TEXAS RIGHT TO KNOW
More Unites Us Than Divides Us

Request: Change the language of "COVID-19 Vaccine" to "Pandemic Disease treatment or medical procedure", since language specific to COVID-19 will make any legislative protections obsolete for the "next pandemic."

I am Sheila Hemphill with www.TexasRightToKnow.com and I work with national and international physicians, researchers. and attorneys regarding the COVID-19 pandemic for the past 3 years and I am not an attorney.

Much of the legislative health protections we rely on, i.e. FDA product safety requirements, labeling requirements, informed consent approvals, etc., become null under the declaration of a "Public Health Emergency of International Concern" as outlined on pg. 9 of The American Domestic Bioterrorism Program (ADBP) by Katherine Watt. This ADBP report is a forensic review of decades of public health federal laws and outlines the following changes in Federal statute and makes actions that we have known to be "illegal" become "legal" under emergency declarations. These statute changes below are under an emergency declaration and were applied during the COVID-19 pandemic and would apply to any current or future declared pandemic disease.

1. The use of the EUA products marketed as Covid-19 vaccines "shall not be considered to constitute a clinical investigation," and **the products are exempt from laws regulating use of investigational, experimental drugs or devices on human beings.** Federal Food Drug and Cosmetics Act, 21 USC 360bbb3(k). 1997, 2004, 2005, 2013. (See Excerpts from Pfizer's Motion to Dismiss on pg. 2)

2. There are **no required standards for product safety**, and **only one standard for efficacy**: **a declaration by the HHS Secretary that a product "may be effective."** Federal Food Drug and Cosmetics Act, 21 USC 360bbb-3(c)(2)(A). 1997, 2004.

3. **There are no informed consent duties** for those who administer the products (to provide risk and benefit information and obtain consent) or rights for those who receive the products (to receive risk and benefit information and give consent). 21 USC 355(i)(4), for drugs, and 21 USC 360j(g)(3), for devices. 2016.

4. There are **no labeling requirements** regarding the contents or ingredients in the products marketed as Covid-19 vaccines.

5. There is **no consumer fraud** because the only legal party to the financial transactions is the government's Department of Defense as buyer of the COVID-19 vaccine as a medical countermeasure or "prototype" for $19.50 / dose.

REQUEST: As seen in the Public Health Emergency Preparedness and Management bill and in Text 21 USC 360bbb-3 – Authorization for Medical Products for Use in Emergencies language contained in these statutes refers to "medical products for use in Emergencies" rather than the specific term of vaccines.

And since COVID-19 disease is just one of potentially many other declared emergencies i.e. Monkey Pox, Marburg, Ebola etc., and a vaccine is just one of potentially many more Emergency Use Authorization (EUA) products we could be subjected to such as a microchip or implant medical procedure.

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I. THE FEDERAL LAWS WHICH PROHIBIT OVERSIGHT OF HHS SECRETARY UNILATERAL PANDEMIC DECISIONS:

1. 42 USC 247d-6d(b)(7): "No court of the United States, or of any State, shall have subject matter jurisdiction to review, whether by mandamus or otherwise, any action by the Secretary under this subsection."

2. 42 USC 247d-6d(b)(8): Authority of state, local and tribal governments and individuals to manage public health emergency and medical countermeasures classification and regulation outside of HHS/DOD control is preempted.

3. 42 USC 247d-6d(b)(9): There is an extremely limited obligation for HHS to report to Congress on public health emergency status and medical countermeasures classifications, and **no authorization for Congress to override HHS declarations, determination, and decisions**.

II. WHAT WE NOW KNOW ABOUT THE PFIZER "VACCINE" agreement with the Department of Defense:

The following are excerpts In the Pfizer's 04-22-2022 Motion to Dismiss (MtD) in the whistleblower case of Brook Jackson vs Ventavia. The following statements from Pfizer' MtD clearly show that under the **Other Transaction Authority (OTA)** agreement framework with the Department of Defense, the **agreements are "not subject to Federal Acquisition Regulation", nor subject to Good Clinical Practices or FDA regulations.** Nothing about the deployment of the COVID-19 "vaccine" was a normal new drug delivery as believed and as the evidence shows.

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Ex. 10 at 1079.) Such agreements are executed under DoD's Other Transaction Authority ("OTA") and, as a statutory matter, are not subject to the Federal Acquisition Regulation ("FAR"), which is the primary regulation otherwise used by Government agencies in their acquisition of supplies and services with appropriated funds. *See* 10 U.S.C. § 4022(f)(2); *see also NSTI, LLC v.*

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Compl. ¶ 135.) The SOW describes a "large scale vaccine manufacturing demonstration" that imposes no requirements relating to Good Clinical Practices ("GCP") or related FDA regulations. (Am. Compl., Ex. 10 at 1080.) It states explicitly that Pfizer's "clinical trials" are "out-of-scope," "not related" to the agreement, and that the relevant studies were undertaken at Pfizer's expense

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[24] Again, the "agreement" at issue, Pfizer's OTA agreement with DoD, specifies the number of doses the Government would buy and the price the Government would pay, but does not impose any requirements relating to Pfizer's clinical development activities, FDA regulations, or FAR. And, regardless, the Government paid the resulting invoices with actual knowledge of Relator's allegations concerning regulatory noncompliance.