Testimony before the Select Subcommittee on the Coronavirus Pandemic

Anthony S. Fauci, MD

Former Director (1984-2022)
National Institute of Allergy and Infectious Diseases
National Institutes of Health

Currently
Distinguished University Professor
Georgetown University
School of Medicine and McCourt School of Public Policy

June 3, 2024

Mr. Chairman, Ranking Member Ruiz, and members of the Committee. Thank you for the opportunity to discuss with you my role as the former Director of the National Institute of Allergy and Infectious Diseases (NIAID), a component of the National Institutes of Health (NIH), in the nation's research preparedness for and response to the COVID-19 pandemic. I was a scientist, clinician, and science administrator at NIH for 54 years and served as Director of NIAID for more than 38 years. As Director of NIAID, I had the privilege of advising seven Presidents of the United States, beginning with President Ronald Reagan in 1984 and culminating with my position as Chief Medical Advisor to President Joseph Biden on matters of domestic and global health in 2021 and 2022.

I begin with some background on my personal roles, responsibilities, and priorities during my tenure at NIAID/NIH. As a lifelong scientist, I believe that research is essential to our nation's ability to respond to the threat of emerging and re-emerging infectious diseases. When the HIV/AIDS pandemic was first recognized in 1981, I devoted my own personal research activities to identifying the fundamental pathogenic mechanisms of the disease. This research ultimately provided critical insight into the optimal therapeutic approach for suppressing virus replication early in the course of HIV infection.

When I became Director of NIAID in 1984, I dramatically increased the resources devoted to the study of HIV/AIDS, focusing particularly on the development of anti-retroviral drugs to suppress virus replication and prolong lives. In 1986, I created the Division of AIDS (DAIDS) within NIAID. Over a period of several years, DAIDS worked in partnership with several pharmaceutical companies to develop and test a panel of anti-retroviral drugs that have dramatically improved the lives and prognosis of persons living with HIV. Before the development of these drug combinations, HIV patients would almost invariably succumb to their

infection within one to two years of the development of clinically recognizable disease. With the availability of such drugs, persons with HIV can now live to an almost normal life expectancy. These efforts have saved hundreds of thousands of lives in the United States and millions of lives throughout the world.

Relatedly, in 2002 I had the privilege of being asked by President George W. Bush to be one of the principal architects of the President's Emergency Plan for AIDS Relief (PEPFAR) to bring treatment, prevention, and care for HIV infection to the developing world, particularly southern Africa. This program recently celebrated its 20th anniversary and has been responsible for saving 25 million lives. Our successful efforts in HIV/AIDS prevention and treatment are a cogent example of the dramatic life-saving outcomes that can follow from investments in basic and clinical research in response to emerging infectious diseases.

During my years as Director of NIAID, we witnessed similar success stories, albeit not as dramatic as that with HIV/AIDS, with NIAID-sponsored research in the development of diagnostics, therapeutics, and vaccines for other emerging infections such as pandemic influenza, bird flu, Ebola, and Zika among others. And so, under my leadership as Director of NIAID, we were well-positioned to respond scientifically to the unprecedented and historic pandemic of COVID-19.

For at least two decades before the SARS-CoV-2 virus that caused the COVID-19 pandemic emerged, NIAID had invested billions of dollars in basic and clinical research that led to the development of mRNA platform technology and structure-based immunogen design that ultimately led to the development of safe and highly effective vaccines for COVID-19. This research allowed my colleagues at the NIAID Vaccine Research Center, through long-standing collaborations with pharmaceutical companies, to respond swiftly to the COVID-19 pandemic

and to develop a vaccine on a historically unprecedented timetable. The implementation of this process was aptly coined Operation Warp Speed.

More specifically, on January 10, 2020, the genomic sequence of the novel coronavirus that was causing severe pneumonias and deaths in Wuhan, China, was published in a public database. Within five days, my team began development of a COVID-19 vaccine in collaboration with the Moderna company. Within 65 days, a phase 1 clinical trial of the vaccine was initiated; within 139 days, a phase 2 clinical trial began; and within 198 days, a phase 3 clinical trial began. The clinical trial networks that NIAID had put into place over decades for the testing of anti-retroviral drugs and vaccines for HIV/AIDS were used in these trials, which tested the safety and efficacy of the COVID-19 vaccine with the assistance of tens of thousands of volunteers. At day 311 after the genomic sequence of the novel coronavirus was published, an interim analysis of the data from the clinical trials found evidence of preliminary efficacy of the vaccine. At day 325, an Emergency Use Authorization (EUA) for the vaccine was submitted to the Food and Drug Administration (FDA). ***Thus, less than 11 months after the recognition of this new virus, vaccine doses were ready to go into the arms of individuals***. The Pfizer company and BioNTech accomplished a similar feat using their mRNA vaccine.

In addition, Operation Warp Speed anticipatorily invested billions of dollars "at risk" in the mass production of vaccine doses even before the safety and efficacy of the vaccines were proven. These combined investments and efforts led to an achievement unprecedented in the history of vaccinology – safe and highly effective vaccines were available to the public less than one year after a novel and deadly pathogen was identified. Other pharmaceutical companies developed effective COVID-19 vaccines using platform technologies other than mRNA.

