

## **Text of the**

### **Prepared Testimony and Remarks, Pandemic Response**

#### **The Senate of the Republic, Mexico, LXV Legislatura**

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**Senator Rafael Espino thank you so much for the invitation to participate in this important conference.**

**Dear Senate Members and Attendees:**

My name is Robert Wallace Malone. I am a US-trained physician licensed to practice Medicine and Surgery in Maryland, USA and a graduate of University of California Davis, University of California San Diego, Northwestern University Medical School and Harvard Medical School. I have previously served as Assistant and Associate Professor of Pathology and Surgery at UC Davis, University of Maryland, and the Uniformed Services University of the Health Sciences. I have attached my biography and CV for

your review and consideration to save 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), hold nine US issued patents in that area, and am a specialist in molecular virology, immunology, clinical research, medical affairs, regulatory affairs, project management, proposal management (large grants and contracts), vaccines and biodefense.

I have traveled to Mexico City to speak to you today at the kind invitation of Dr. Alejandro Diaz Villalobos, who has provided his Keynote Speech regarding “**Pandemic and Vaccines, Lessons Learned**”, which has been followed by comments from my dear respected colleague Steve Kirsch.

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. This expertise and experience includes writing, developing, reviewing and managing vaccine, bio-threat and biologics clinical trials and clinical development strategies. I have worked for Academia, the US Government (DoD and HHS), Solvay Pharmaceuticals, Bill and Melinda Gates-funded vaccine developers, Regulatory and Clinical Contract Research Organizations, and a wide variety of other small and large biopharmaceutical companies.

My credentials have been investigated and verified by the US Department of Defense, and I have been granted “Secret” security clearance. I do not currently work for nor do I represent the US Government in any way, and my opinions and remarks here are my own.

I'm here to share my perspective regarding policies related to public health, vaccines and early treatment for SARS-CoV-2 throughout the various surges, and my thoughts and recommendations for future public health events. My remarks will focus on the United States' COVID response, but will also cover some international aspects.

## **COVID Pandemic, Drugs and Vaccines, Lessons Learned (Part II)**

Prior to SARS-CoV-2, the teaching and practice in US governmental response to infectious disease outbreaks 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 the U.S. Constitution) to manage their own public health policies and regulate the practice of medicine.

During prior outbreaks, the US CDC served as a reliable source of impartial, up to date and accurate public health data for physicians, state and local public health officers, and in some cases to PAHO and the WHO.

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 which have circumvented or eliminated well-established pharmaceutical, regulatory and clinical development norms including established FDA, EMA, and ICH (International Council for Harmonisation) guidance. Furthermore, there has been an intentional and systematic failure to comply with established bioethical norms, including the 1947 Nuremberg Code, Geneva Convention, the 1964 Declaration of Helsinki, the US Belmont Report, and the US “Common Rule”.

The willful disregarding of these fundamental, globally accepted bioethical norms has been justified on the basis of the presumed extreme threat to global health posed by a laboratory-engineered coronavirus which apparently was transmitted into the general population of Wuhan, China sometime in 2019.

This virus, subsequently named SARS-CoV-2, then rapidly circumnavigated the world, and was associated with moderate levels of disease and death, with markedly lower risk than the historic risk of the 1918 H1N1 “Spanish Flu” outbreak. Current best evidence, including consensus from both US FBI and the US Department of Energy, indicates that

SARS-CoV-2 is in fact a laboratory engineered pathogen. The current leading hypothesis concerning the entry of this pathogen into the human population is that the engineered SARS-CoV-2 virus was released into the civilian population of Wuhan, China consequent to an unspecified laboratory containment accident, but other credible theories remain under consideration.

Information supporting this claim obtained from US Government sources indicate that the biological engineering of this pathogen was performed in part in the Peoples Republic of China, Wuhan Institute of Virology, Chinese Academy of Sciences (WIV), which received at least partial funding for this developmental work from the US National Institutes of Health and the Threat Mitigation branch of the US Defense Threat Reduction Agency, DoD (DTRA). This work involved scientific and technical collaboration with the Eco Health Alliance, a US-based research and development company. This collaboration included significant technology and reagent transfer from Eco Health Alliance to the WIV.

