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December 17, 2021

To: Members of the Louisiana State Legislature via email Re: Louisiana Department of Health's Shots for Santa Campaign

The Shots for Santa campaign spearheaded by the Louisiana Department of Health (LDH) to increase uptake of COVID-19 vaccination in the pediatric population raises serious human rights and medical ethics concerns.

There are several points of interest in the Pfizer Fact Sheet for Providers¹ that we would like to bring to your attention as a matter of concern as children are being administered vaccinations in malls and museums and outside the purview of their pediatrician or primary care physician. First, the document states:

"Do not administer Pfizer-BioNTech COVID-19 Vaccine to individuals with known history of a severe allergic reaction (e.g., anaphylaxis) to any component of the Pfizer-BioNTech COVID-19 Vaccine (see Full EUA Prescribing Information)."

While the goal of these events is to increase vaccine uptake in the pediatric community, they undermine the fundamentals of medical care by removing the necessary opportunity to fully review the child's medical history and appropriately address any parental concerns.

Second, the Fact Sheet for Providers states:

"Appropriate medical treatment used to manage immediate allergic reactions must be immediately available in the event an acute anaphylactic reaction occurs following administration of Pfizer-BioNTech COVID-19 Vaccine."

Will there be appropriate medical treatment available at these various venues should the need arise? Vaccination is not without risks. Notably, for almost a year now the public has been told that all of the COVID-19 vaccines are equally safe yet just yesterday the CDC announced they now recommend the Pfizer or Moderna over the Johnson & Johnson because of the risk of serious adverse effects. The point being, all of these vaccines are novel and experimental and their complete side effect profiles are unknown and ongoing. As such, we encourage that it always take place with the supervision of a treating physician and in settings well-equipped for emergency care in case life-threatening anaphylaxis occurs as indicated in the Fact Sheet for Providers.

Third, there is extensive information under *Warnings* and *Adverse Reactions* that need to be conveyed in a setting where parents are not distracted by the environment or festivities. Can informed consent be truly acquired in such settings outside the clinic?

¹ <u>labeling.pfizer.com/ShowLabeling.aspx?id=16073&format=pdf</u>

In addition, federal law² requires that the consumer be made aware that the drug is being administered under Emergency Use, meaning it is not FDA approved. All COVID-19 vaccines available to the pediatric population are authorized for Emergency Use under an Investigational New Drug (IND) Application.³ It is important to note that the Food and Drug Administration (FDA) states on their website:

"Emergency Use IND 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, <u>Sec. 312.23</u> or Sec. <u>312.20</u>."⁴

At the Shots for Santa events, parents will be paid for administering an experimental drug to their child. We are very concerned that this information will not be conveyed to parents or guardians given the repeated false and misleading messaging set forth by LDH's marketing.⁵ Coercive measures like this undermine *voluntary* informed consent, a crucial aspect of medical ethics, and target the already vulnerable minority and poor populations.

Further, paying parents to have their child undergo medical treatment outside the clinical setting offers unlimited opportunities for abuse. Because of the government's reaction to the SARS-CoV-2 epidemic, many families are suffering financially. Unfortunately, it is not outside the realm of possibilities that children will be subjected to this medical procedure many times as parents take the opportunity to earn money.

Finally, the psychological manipulation in the messaging must be addressed. *See graphic*. The coercive nature of the messaging crosses ethical boundaries. Children, nor their parents, should equate vaccination with being "nice." It is a medical procedure with clearly stated risks. Coercion has no place in medicine or public health.

We hope you will join us in communicating these concerns to the Louisiana Department of Health and those facilities hosting Shots for Santa and work towards stopping them.

Sincerely, Jill Hines and Fiorella Trapani Co-Directors Health Freedom Louisiana

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uscode.house.gov/view.xhtml?hl=false&edition=prelim&req=granuleid%3AUSC-prelim-title21-section360bbb-3&num=0&saved=%7CZ3JhbnVsZWlkO IVTQy1wcmVsaW0tdGl0bGUyMS1zZWN0aW9uMzYwYmJiLTNh%7C%7C%7C0%7Cfalse%7Cprelim

³ <u>fda.gov/media/150386/download</u>, section III(G)

⁴ <u>fda.gov/drugs/types-applications/investigational-new-drug-ind-application</u>

⁵ healthfreedomla.org/wp-content/uploads/2021/11/Dr-Phillips-Misleading-Messaging.pdf

Graphic.

