HEALTH FREEDOM LOUISIANA

HealthFreedomLA.org

March 20, 2020

To: President Donald Trump
Secretary Alex Azar, Health and Human Services
Governor John Bel Edwards
Interim Secretary Stephen Russo, Louisiana Department of Health
Senator Bill Cassidy, Senator John Kennedy
Congressmen Ralph Abraham, Garret Graves, Clay Higgins, Mike Johnson, Cedric Richmond, and Steve Scalise

Re: COVID-19 vaccine testing

Many citizens and scientists are voicing their concerns over the way COVID-19 vaccine testing is being rushed. Of particular concern is:

- the absence of completed animal studies, which are necessary to assess product efficacy and safety before being given to humans for the first time, and
- no inert placebo control group in the very first human trial of the vaccine compound (NCT04283461), making its safety profile undeterminable without knowing the baseline rate of adverse medical events in a placebo group.

The COVID-19 virus is in a family of viruses for which vaccine development has proven very dangerous, as animals receiving experimental SARS vaccines were not protected but instead predisposed to more severe disease when challenged with the wild virus [ref]. While we understand the urgency behind the push for rapid development of a COVID-19 vaccine, skipping animal testing may endanger the trial participants who are recruited from the area where the virus is circulating, as well as the general population, if the vaccine is fast-tracked.

> "The concern that is extrapolated from the FIPV vaccine experience to human SARS-CoV vaccines is whether vaccine recipients will develop more severe disease if they are exposed to or infected with SARS-CoV after neutralizing antibody titers decline. The second concern is whether recipients of a SARSCoV vaccine would be at risk of developing pulmonary immunopathology following infection with an unrelated human coronavirus e.g. 229E, OC43, HKU1 or NL63 that usually causes mild, self limited disease. Although findings from preclinical evaluation have revealed these concerns, studies in animal models may not be able to provide data to confirm or allay these concerns."
>
> ***Animal models for SARS and MERS coronaviruses***
> https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4550498

Please reconsider the rapid-pace of development, complete needed animal trials, require inert-placebo control groups before licensing, and proceed with caution. Public trust in vaccine products is at an all-time low. Failure to ensure the trials on any COVID-19 vaccine product are conducted ethically and thoroughly will further erode trust.

Bernard D. Goldstein, Professor Emeritus with the University of Pittsburgh Graduate School of Public Health, Pittsburgh, PA. wrote:

> "We in public health must recognize that the precautionary principle applies to our own actions, that when a public health action is proposed, the burden of proof—to ensure that all risks and consequences are taken into account—rests on us just as surely as it rests on others."
>
> ***The Precautionary Principle Also Applies to Public Health Actions***
> https://www.ncbi.nlm.nih.gov/pmc/articles/PMC1446778/

Pandemics of novel pathogens require immediate focus on prophylactic and treatment therapeutics to protect as many as possible from infection and to minimize loss of life. Recovery protocols, such as Vitamin C infusions and chloroquine, are saving lives worldwide; plasma convalescent therapy must begin as soon as available. Links to studies on known options can be found in Dr. Lyons-Weiler's article cited below. There is growing concern that social-distancing alone is not enough. China utilized both distancing and therapeutics and have brought their cases under control in a remarkably short period of time. Without therapeutic interventions, the outbreak could go on for many months.

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

Excerpts from the SARS-CoV animal studies:

Immunization with inactivated Middle East Respiratory Syndrome coronavirus vaccine leads to lung immunopathology on challenge with live virus. "Lung mononuclear infiltrates occurred in all groups after virus challenge but with increased infiltrates that contained eosinophils and increases in the eosinophil promoting IL-5 and IL-13 cytokines only in the vaccine groups. Inactivated MERS-CoV vaccine appears to carry a hypersensitive-type lung pathology risk from MERS-CoV infection that is similar to that found with inactivated SARS-CoV vaccines from SARS-CoV infection."
https://www.ncbi.nlm.nih.gov/pubmed/27269431

Vaccine efficacy in senescent mice challenged with recombinant SARS-CoV bearing epidemic and zoonotic spike variants."VRP-N vaccines not only failed to protect from homologous or heterologous challenge, but resulted in enhanced immunopathology with eosinophilic infiltrates within the lungs of SARS-CoV-challenged mice. VRP-N-induced pathology presented at day 4, peaked around day 7, and persisted through day 14, and was likely mediated by cellular immune responses." https://www.ncbi.nlm.nih.gov/pubmed/17194199

Immunization with Modified Vaccinia Virus Ankara-Based Recombinant Vaccine against Severe Acute Respiratory Syndrome Is Associated with Enhanced Hepatitis in Ferrets "Immunized ferrets developed a more rapid and vigorous neutralizing antibody response than control animals after challenge with SARS-CoV; however, they also exhibited strong inflammatory responses in liver tissue."
https://jvi.asm.org/content/78/22/12672.abstract

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