I first learned of the “2019 novel coronavirus” when I received a warning phone call from a Physician-CIA officer-infectious disease specialist on January 04, 2020. He requested that I work to assemble a civilian scientific response team to support US government-funded medical countermeasure research, much as I have for prior outbreaks. As usual, I prepared a threat assessment based on January 2020-available information, which was heavily biased by propaganda originating in China indicating that this novel virus was highly lethal. In retrospect, this propaganda overstated the true threat, and appears to have been designed to elicit fear and overreactions by non-PRC nations. My assessment was that the development of safe and effective novel drugs and vaccines for this coronavirus (since named SARS-CoV-2) would take considerable time, and that initial pharmaceutical and biological research and development should focus on repurposing existing drugs for early treatment of the disease caused by this novel coronavirus. I gathered a group of experts which began working on a voluntary basis to identify repurposed drugs for treating the disease, but were eventually funded by the US Department of Defense.

Parallel to our activities, the NIH (and particularly) NIAID developed and propagated treatment protocols throughout the United States, relying primarily on hospital-based mechanical ventilation to support those with inadequate blood oxygenation in combination with the toxic intravenously-administered drug Remdesivir. These protocols have been developed in a non-transparent manner without hearings, 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 employing gene therapy technology platforms (recombinant adenovirus, pseudo-mRNA non-viral delivery) were specifically and exclusively accelerated by the US Government, and historic non-clinical, clinical development and regulatory practices were discarded in a quest for speed under specific pressure from the executive branch under a program named “Operation Warp Speed”. This was performed under the justification that SARS-CoV-2 represented a major public health and national security threat.

Development of repurposed drugs and treatment strategies (such as Hydroxychloroquine, and Ivermectin) were initially accelerated, and then paradoxically aggressively blocked or inhibited by NIH, BARDA and FDA leadership, 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 blocking of “early treatment” and/or “drug repurposing” as well as advocacy for genetic vaccines which were presumed (without adequate testing) to be “safe and effective” was supported by an aggressive, harmonized global censorship and propaganda campaign, with significant funding (~US \$10 Billion) provided by the US Government. Concurrent with the resulting WHO and US-backed global vaccination campaign, SARS-CoV-2 variants which are increasingly able to bypass vaccine-induced antibody responses have repeatedly and progressively emerged in the global population, consistent with “natural selection of the fittest” evolutionary pressure exerted by vaccine-induced antibody responses.

In addition to US and global suppression (notably except in Mexico) of the prompt use of known (often off-patent) drug therapies to treat the respiratory symptoms of COVID-19 disease, and the disproportionate emphasis on genetic vaccine development and deployment, a number of other counterproductive actions were taken in the name of public health. Most or all of these were modeled after measures implemented by the CCP in China. In many cases, these actions were previously not recommended by the WHO or national health authorities, but these policies were changed in response to the fear of COVID-19. These included arbitrary “lockdowns”, prevention of public assembly, mandated use of particle masks which were neither effective nor designed for preventing viral transmission, arbitrary six foot “social distancing” policies, school closure, alterations in normal medical procedures (diagnostic testing and evaluation, elective surgeries), travel restrictions, vaccine passports and tracking, and many other related procedures justified as advancing “public health” objectives but which were not supported by established scientific evidence.

Much of the national US and global response was managed by the National Security apparatus and Department of Defense of the United States, acting together with the Department of Homeland Security, and these activities included a massive propaganda, psychological operations and censorship program which acted as part of a globally harmonized program in coordination with the World Health Organization, GAVI, CEPI, CDC, EMA and the BBC-Managed Trusted News Initiative to restrict public access and counter any information different from the WHO-approved narrative regarding SARS-CoV-2, COVID, drug treatment protocols and vaccine safety and efficacy . Distribution of any information contradicting official WHO or CDC messaging was deemed mis- dis- or mal-information and defined as potential domestic terrorism. The US Government, and many separate US federal agencies, coordinated closely with WHO, large technology and social media companies to censor and control all information concerning virus, drugs, and vaccines.

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

As acknowledged by both NY Times and internal government studies, the US CDC has become politicized, particularly during the current administration, and has actively withheld relevant public health information which has been deemed as posing risk for exacerbating “vaccine hesitancy”.

During the current outbreak, the US 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 \$10 Billion USD in federal funding expended to both market the products and to censor those who have raised concerns regarding vaccine safety and effectiveness. This censorship, propaganda and psychological operations campaign was pre-planned (Bill and Melinda Gates Foundation and World Economic Foundation-funded Event 201) and remains active to the present day, ostensibly to mitigate the threat of vaccine skepticism reducing uptake and acceptance of unlicensed experimental (Emergency Use Authorized) medical products which have proven neither fully safe nor effective at stopping infection, replication, or spread of the SARS-CoV-2 virus.

