

Exhibit 110

Texas Senate Health and Human Services Committee

Prepared Testimony and Remarks, Pandemic Response

Dr. Robert Malone, MD, MS

President, International Alliance of Physicians and Medical Scientists

Chief Medical and Regulatory Officer, The Unity Project

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<https://rwmalonemd.substack.com/p/testimony-and-remarks-pandemic-response>

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Chair Kolkhorst and Members:

I. Introduction: Your name, title, org, and a brief summary of your background and your work with mRNA and DNA vaccines

My name is Robert Wallace Malone. I am a physician licensed in Maryland and a graduate of University of California Davis, UC San Diego and University of Maryland School of Medicine. I have attached my biography and CV to save a bit of time. I've spent my career working in the field of medicine and vaccine technology. I was an original inventor of core mRNA and DNA vaccination technology (1989), and am a specialist in clinical research, medical affairs, regulatory affairs, project management, proposal management (large grants and contracts), vaccines and biodefense.

This includes writing, developing, reviewing and managing vaccine, bio-threat and biologics clinical trials and clinical development strategies.

I'm here today to talk about policies related to vaccines and early treatment for SARS-CoV-2 throughout the various surges and my thoughts and recommendations for future public health events.

II. Explain the origin of the policies related to vaccines and early treatment (high-level overview) for COVID throughout the various surges.

I have been deeply involved in multiple prior outbreak responses including AIDS, the Post Anthrax/Smallpox scare, Pandemic Influenza, Ebola, Zika, and now SARS-CoV-2.

Prior to SARS-CoV-2, the teaching and practice in governmental response has been that the federal Centers for Disease Control and Prevention (CDC) advises state public health authorities, who have the authority and responsibility (based on U.S. Constitution) to manage their own public health policies and regulate the practice of medicine.

During prior outbreaks, CDC served as a reliable source of impartial, up to date and accurate public health data for physicians, state and local public health officers.

In my professional experience, during all prior outbreaks and vaccine development programs, risks and benefits have always been evaluated and stratified by risk group, and public health recommendations have been tailored to account for differences in risk/benefit ratios (often adjusted based on actuarial “quality adjusted life year” calculus).

This approach has not been implemented during the COVID crisis. During the SARS-CoV-2/COVID-19 outbreak, new policies and practices have been implemented.

The NIH (and particularly) NIAID have developed and propagated treatment protocols throughout the United States. These protocols have been developed in a non-transparent manner without hearings or significant public comment or independent practicing physician input, apparently largely under the strong influence and oversight of a small number of government officials (predominantly Dr. Anthony Fauci and his former trainee Dr. Deborah Birx).

Development of vaccine products has been accelerated and historic non-clinical, clinical development and regulatory practices have been discarded in a quest for speed under specific pressure from the executive branch.

Development of repurposed drugs and treatment strategies have paradoxically been aggressively blocked or inhibited by both NIH and FDA, apparently due to requirements in the federal Emergency Use Authorization statute language requiring lack of available alternatives as a predicate to granting EUA to a new (vaccine) product.

The CDC has played a more supportive role to NIH, in contrast to prior where NIH/NIAID has focused on clinical research and early product development, and CDC focused on public health policy.

CDC has become politicized, particularly during the current administration, and has actively withheld information which has been deemed as posing risk for exacerbating “vaccine hesitancy”.

During the current outbreak, CDC has not fulfilled its traditional role as a neutral collector, arbiter and reporter of public health data. CDC has, under

FOIA, admitted to failing to perform obligated monitoring, analysis and reporting of VAERS and related vaccine safety data. As a consequence, neither patients, physicians, nor public health officials have been able to access up-to-date information concerning vaccine effectiveness and safety. This has compromised the informed consent process.

CDC has actively promoted and marketed vaccination with unlicensed (emergency use authorized) products, with over \$1 Billion USD in federal funding expended to both market the products and to censor those who have raised concerns regarding vaccine safety and effectiveness

FDA, NIH, and CDC (together with WHO) have cooperated to actively restrict, demean, and deprecate use of multiple currently available licensed drugs for treatment of COVID-19 by licensed practicing physicians, and have facilitated retaliation against physicians who do not follow the treatment guidelines established and promoted by the NIH – which has neither mandate nor significant prior experience in developing and implementing universal treatment guidance and protocols, and which has done so in a unilateral manner without seeking meaningful input from practicing physicians.

