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December 4, 2021

Dr. Courtney Phillips, Secretary
Louisiana Department of Health
P.O. Box 629
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Via email Courtney.Phillips@la.gov

Dr. Phillips,

On December 10, 2020, the Food and Drug Administration (FDA) issued their first Briefing Document[1] explaining the justification for granting Emergency Use Authorization for the Pfizer-BioNTech COVID-19 vaccine. In the opening paragraph of the Executive Summary of that document, it states:

> "On November 20, 2020, Pfizer and BioNTech (the Sponsor) submitted an Emergency Use Authorization (EUA) request to FDA for an ***investigational*** COVID-19 vaccine (BNT162b2) intended to prevent COVID-19 caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2)."

Section 2.2. EUA Request for the Pfizer and BioNTech COVID-19 Vaccine BNT162b2 states:

> "On November 20, 2020, Pfizer and BioNTech submitted an EUA request to FDA for its ***investigational*** COVID-19 vaccine (BNT162b2) intended to prevent COVID-19 caused by SARS-CoV-2."

Section 2.3. U.S. Requirements to Support Issuance of an EUA for a Biological Product states:

> ***"In the event an EUA is issued for this product, it would still be considered unapproved and it would be under further investigation*** (under an ***Investigational*** New Drug Application) until it is licensed under a Biologics License Application (BLA)."

The FDA refers to the vaccine as ***investigational*** two more times in the Briefing Document.

What does ***investigational*** mean? As defined by the FDA:

[1] fda.gov/media/144245/download

> "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."[2]

Also:

> "Emergency Use IND [Investigational New Drug] allows the FDA to authorize use of an ***experimental*** drug in an emergency situation that does not allow time for submission of an IND in accordance with 21CFR ,Sec. 312.23 or Sec. 312.20."[3]

Following the VAERS oversight hearing on November 8, 2021, we submitted several questions to Public Health Officer Dr Joseph Kanter and other members of your staff. We are terribly concerned by this reply:

> "The three COVID-19 vaccines authorized/approved in the U.S. are actually not experimental at all. The "e" in EUA stands for emergency, not experimental. The FDA makes clear distinction between "investigatory or experimental" drugs/vaccines and drugs/vaccines authorized for use under an EUA. Each of the three available vaccines have undergone rigorous phase 1/2 and 3 trials. The phase 3 trials in particular are designed to prove safety and efficacy. As noted by the NIH, "a Phase 3 trial of an investigational vaccine enrolls thousands of people to evaluate if the vaccine is safe and can effectively prevent symptomatic COVID-19 disease. All vaccine candidates being tested in Phase 3 clinical trials have been previously tested in early-stage clinical trials that showed they were well tolerated and elicited an immune response in adult volunteers. Participants in Phase 3 clinical trials are assigned randomly to receive either the investigational vaccine or a placebo. The trials are double-blind, meaning neither the trial investigators nor the participants know who received the vaccine candidate. Investigators evaluate if the vaccine works by comparing the number of cases of symptomatic COVID-19 in the vaccine group versus the placebo group. Participants are monitored throughout the trial for safety." The currently-available COVID-19 vaccines would have been appropriately referred to as experimental while they were still in any of the Phase 1/2 or 3 trials. In the case of these vaccines, once the independent Data and Safety Monitoring Board (DSMB) reviews the internal trial data and determines the vaccine is safe and effective, the FDA reviews and authorizes the vaccine, and the CDC reviews and issues recommendations for its use, it is no longer accurate to refer to the vaccine as experimental. **In fact this is a major source of misinformation and contributes to further misunderstanding of the vaccine development process."**

To support this statement, three web links were provided, including one from the FDA titled *Understanding the Regulatory Terminology of Potential Preventions and Treatments for COVID-19*,[4] which again defines an investigational drug as an experimental drug. Your staff also included a fact check article[5] from Reuters to support this claim. James C. Smith, a Pfizer board member, is Chairman of the Thomson Reuters Foundation and former President, Chief Executive officer and Director of Thomson Reuters Corporation.[6] Not only is the article abysmal, but the conflict of interest is astounding.

The only COVID-19 vaccine product to have received full FDA approval is Pfizer's Comirnaty, for which a BLA was granted on August 23, 2021. All other COVID-19 vaccines are still ***investigational*** under Emergency Use Authorization. Pfizer recognizes this regulatory limitation by stating on its FACT SHEET for PROVIDERS website:

> "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.***"[7]

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[2] fda.gov/patients/learn-about-expanded-access-and-other-treatment-options/understanding-investigational-drugs
[3] fda.gov/drugs/types-applications/investigational-new-drug-ind-application
[4] fda.gov/media/138490/download
[5] reuters.com/article/factcheck-covid-vaccines/corrected-fact-check-covid-19-vaccines-are-not-experimental-and-they-have-not-skipped-trial-stages-idUSL1N2M70MW
[6] pfizer.com/people/leadership/board-of-directors/james_smith
[7] cvdvaccine.com

Frankly, we are astounded. For many months, we have been concerned about the motives of your department and the lack of respect for the experimental nature of the drugs that you promote like candy to every demographic.