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. 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 WHO and federal positions

and policies, and to censor any discussions of policies, risks, adverse events, or treatment options other than those which they have endorsed.

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.

There is evidence, in the case of the State of Florida and Governor Ron DeSantis, that the US Federal Government has intentionally withheld monoclonal antibody therapeutics as political retaliation for COVID crisis management policies implemented by the State of Florida which have not been aligned with Federal Government policies and mandates. Governor DeSantis and his Surgeon General Dr. Joe Ladipo, MD, PhD have also questioned the safety and effectiveness of the genetic SARS-CoV-2 (COVID-19) vaccines available in the United States.

In the case of the genetic vaccines (mRNA and recombinant adenovirus-vectored), the data are clear: These products do not provide clinically significant protection against infection, replication and spread of currently circulating SARS-CoV-2 viral variants. This has been clear since the advent of the Omicron-like viral variants. Due to the “leakiness” of these products (in terms of viral infection), there is no level of general population vaccine uptake which can achieve “herd immunity” in either Mexico or the world. Furthermore, Pfizer leadership has acknowledged that, at the time of widespread deployment into the global population, there were no data available demonstrating that the Pfizer mRNA vaccine product was effective in protecting against infection, or that it would be useful in achieving “herd immunity”.

Over the last year, the existence of the previously known immunologic risk of “vaccine imprinting” has been well documented as occurring with the genetic COVID vaccines by multiple large scientific research teams from all over the world. In part, this has phenomenon has been driven by the continued administration of vaccines designed using a single Spike antigen obtained from the historic “Wuhan-1” strain of SARS-CoV-2, which has long since been evolutionary out-competed by more modern vaccine-resistant viral variants. Concurrent with these scientific findings, data from the



Cleveland Clinic (USA) and databases from around the world have demonstrated that the more doses of these “genetic vaccines” administered to a patient, the more likely that patient will develop clinically significant (hospitalized COVID) – or even die. Vaccination does not prevent hospitalized disease or death, and current data indicated that repeated vaccination increases risk of hospitalized disease or death. Currently available “booster” vaccines appear to exacerbate the clinical damage associated with immune imprinting.

I will now turn to speak regarding the safety of these genetic “vaccine” products which, unlike more traditional licensed vaccines, do not prevent infection, replication, transmission to others, disease or death from the virus they are directed against. Despite the lack of adequate early safety testing during the pre-clinical and clinical development stages, the safety risks are also becoming much more clear.

Current best estimates of the incidence of clinically significant heart damage (myocarditis, pericarditis) in young males are approximately one case per two thousand vaccine doses administered, with additive cumulative risk for the multiply vaccinated. Some studies have indicated up to half of “vaccine” recipients have some degree of damage to the heart. The list of additional clinical risks associated with Spike-based genetic vaccines is quite long, including stroke, sudden death, pathologic clotting of the blood, and particularly worrisome is reproductive risks. These reproductive risks include alterations in menstruation, but according to one senior Pfizer executive involved in global mRNA vaccine strategies may include damage to the hypothalamic/pituitary/adrenal/gonadal axis (ergo the endocrine system). Additionally, there appear to be non-specific damages caused to the immune system of repeatedly dosed patients, as demonstrated by the documented risks of re-activation of a variety of latent DNA viruses (EBV, VZV (Shingles) for example) and emerging data suggesting elevated risks of certain cancers post-inoculation.

Virtually all of these risks appear associated with SARS-CoV-2 viral infection to some extent, but data suggests that they are more prevalent and severe in those dosed with the genetic vaccine products. US Government and other official and unofficial organizations have used propaganda and censorship to suppress public access to

information about these risks, resulting in a widespread failure to allow patients to understand vaccination risks (and limitations to benefits) and thereby prevention of informed consent by those accepting or being compelled to take these products.

Due to the rush to develop and deploy the genetic COVID vaccines, key pharmacologic properties of these products were not well characterized prior to global deployment, including the pharmacodistribution (where do they go in the body), pharmacokinetics (what the body does to the drug), and pharmacodynamics (what the drug does to the body). Among the many initially deficient studies and data include studies designed to determine how long the synthetic pseudo-mRNA remains in the body, where it goes in the body, how much protein antigen (“Spike”) does it cause a patient’s body to make, and how long that protein remains in the body.