NIH leadership have acted to restrict and retaliate against highly qualified, independent physicians and medical scientists who have questioned federal management policies, most notably in the case of the Great Barrington Declaration and the primary authors of that document.

On a national basis, without respect for state boundaries or coordination with state governments, NIH and CDC have actively engaged with and directly paid corporate media and technology/social media companies to promote federal positions and policies, and to censor any discussions of policies, risks, adverse events, or treatment options other than those which they have endorsed.

There is evidence, in the case of the State of Florida and Governor Ron Desantis, that the Federal Government has intentionally withheld monoclonal antibody therapeutics as political retaliation for COVID crisis management policies implemented by the State of Florida, which are not aligned with Federal Government policies and mandates.

III. Describe the effects of vaccines and re-infection rates in US population.

I would also like to comment on the efficacy of vaccines and re-infection rates in US population.

Vaccine efficacy is a term describing an outcome from a selected clinical trial population involving a test of the ability of a vaccine to achieve an endpoint.

Typical efficacy endpoints include:

- Prevention of infection;
- Prevention of disease or death associated with a pathogen;
- Prevention of infection spread to others; and
- Prevention of death or hospitalization (from any cause).

Vaccine effectiveness is a term describing an outcome in the general population that have been administered the vaccine involving an endpoint.

Effectiveness typically measures similar endpoints as efficacy, but in the general vaccinated population. Because of a variety of things including differences between general populations and those selected for clinical trials, *measured effectiveness in the field is almost always significantly lower than efficacy measured in a prospective clinical trial.*

Infection by a pathogen typically confers equal or superior protective effectiveness relative to a vaccine. Some vaccines employ “live attenuated” pathogens (example: yellow fever virus) and these are often associated with high levels of effectiveness similar to infection by the pathogen (ergo natural infection).

In some cases (ex: Dengue hemorrhagic fever), a vaccination approach may achieve a protection which infection by the pathogen cannot provide. Infection by a pathogen typically involves disease risk which may be substantial, which is why vaccines have been developed.

Vaccines may include ingredients (adjuvants for example) which may have risks which are not present during “natural infection” with the pathogen. In some cases, vaccine/adjuvant system risks are short term (swelling, fainting, fever, pain, redness), and other cases longer term (neurological symptoms including paralysis, autoimmune diseases). In some cases, vaccines (or infections) can cause immune imprinting (“Original antigenic sin”) which is a form of bias in the immune response caused by first encountering one form of the vaccine (or pathogen) which makes it difficult for the immune system to properly recognize a different (or mutated) form. This seems to be a major

reason why the SARS-CoV-2 vaccines are not providing strong, long lasting protection against the Omicron variants.

“Immunity” is a subjective term. What one person defines as immunity may be different from another. “Sterilizing immunity” is when a vaccine or infection completely prevents infection and replication by a pathogen. This is rarely if ever achievable. Virtually any “immunity” can be overwhelmed by a sufficiently large “challenge” of the pathogen. “Immunity” may involve protection from disease, or may involve protection from infecting others even if you are exposed to a pathogen and have some sickness.

During the COVID crisis, the use of the terms “immunity” and “effectiveness” have been applied creatively by NIH and CDC leadership. First to refer to prevention of infection, replication and spread. Then, as those endpoints were not being met, to prevention from hospitalization and death. Then, as those endpoints were only partially achievable, to a relative reduction in hospitalization and death (currently between 30-60% of fully vaccinated persons in high-risk categories are still at high risk of hospitalization and death).

“Durability” of immunity (how long does it last) is also subjective. As you can appreciate from the above, you really have to define vaccine durability in terms of the effectiveness of the product to prevent some outcome like infection, disease, hospitalization or death. In general, the durability of protection from disease, hospitalization or death from “natural infection” appears to be equal to or considerably greater than that provided by currently available SARS-CoV-2 vaccines, which is why frequent re-administration of these EUA products is required.

The high reinfection rates currently observed with Omicron appears to be the consequence of three key factors:

1. Evolution of viral antibody escape mutants, particularly involving alterations in the Spike S1 protein subunit, and in particular in the receptor binding domain region, which are able to evade antibody binding by either therapeutic monoclonal antibodies or naturally occurring antibodies – particularly those elicited by the original Wuhan version of S1 (which is present in the vaccines).