However, most utilized the immunogen called S-2P developed by my team at the NIAID Vaccine Research Center.

In sum, the development of safe and highly effective COVID-19 vaccines was a team effort involving multiple partners, and NIAID made numerous, undeniably critical contributions to the success of the effort. (Fauci AS: The story behind COVID-19 vaccines. *Science* 372:109, issue 6538, April 9, 2021). A study conducted by the Commonwealth Fund from December 2020 through November 2022 estimated that the COVID-19 vaccination program in the United States prevented more than 18.5 million hospitalizations and 3.2 million deaths. The vaccination program also saved the United States $1.15 trillion in medical costs that otherwise would have been incurred.

In addition to its contribution to the development of COVID-19 vaccines, NIAID has supported the basic research that formed the foundation for the development by pharmaceutical companies of effective anti-viral drugs used for the treatment of COVID-19 disease. Also, NIAID intramural researchers and extramural grantees played major roles in the development of monoclonal antibodies for the treatment and/or prevention of SARS-CoV-2 infection.

Before I stepped down as Director of NIAID, my team developed a pandemic preparedness and response plan aimed at developing next-generation vaccines that would be effective against present and future variants of SARS-CoV-2 as well as other coronaviruses that may emerge in the future. The aspirational goal of the plan is to develop "pan-coronavirus" vaccines. Furthermore, work has already begun in developing vaccines administered via the nasal and oro-pharyngeal mucosa with the goal of better preventing initial infection and thus transmission of the virus. Another aspect of NIAID's research response to pandemics is the Anti-Viral Program for Pandemics (APP) which aims to develop safe and effective antivirals to combat SARS-CoV-2, as

well as to build sustainable platforms for targeted drug discovery and development of a robust pipeline of antivirals to combat viruses with pandemic potential.

A critical component of the NIAID pandemic preparedness and response plan is the "prototype pathogen" approach. This involves selecting several (approximately 7 to 10) families of viruses with a high potential for becoming the source of a pandemic outbreak. Such families would include coronaviridae (SARS, MERS, SARS-CoV-2), orthomyoviridae (influenza), and paramyxoviridae (Nipah, RSV), among others. The strategy is to intensively study a prototype virus in each family in anticipation of the potential emergence of a novel and potentially pandemic pathogen from within that family. This prior experience with a prototype virus within a given family of viruses (*i.e.*, with regard to basic virology, diagnostic assays, animal models, antigenic targets, optimal vaccine platforms, and potential immune correlates of protection) would facilitate an informed, rapid response in the event that a potentially pandemic virus emerges from within that family. For example, our prior experience with SARS and MERS greatly informed our response to SARS-CoV-2. We fully expect that baseline studies of prototype pathogens in the "higher risk" families of viruses will prove extremely useful in allowing a rapid and effective response to the emergence of pathogens of pandemic potential in any of the viral families in question.

In my approach to pandemic preparedness and response, activities fall into one of two general "buckets": 1) scientific preparedness and response and 2) public health preparedness and response. Clearly, the public health response has met with some difficulty. I am hopeful that lessons learned in recent years will help us to address and mitigate problematic areas in this bucket in the future. What is eminently clear, however, is that the decades of investment in basic and clinical biomedical research made by NIAID and its partners were absolutely critical to the

scientific successes in our approach to the COVID-19 pandemic, particularly to the unprecedented speed in which a safe and highly effective vaccine was made available to the public, resulting in the saving of millions of lives worldwide. That is a lesson we should not forget. NIH has been fortunate to have strong and enduring bipartisan support throughout multiple administrations and congresses of both parties. If we are to be adequately prepared for the next inevitable pandemic, this support must continue.

I also wish to address certain issues that, through misinformation and disinformation, have led to considerable and understandable confusion on the part of the public. The first issue relates to reports of *my response* to the possibility that SARS-CoV-2 could have resulted from a leak from a laboratory in Wuhan, China. I want to set the record straight.

On January 31, 2020, Jeremy Farrar (then the Director of the Wellcome Trust in the UK) and Kristian Andersen (a highly regarded scientist at Scripps Research Institute) informed me in phone calls that they and Edward Holmes (Professor of Viral Evolution at University of Sydney, Australia) were concerned that the recently published genomic sequence of SARS-CoV-2 suggested that the virus had been manipulated in a laboratory. I participated in a conference call the next day (February 1, 2020) with about a dozen highly regarded virologists and other relevant individuals to discuss the possibility that the virus emerged as the result of manipulation in a laboratory rather than from a natural spillover from an animal reservoir.

