COMMONWEALTH OF VIRGINIA

HOUSE OF DELEGATES
RICHMOND

DAVE LaROCK
POST OFFICE BOX 6
HAMILTON, VIRGINIA 20159

THIRTY-THIRD DISTRICT

COMMITTEE ASSIGNMENTS:

COUNTIES, CITIES, AND TOWNS
COMMUNICATIONS, TECHNOLOGY AND INNOVATION

September 7, 2021

The Honorable Ralph S. Northam
Governor of Virginia
Patrick Henry Building
1111 East Broad Street, 3rd Floor
Richmond, VA 23219

Governor Northam:
After more than a month, I have not received answers to the questions I posed in my August 5th request sent to you. I write today with further inquiry based on recent events. Here are some questions; further background information is below, if needed:

- Is the Comirnaty shot available in the Commonwealth of Virginia, and if so where? If not, when do you expect it will be available?
- Under what authority are you requiring an EUA product for all Executive Branch employees, when the EUA statute requires that recipients "…have the option to accept or refuse the EUA product…."?
- For those who refuse the EUA product, what testing will be required? Particularly, after December 31, 2021, when CDC will withdraw the request to the U.S. Food and Drug Administration (FDA) for Emergency Use Authorization (EUA) of the CDC 2019-Novel Coronavirus (2019-nCoV) Real-Time RT-PCR Diagnostic Panel?

On August 23rd, the FDA issued a couple of decisions that are causing significant confusion in the media as well as in the general public.

First, my understanding is that the Comirnaty shot which was approved by the FDA is not available to the public in the United States, and if, or when, it is available, it is only approved for ages 16 and up, presumably due to the fact that "…observed risk [of myocarditis and pericarditis] is highest in males 12 through 17 years of age".

Secondly, the FDA announcement includes hints that the heart issues and pregnancy-related issues are still a concern with the Comirnaty product and the identical Pfizer-BioNTech COVID-19 product. Here is some of the information, which can be found at https://www.fda.gov/news-events/press-announcements/fda-approves-first-covid-19-vaccine

> *"Additionally, the FDA conducted a rigorous evaluation of the post-authorization safety surveillance data pertaining to myocarditis and pericarditis following administration of the Pfizer-BioNTech COVID-19 vaccine, and has determined that the data demonstrate increased risks, particularly within the seven days following the second dose. The observed risk is higher among males under 40 years of age compared to females and older males. The observed risk is highest in males 12 through 17 years of age. Available data from short-term follow-up suggest that most individuals have had resolution of symptoms. However, some individuals required intensive care support. Information is not yet available about potential long-term health outcomes. The Comirnaty prescribing Information includes a warning about these risks.*

Ongoing Safety Monitoring

The FDA and Centers for Disease Control and Prevention have monitoring systems in place to ensure that any safety concerns continue to be identified and evaluated in a timely manner. In addition, the FDA is requiring the company to conduct postmarketing studies to further assess the risks of myocarditis and pericarditis following vaccination with Comirnaty. These studies will include an evaluation of long-term outcomes among individuals who develop myocarditis following vaccination with Comirnaty. In addition, although not FDA requirements, the company has committed to additional post-marketing safety studies, including conducting a pregnancy registry study to evaluate pregnancy and infant outcomes after receipt of Comirnaty during pregnancy."

So, the FDA admits they have serious concerns about Comirnaty/ Pfizer-BioNTech causing cardiac issues in men under age 40, as well as pregnancy and infant issues (See OpenVAERS here for counts of miscarriage, etc.)

Just to reiterate, the fact is that none of the COVID-19 shots currently available in the United States, or even the PCR tests, are fully FDA-approved, rather they're all still experimental products under EUA and, according to the EUA statute, must be completely voluntary with full informed consent.

Again, please provide legal justification of your August 5, 2021, mandate of an EUA product for all Executive Branch employees, as there is still no FDA-approved vaccine available to the public in the Commonwealth.

Sincerely,