Initial messaging and marketing materials provided to physicians, patients and the general public indicated that the synthetic pseudo-mRNA would degrade in the body within hours, and that adverse event risks were therefore short lived. It is now known that the synthetic pseudo-mRNA persists in the body for weeks to multiple months, and that the levels of Spike protein (SARS-CoV-2 Spike is a known toxin) produced by the genetic “vaccine” products are significantly higher and longer-lived in the body and blood relative to the levels produced by typical “natural infection” with the SARS-CoV-2 virus. It is also now known that the formulated pseudo-mRNA “lipid nanoplex” particles circulate throughout the body for an extended period, and may be secreted in breast milk of nursing mothers. Reproductive toxicology and genotoxicity (effects on the human genome) of the genetic vaccines including the synthetic pseudo-mRNA products currently remain poorly characterized, unclear and highly controversial.

As the US National Institutes of Health (NIH) so plainly put it, “Characterizing the relationship between the pharmacokinetics (PK, concentration vs. time) and pharmacodynamics (PD, effect vs. time) is an important tool in the discovery and development of new drugs in the pharmaceutical industry.” When it comes to developing responsible drug treatments it is extremely important that pharmaceutical companies and prescribers have accurate data as it pertains to dosage and PD effect. This essential data should be derived from the non-clinical and clinical studies

conducted prior to approval, informing the proper dose that is eventually delivered to patients. In the case of the genetic COVID vaccines, normal characterization of these key characteristics were bypassed in the rush to develop and then administer biological products which have proven neither safe nor effective to a global population in an effort to mitigate the impact of a laboratory engineered pathogen which has proven to cause disease symptoms which can largely be treated using prompt administration existing known drugs.

Nearly 500 years ago, Swiss physician and chemist Paracelsus expressed the basic principle of toxicology: “All things are poison and nothing is without poison; only the dose makes a thing not a poison.” Today, we would simply say it’s “too much of a good thing...” You can see why it is extremely important to understand the exact dosage, side effects, intensity, and how long a patient can use a specific drug or vaccine to maximize the beneficial effects while minimizing any associated toxicities. During the global panic and manufactured fear of COVID, in the United States, the wisdom of centuries of pharmaceutical development and established public health practices were jettisoned in a mad rush to develop and deploy vaccines while suppressing prompt use of inexpensive, off-patent drug treatments which have proven effective in preventing hospitalization and death.

In stark contrast to the response of the United States and many other western governments (notably Canada, the UK, New Zealand, Australia, Austria and much of the EU), the government of Mexico has adopted a much more permissive public health posture during the last three years, and has become known worldwide as a haven of public health sanity in a world otherwise driven mad with irrational fear.

Moving forward, under the false rationalization that the World Health Organization has effectively managed the global COVIDcrisis, there is currently an effort in progress to amend the International Health Regulations and supporting national financial commitments to the WHO to provide more funding and enhanced authority and power for the WHO to intervene in the internal affairs of sovereign nations in the event of a self-declared public health emergency.

These policies and revisions are based on proposals developed and submitted by the United States and its Department of Health and Human Services a year ago, which were largely rejected by a consortium of African and Latin American states largely due to concerns regarding loss of national sovereignty. In the face of these objections, further discussion and action was tabled at that time for later discussion, and reconsideration of potential modifications are currently in progress. In theory, what is proposed would allow the WHO to set and enforce global policies in response to a future public health crisis, and to override national policies in the event of a declared pandemic or other event as defined by the WHO Director General. The intent is that these modifications will carry the weight of an international treaty, although formal treaty endorsement by individual member states will not be sought.

It is my personal opinion and testimony that the experience of the sovereign nation of Mexico in its management of the COVIDcrisis clearly demonstrates that it is not in the interest of either Mexico or other sovereign and independent/unaligned nations to cede national control of public health to the World Health Organization, World Trade Organization, PAHO, or any other international body at this time. The clearly arbitrary and capricious US Government and WHO mismanagement and over reaction to the COVIDcrisis, to Monkeypox, and to many other infectious disease outbreaks in the past demonstrate that neither US nor WHO have the organizational maturity and capabilities to merit trusting and conceding Mexican public health sovereignty to these organizations.

In contrast, during the COVIDcrisis, Mexico demonstrated remarkable balance and maturity in its response to this event. I suggest that the persons responsible for helping guide the Mexican public health response in this way should be identified and rewarded, and that Mexico should continue to maintain its history of national sovereignty, maturity and balanced rationality in responding to similar future public health events.