID-19 vaccines are safe for kids. A vaccine goes through intensive testing before people can get it. Millions of U.S. kids have already received their safe and effective vaccine.

Q: Why should we vaccinate healthy children?

A: Having your child vaccinated against the virus will help prevent them from getting severe COVID-19 disease. Although COVID-19 in children is often milder than in adults, some children can get severe lung infections, become very sick and need hospital care. The shot makes them stronger and better able to fight off the virus if they come in contact with it.

Since the beginning of August, 25% of all new COVID-19 cases in Louisiana were in children. LDH reported 9 pediatric deaths tied to the fourth surge alone. A total of 18 children in Louisiana have died of COVID since the pandemic began.

Q: Are children at risk of getting COVID-19?

A: According to the FDA, at least 94 children ages 5 to 11 have died of COVID-19 since the pandemic began, and 8,300 have become so sick they needed to be hospitalized. **In fact, COVID was the eighth-leading cause of death in the age group** over the past year, after accidents, cancer, malformations, murder, heart disease, chronic lower respiratory disease, and flu or pneumonia.

Q: Are there any side effects from the COVID-19 vaccine?

A: Like many vaccines, COVID-19 vaccines can cause mild, short-term side effects, like a sore arm, body aches, headache, a fever, or tiredness for a day or two. These are signs that the immune system is responding to the vaccine and building immunity to the virus.

Q: What are other serious effects of COVID-19?

A: Some children that had only mild symptoms went on to develop multi-system inflammatory syndrome in children (MIS-C), a serious condition in which the immune system goes haywire and starts attacking otherwise healthy parts of the body. Children with MIS-C often become severely sick and require hospitalization. MIS-C is most common in children between the ages of 5 and 13. Since July 1 of this year, 107 cases of MIS-C have occurred in Louisiana children. (Nationally, by early October, 5,217 kids had come down with MIS-C, including 2,034 between 6 and 11, according to the CDC.)

Q: Can kids get the COVID vaccine at the same time as their annual immunizations?

A: Yes. In fact, the American Academy of Pediatrics (AAP) supports kids getting routine immunizations at the same time they get a COVID-19 vaccine, including the flu shot.

Getting your children vaccinated can help protect them against COVID-19, as well as reduce disruptions to in-person learning and activities by helping curb community transmission.

We know parents and families want to make the best decision for their children. And we know that families have questions – that's good! Talk to your doctor or other healthcare provider today about the shot and to make an appointment. To find a nearby vaccination location, go to www.vaccines.gov, call Louisiana's COVID-19 Vaccine Hotline at 855-453-0774, or visit ldh.la.gov/kidsvax.

Some
superheroes
wear capes ...

**SOME WEAR
BANDAIDS.**



Our kids deserve to be protected, too.

THE COVID-19 VACCINE IS SAFE FOR CHILDREN.

The CDC has recommended that all children ages 5 and up get vaccinated against COVID-19.

The vaccines have proven to be safe and effective in children as young as 5 years old. The vaccine is so safe that the CDC and American Academy of Pediatrics (AAP) urge all eligible people to get the COVID-19 vaccine as soon as it is available to them. When your child gets vaccinated against COVID-19, they also have a better chance at staying in school and participating in the activities they enjoy.



"This vaccine for children has passed rigorous clinical trials and is safe – just like the other common vaccines we recommend our children receive."

DR. WANDA THOMAS
PROFESSOR OF
PEDIATRICS,
LSU Health
Shreveport



"These vaccines are as safe and as effective as any vaccines we've ever had for any disease."

DR. MARK KLINE
PHYSICIAN-IN-CHIEF
AND PEDIATRICIAN,
Children's Hospital
New Orleans



 **LOUISIANA
DEPARTMENT OF
HEALTH**

**BRING BACK
LOUISIANA**

GET THE FACTS:

visit ldh.la.gov/kidsvax
or call the Vaccine Hotline
at 1-855-453-0774





Louisiana Department of Health

6h · 🌐

There were no tears from 5-year-old Gabriel when he bravely got his COVID-19 and flu vaccines at the same time! LDH and [CDC](#) recommend all children ages 5+ go [#SleevesUp](#).

If you have questions, that's OK! Talk to your child's pediatrician, or call 211 or the COVID-19 Vaccine Hotline at 1-855-453-0774.



Louisiana Department of Health limited who can comment on this post.



Louisiana Department of Health

2d · 🌐

Olivia (age 9) was thrilled to find out she could now protect herself, her friends, and her school! Olivia went [#SleevesUp](#) and got her [#COVID19](#) vaccine.

LDH and CDC recommend all children ages 5 and older be vaccinated against COVID-19. To find a vaccination location near you or get your questions answered, we encourage you to speak with your child's pediatrician, call 211, or call the COVID-19 Vaccine Hotline at 1-855-453-0774 to be connected with a medical professional.

