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December 7, 2023

Mr. Stephen Russo, Secretary
Louisiana Department of Health
P.O. Box 629
Baton Rouge, LA 70821-0629
Via email: stephen.russo@la.gov

Dear Secretary Russo,

When the Food and Drug Administration (FDA) granted Emergency Use Authorization (EUA) for covid vaccines in December 2020, the agency stipulated in its terms of use, established under federal law,¹ the **mandatory requirements** for serious adverse event reporting by providers, including:

- Vaccine administration errors whether or not associated with an adverse event
- Serious adverse events (**irrespective of attribution to vaccination**)
- Cases of myocarditis
- Cases of pericarditis
- Cases of Multisystem Inflammatory Syndrome
- **Cases of COVID-19 that result in hospitalization or death**

The EUA stipulates that “**vaccination providers administering the vaccines must report**” the stated list of serious adverse events “of which they become aware to VAERS.”² The EUA goes on to state that these serious adverse events must be reported “irrespective of attribution to vaccination.” This directive to report serious adverse events is repeated on the Centers for Disease Control and Prevention (CDC) website, noting that “healthcare providers who administer COVID-19 vaccines are **required** to report the following [serious adverse events] to VAERS,”³ as well as on the vaccine manufacturer’s Fact Sheet for Providers which refers to serious adverse event reporting as a “mandatory requirement.”⁴

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<https://uscode.house.gov/view.xhtml?hl=false&edition=prelim&req=granuleid%3AUSC-prelim-title21-section360bbb-3&num=0&saved=%7CZ3JhbnVsZWlkOIVTQy1wcmVsaW0tdGl0bGUyMS1zZWNoaW9uMzYwYmJlLTNh%7C%7C%7C0%7Cfalse%7Cprelim>

² <https://www.fda.gov/media/150386/download> pg. 32

³ <https://www.cdc.gov/vaccinesafety/ensuringsafety/monitoring/vaers/reportingaes.html>

⁴ <https://web.archive.org/web/20230102170448/https://www.fda.gov/media/159312/download>

As was noted in the December 2020 FDA Briefing Document for each of the covid vaccines, the initial clinical trials left significant data gaps about the experimental vaccines that were about to be rolled out on the market, including:⁵

- Duration of protection
- Effectiveness in certain populations at high-risk of severe COVID-19
- Effectiveness in individuals previously infected with SARS-CoV-2
- Effectiveness in pediatric populations
- Future vaccine effectiveness as influenced by characteristics of the pandemic, changes in the virus, and/or potential effects of co-infections
- Vaccine effectiveness against asymptomatic infection
- Vaccine effectiveness against long-term effects of COVID-19 disease
- **Vaccine effectiveness against mortality**
- **Vaccine effectiveness against transmission of SARS-CoV-2**
- Safety in certain subpopulations
- Adverse reactions that are very uncommon or that require longer follow-up to be detected
- **Vaccine-enhanced disease**

These data gaps make adverse event reporting essential to help inform the manufacturers, public health officials, and the public at large of possible risks associated with the vaccine, and to catch any safety signals. Hence the reason the FDA, CDC, and vaccine manufacturers emphasize that adverse event reporting is *mandatory*⁶ and *required*⁷ for vaccine providers.

Two metrics that the Louisiana Department of Health (LDH) has cataloged and used to promote vaccine uptake are the number of individuals who have received a covid vaccine and the number of individuals that have died from covid. At one point, those two metrics were combined on the LDH covid dashboard to determine the percentage of individuals who had died of covid without a vaccine. In fact, Louisiana law requires that adult vaccine information be input into the state's Louisiana Immunization Network (LINKS) system for, among other things, "associated public health research."⁸

Because LDH tracks covid vaccination rates and covid deaths for Louisiana, we submitted a public records request (PRR) asking:

"On 6/1/23, an LDH social media post stated that 19,000 Louisianans had died of covid since March 14, 2020. <https://twitter.com/LADeptHealth/status/1664328153978773507?s=20> The post goes on to offer locations for covid vaccinations: <https://twitter.com/LADeptHealth/status/1664328156650545165?s=20> Covid vaccinations became available in Louisiana under EUA in December 2020. Covid vaccination and covid deaths are both metrics LDH tracks. How many Louisianans received a covid vaccination, then subsequently died of covid? I am not asking for any identifying information, only the number of individuals who died of covid following covid vaccination. Time from vaccination to death is not relevant and should not exclude anyone from this request."

