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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

² fda.gov/drugs/types-applications/investigational-new-drug-ind-application, 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 Providers³ 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 Providers³ 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 Providers³ 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

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 Providers⁶:

"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

Know Your Rights, Protect Your Freedom.

⁴ medrxiv.org/content/10.1101/2021.09.28.21264262v1, bit.lv/cdcslidesdelta, thelancet.com/journals/lancet/article/PIIS0140-6736(21)02183-8/fulltext, bit.ly/studywaningimmunitycovidyaccines. 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.



Should kids get a COVID-19 vaccine?



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



Are COVID-19 vaccines safe for kids?



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.



Why should we vaccinate healthy children?



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.



Are children at risk of getting COVID-19?



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.



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



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.



What are other serious effects of COVID-19?



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.)



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



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.



Our kids deserve to be protected, too. THE COVID-19 VACCINE IS SAFE FOR CHILDRE

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.





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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

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

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.