It is also apparent from the email reply to our follow up questions that the *thousands* of adverse events reported by Louisiana citizens directly to the Vaccine Adverse Event Reporting System (VAERS) are not investigated or included in any safety statistics reported to the legislature or the public, and that you are only considering calls made to an 800 number that is not advertised to the general public and not well known by the medical community. To completely disregard VAERS is unconscionable.

In addition, there has been a clear disregard for medical ethics and human rights as policies have been enacted in regards to COVID-19 vaccinations which include false and misleading messaging[8] and monetary incentives[9] for minors to participate in an experimental medical procedure.[10] Instead of informing the public that COVID-19 vaccines for children ages 5-15 are granted "emergency use" as federal law[11] requires, parents have consistently been misinformed by LDH that the drug is "safe and effective."[12] [13] An email from LDH dated November 30 even states COVID-19 vaccination for ages 5-15 is FDA approved:

> "Due to its new FDA approval, the Louisiana Department of Health (LDH) and Centers for Disease Control and Prevention (CDC) recommend all children ages 5 and older be vaccinated against COVID-19. We know families have been anxiously awaiting this announcement and that others may still have questions. As the holiday season approaches, please join us and a panel of experts for a conversation on the safety and importance of vaccinating children against COVID-19!"

This is in blatant violation of the FDA's authorization for Pfizer's BioNTech COVID-19 vaccine currently in use pursuant to the EUA which requires that "**[a]ll promotional material relating to the COVID-19 Vaccine clearly and conspicuously ... state that this product has not been approved or licensed by the FDA..**."[14]

These actions indicate a disturbing level of incompetence and malfeasance.

Finally, the Louisiana Department of Health has further undermined public confidence by willfully obfuscating from the public the intent to add COVID-19 vaccination to the required list of childhood vaccinations for schools and daycares. On September 20th, LDH posted a Notice of Intent online and in the Louisiana Registry[15] declaring the intent to add COVID-19 vaccination to the required list of vaccinations to attend public and private schools in Louisiana. While fulfilling statutory obligations, LDH made no attempt to notify the general public through press releases or press conferences regarding a change in policy that will affect the vast majority of Louisiana families.

The lack of transparency from this office, while not surprising considering the less than ethical policies that have already been enacted, is reflective of LDH's general lack of respect for the citizens of Louisiana.

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[8] healthfreedomla.org/wp-content/uploads/2021/11/Dr-Phillips-Misleading-Messaging.pdf
[9] shotfor100.com/
[10] fda.gov/drugs/types-applications/investigational-new-drug-ind-application
[11] 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
[12] ldh.la.gov/assets/5-11-vaccine/LDH_SuperheroKids_Flyer_HR.pdf
[13] ldh.la.gov/assets/5-11-vaccine/LDH_FDA_Approval_OnePager-Nov8-HR.pdf
[14] fda.gov/media/150386/download
[15] doa.la.gov/media/0yyotnwa/2109.pdf

Children deserve to not live in fear, to not worry that they will "kill grandma," to not be scared of maskless faces or interaction with friends. Children should be empowered knowing their immune systems are enough; that with a healthy diet and lifestyle their bodies will be well-equipped to handle sickness, as the data shows.[16] Instead, LDH has relentlessly fear mongered the public, parents, and children, putting out a false narrative that vaccination is the *only* way to protect yourself and others, with no mention of contributing lifestyle factors and comorbidities or early treatment. In stark contrast, Florida's Surgeon General, Dr. Joseph Ladapo, has created a marketing campaign called Let's Live to promote these core beliefs that are backed by science.

Louisiana children deserve the same.

For these reasons, including the blatant incompetence and malfeasance of the department under your direction, we ask for your immediate resignation along with State Health Officer Dr Joseph Kanter.

Sincerely,

Jill Hines and Fiorella Trapani
Co-Directors
Health Freedom Louisiana

Cc: Members of the Louisiana State Legislature via email
Elizabeth Murrill, Solicitor General, MurrillE@ag.louisiana.gov
Matthew Block, Executive Counsel Matthew.Block@la.gov
Dr. Joseph Kanter, State Health Officer, Joseph.Kanter@la.gov

[16] brownstone.org/articles/dear-pfizer-leave-the-children-alone/