⁵ <https://www.fda.gov/media/144245/download>

⁶ <https://web.archive.org/web/20230102170448/https://www.fda.gov/media/159312/download>

⁷ <https://www.cdc.gov/vaccinesafety/ensuringsafety/monitoring/vaers/reportingaes.html>

⁸ <https://legis.la.gov/legis/law.aspx?d=98367>

As noted in the PRR, LDH used the state’s number of covid deaths as a reason to get a covid vaccine, stating that individuals can “protect themselves and loved ones.” The post reads:⁹

“Louisiana has tragically surpassed 19,000 #COVID19 deaths since March 14, 2020. We can protect ourselves and our loved ones by staying up to date on our #COVIDvaccines and the latest #COVID guidance.”

Below is the response from LDH to our PRR for the number of individuals in Louisiana who received a covid vaccine and subsequently died of covid:

+ Date range: 12/14/2020 - 8/1/2023

Total number of COVID deaths during date range	11994	
Number of all COVID deaths classified with primary series completed at least 14 days prior to death (also includes those with boosters)	3091	25.77%
Number of COVID deaths with booster	1062	8.85%
Number of COVID deaths with additional booster dose	171	1.43%
Number of COVID deaths with bivalent dose	103	0.86%

According to LDH, 3,091 individuals died of covid despite *repeated* covid vaccinations. Of note, because the response from LDH stipulates that only covid deaths fourteen days after the completed primary series are provided, we then requested the number of covid deaths that occurred after the first dose and within fourteen days of the second dose, but LDH was unable to provide that information. We also inquired how many individuals died of covid with unknown vaccination status but an unsatisfactory answer was provided. Why LDH is unable to provide these data is perplexing, and quite frankly unacceptable, given that it falls under mandatory reporting requirements.

In a separate PRR, we requested the VAERS ID numbers of any reports LDH had filed in connection with covid vaccines and received this response:

“The Louisiana Department of Health completed a diligent and thorough search of records maintained in the usual course of business, but found no records in the Department’s possession for the above-referenced request.”

It is statistically and scientifically impossible for there to NOT BE A SINGLE event warranting a VAERS report by LDH from the millions of vaccine doses administered in Louisiana.

In our own cursory search of VAERS on December 3, 2023, we quickly found three Louisiana reports of covid death following covid vaccination:¹⁰

⁹ <https://twitter.com/ladepthhealth/status/1664328153978773507?s=12&t=I2wQOoBVjmDQKEo882eV7g>

¹⁰ <https://vaers.hhs.gov/>

Messages:

- ▶ VAERS data in CDC WONDER are updated every month. Hence, results for the same query can change from month to month.
- ▶ These results are for 3 total events.
- ▶ When grouped by VAERS ID, results initially don't show Events Reported, Percent, or totals. Use Quick or More Options to restore them, if you wish.
- ▶ Click on a VAERS ID to see a report containing detailed information for the event.
- ▶ Rows with zero Events Reported are hidden. Use Quick Options above to show zero rows.

Some measures are hidden, use Quick or More Options above to restore them.

Vaccine Type ↓	Symptoms	VAERS ID	Adverse Event Description ↑↓
COVID19 VACCINE (COVID19)	COVID-19	1024627-1	covid shot 2/2; feel bad 2/5; covid positive diagnosis - 2/8 s/s cough, fever, shortness of breath , hypertension, afib (in er) - admitted went into DIC per intensivist 2/11 patient died
		1114822-1	Diagnosed with COVID (confirmed with a positive COVID test) the day after her vaccine. Eventually died from complications of COVID. Because vaccine was administered prior to her illness, I am putting this in the VAERS system. Symptoms included SOB, coughing, muscle aches. headache, fever.
		2567595-1	Patient had breakthrough infection and passed away.

Note: Submitting a report to VAERS does not mean that healthcare personnel or the vaccine caused or contributed to the adverse event (possible side effect).