- The ability of the virus to evolve to escape T cell responses seems more limited, particularly in the case of natural infection which provokes a broader T cell response.
- Administration of “leaky” vaccines largely unable to block infection, replication and spread of the virus may contribute to this evolution.
- There is evidence that infection of individuals who are immunologically impaired or compromised (those with immunodeficiencies) may often lead to chronic infection, and these individuals may have a disproportionately large impact on development of escape mutants.

2. Multiple, high-profile peer-reviewed papers indicate that “immune imprinting” by prior infection or vaccination, which may be further exacerbated by infection followed by vaccination, followed by infection by Omicron appears to be yielding a paradoxical reduction in neutralizing antibody, SARS-CoV-2 antigen-specific memory B cells, and SARS-CoV-2 antigen-specific T-cell populations.

3. Up to 30% of individuals who are infected by Omicron after vaccination (with or without prior infection by an earlier strain) are not well protected from hospitalization and death, and appear to develop a reduced immunity which can enable frequent and rapid re-infection or chronic infection.

- As with the immunosuppressed, these individuals may disproportionately contribute to further development of more infectious and/or pathogenic viral escape mutants.

IV. What can Texas do in the future to ensure the state has its own data-driven model that provides a counter balance to federal directives?

It is my professional opinion that in the case of the COVID crisis, we have seen an unprecedented weaponization of public health policies to advance political and economic agendas which are not directly related to public health.

The State of Texas must implement independent state-based public health monitoring and analysis of infectious disease risks and outcomes, as the CDC is no longer providing the reliable, transparent and comprehensive data necessary for Texas physicians, public health officials, and patients to make treatment and management decisions based on complete and accurate data.

It is also my opinion that the federal government has incrementally usurped the constitutional rights of states to regulate health care and the practice of

medicine, and that this has been accomplished using a variety of coercive tactics.

These tactics have included but have not been restricted to just perverse financial incentives leading to over-reporting COVID morbidity and mortality. Coercive, arbitrary and capricious federal tactics have included incentives and mandates for inappropriate use of experimental emergency use authorized pharmaceuticals.

As with other aspects and activities of the federal bureaucracy, such as education, agriculture, and transportation, states' rights to regulate health care and practice of medicine have been usurped through threats of withholding federal tax dollars and programmatic funding in the event of non-compliance with federal guidance and mandates.

It is my opinion as a specialist in regulatory affairs that the rights of the FDA to regulate pharmaceuticals arises from the federal rights to regulate interstate commerce. It is my opinion that these rights do not extend to practices such as pharmaceutical compounding in which the commerce is restricted to within state boundaries.

It is my opinion that states such as Texas have the constitutional right to regulate their own food, medical and health industrial practices, and therefore an opportunity to foster both innovation and economic development through establishment of a state-based regulatory authority to oversee and direct those activities for which the federal FDA provides oversight in the context of interstate commerce.

It is my opinion that outsourcing biological and drug manufacturing and development to non-U.S. providers, typically based in China and India, represents both a threat to national security as well as a threat to the health and safety of the people of Texas. I believe that there is both a pressing unmet need for domestic biological and drug manufacturing, an obligation of the State of Texas to protect the health of its citizens by addressing this unmet need, and a business and economic development opportunity for the citizens of the state to work with the government of the State of Texas to expeditiously address this problem.

In sum, during the COVID crisis, I believe that we have seen an unprecedented encroachment of the U.S. Federal Government into the practice of medicine, the circumventing of both bioethical and regulatory norms that have been developed over decades, and heavy handed and politicized federal implementation of a wide range of interventions in our communities, businesses, churches, schools, government, monetary policy and general commerce. In retrospect, it is difficult to interpret these actions as representing rational responses to the true public health threat of COVID. The U.S. Department of Health and Human Services, which should serve to protect the health of all citizens, has been politicized and weaponized for advancement of political objectives. Going forward from this point, responsible stewardship and protection of Texans' public health will require courageous political and individual leadership coupled with a willingness to enable development of state-based innovative, entrepreneurial solutions to both the current and future public health needs of the citizens of the State of Texas.

Thank you, and I'm happy to answer any questions.