Again, the terms of the EUA stipulate that vaccine providers “must report” serious adverse events “of which they become aware.”¹¹ Because covid vaccines were administered in an unconventional (we would argue unethical) manner via drive-through clinics, pop-up clinics, etc., the original covid vaccine provider in these situations would, in most instances, never learn of serious adverse events following vaccination, leaving a significant gap in the reporting process when the individual dies. A serious issue with a passive reporting system like VAERS is, according to one Louisiana coroner, “The deceased do not report.” As the holder of the information pertinent to reporting, LDH is obligated to complete the VAERS process when “they become aware.”¹² Additionally, LDH is mandated to report these findings *irrespective of attribution to vaccination*, meaning LDH is not required or permitted to determine if the two events, covid vaccination and subsequent covid death, are correlated.

We write this as a formal notice of LDH’s obligation as a vaccine provider to report serious adverse events to VAERS following covid vaccination, which includes individuals who died of covid following covid vaccination.

We request that VAERS reports be filed by LDH for the 3,091 Louisianans identified in the PRR who died of covid following a covid vaccine, as stipulated by the vaccine manufacturers, the FDA, and the CDC.

We also request that LDH conduct a search of records to determine if any individuals died of covid in the days before the primary series is considered completed (after the first shot and within 14 days of the second) and, if any are found, that a VAERS report is filed for those individuals as well. As required by the terms of the EUA, LDH should continue to file a VAERS report for EVERY covid-vaccinated person who dies of covid. This means that *at a minimum* LDH needs to submit 3,091 VAERS reports to account for the 3,091 covid deaths following covid vaccination, as mandated by the vaccine manufacturers, FDA, and CDC.

Additionally, more and more research^{13,14,15} has demonstrated negative efficacy associated with covid vaccination, meaning that covid vaccination is actually *increasing* an individual's likelihood of contracting covid. **We request, as a matter of responsible and ethical public policy and informed consent, that LDH send out a Health Alert Network Advisory to all vaccine providers to notify them of this risk as well as issue public messages to inform all Louisianans, especially those who have received one or more covid vaccines, as is required under**

¹¹ <https://www.fda.gov/media/150386/download>

¹² <https://www.fda.gov/media/150386/download> pg. 32

¹³ <https://www.mdpi.com/2076-393X/11/8/1325>

¹⁴ <https://link.springer.com/article/10.1007/s40121-023-00863-5>

¹⁵ <https://www.medrxiv.org/content/10.1101/2023.09.29.23296354v1.full.pdf>

the federal law governing EUA's, 21 US CODE 360bbb-3(c)(1)(A)(ii)(II),¹⁶ which states patients are to be informed:

“(II) of the significant known and potential benefits and risks of such use, and of the extent to which such benefits and risks are unknown.”

Lastly, continuing to tell Louisianans that a covid vaccine will “protect them and their loved ones” is blatantly false. In addition to the studies referenced above, the data provided in our public records request is evidence that cannot be ignored especially while vaccine manufacturers, the FDA, and the CDC *require* that it be reported in an effort to fill the known data gaps which were acknowledged when the vaccines were released.

Refusing to provide this information to the appropriate agencies through the established reporting system, VAERS, while continuing to make exaggerated claims about efficacy to the public constitutes malfeasance.

We request an acknowledgment of this letter and a response to our requests.

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

Cc: Governor John Bel Edwards, Tina.Vanichchagorn@la.gov
Governor-elect Jeff Landry, LandryJ@ag.louisiana.gov
Attorney General-elect Liz Murrill, MurrillE@ag.louisiana.gov
Joseph Kantor, MD, Public Health Officer, Joseph.Kanter@la.gov
Current and newly elected members of the Louisiana Legislature

¹⁶

<https://uscode.house.gov/view.xhtml?hl=false&edition=prelim&req=granuleid%3AUSC-prelim-title21-section360bbb-3&num=0&saved=%7CZ3JhbnVsZWlkOIVTQy1wcmVsaW0tdGl0bGUyMS1zZWN0aW9uMzYwYmJlLTNh%7C%7C%7C0%7Cfalse%7Cprelim>