The participants on the conference call included Mr. Farrar, Mr. Anderson, and Mr. Holmes, as well as Francis Collins (Director of NIH), Patrick Valance (UK Chief Scientific Advisor), Christian Drosten (Director of Human Virology at the German Center for Infection Research at Charite-Universitatsmedizin, Germany), Andrew Rambaut (Professor of Molecular

Evolution, University of Edinburgh's Institute of Evolutionary Biology), Ron Fouchier (Deputy Head of Department of Viroscience, Erasmus Medical Center, NL), Robert Garry (Professor of Virology, Tulane University School of Medicine), Michael Ferguson (Professor of Life Sciences at University of Dundee, UK), and M.P.G. Koopmans (Head of the Department of Viroscience, Erasmus Medical Center, NL). The discussion on the conference call was lively, and arguments were made for both theories of how the SARS-CoV-2 virus could have emerged. At the end of the call, it was decided that several of the participants would examine the SARS-CoV-2 genomic sequence more carefully to try to clarify the issue. Contrary to the disinformation circulated on social media and elsewhere that I tried to influence the discussion on that call away from a lab leak theory, two participants on that call have verified to this subcommittee that I did not try to steer the discussion in one direction versus another. I am not an evolutionary virologist and would not be qualified to do so in any case. I left the issue of the origin of the virus to the experts on the call.

After the conference call, and upon more careful examination of the genomic sequence of the SARS-CoV-2 virus, several of the participants who at first were concerned about a laboratory manipulation became convinced that there was no indication that the virus was manipulated and that the most likely scenario was that it emerged as a natural spillover from an animal reservoir, even though they kept an open mind. These individuals soon published their opinion in the peer-reviewed literature (Andersen, KG et al: The proximal origins of SARS-CoV-2. *Nat Med* 26:450-452, online March 17, 2020).

An accusation has since been circulated that I influenced these scientists to change their minds by "bribing" them with millions of dollars in grant money. There is no way to answer this accusation except to say that it is preposterous. The NIH system for allocating money to

grantees would make this feat impossible even if someone were foolish enough to attempt it. Furthermore, anyone who knows anything about the culture and integrity of the independent-minded scientists from several different countries who participated in the conference call would confirm how outlandish this accusation is. Importantly, participants on the call have testified before this subcommittee that I had no input into the content of the published paper.

Another unfounded accusation that has circulated is that I actively tried to minimize and "cover up" the possibility that the SARS-CoV-2 virus originated from a laboratory. Assertions have been made that my e-mails prove this supposed "cover up." In fact, those emails prove exactly the opposite, namely, that I was proactive in making sure that any possible "laboratory leak" was actively investigated.

I provide a representative e-mail here to illustrate my point. Below is the content of an e-mail that I sent to Professor Jeremy Farrar with a copy to Kristian G. Andersen on Saturday, February 1 at 12:38 AM with the subject line "Phone call" (this can be verified by reviewing the original email, which is in the public domain). The email reads:

> Jeremy: I just got off the phone with Kristian Andersen and he related to me his concern about the Furine site mutation in the spike protein of the currently circulating 2019-nCoV. I told him that as soon as possible he and Eddie Holmes should get a group of evolutionary biologists together to carefully examine the data to determine if his concerns are validated. He should do this very quickly and if everyone agrees with this concern, they should report it to the appropriate authorities. I would imagine that in the USA this would be the FBI and in the UK it would be MI5. It would be important to quickly get confirmation of the cause of his concern by experts in the field of coronaviruses and evolutionary biology. In the meantime, I will alert my US government official colleagues of my conversation with you and Kristian and determine what further investigation they recommend. Let us stay in touch. Best regards, Tony

It is inconceivable that anyone who reads this e-mail could conclude that I was trying to "cover up" the possibility of a laboratory leak. To the contrary, it demonstrates that I was advocating for a prompt and thorough examination of the data and a totally transparent process.

Another issue that deserves clarification is the insidious accusation that the sub-award of an NIH grant to EcoHealth Alliance, which went to the Wuhan Institute of Virology (WIV) in the amount of approximately $120,000 per year to do scientific surveillance on human serology and bat viruses in the environment in China, resulted in the creation of the SARS-CoV-2 virus that produced the COVID-19 pandemic. Any qualified evolutionary virologist would confirm that the bat viruses that were studied at WIV under the NIH-funded grant were phylogenetically so far removed from SARS-CoV-2 that it would be molecularly impossible for those viruses to be turned into SARS-CoV-2. Information concerning the viruses that the WIV scientists worked on was published in the peer-reviewed literature and described in the grant progress reports. Any suggestion that the viruses studied under the NIH-funded sub-award to WIV resulted in the creation of SARS-CoV-2 is without the slightest bit of evidence or feasibility.

Similarly, I wish to clarify the issue of whether the NIH funded so-called "gain of function (GoF) research" at the WIV. There had been much confusion as to exactly what "GoF research" is and what guardrails should be established for its conduct. Because of that, the United States government imposed a three-year moratorium from 2014 to 2017 on federal funding for experiments that might constitute GoF research. During that moratorium period, experts engaged in a deliberative process to establish a practical framework for defining and regulating GoF research and developing criteria that would trigger additional scrutiny for certain experiments. This three-year deliberative process involved the National Science Advisory Board for Biosecurity (NSABB), the National Research Council (NRC) of the National Academies of Sciences, Engineering, and Medicine, and multiple risk-benefit assessment conferences.

On January 9, 2017, this deliberative process resulted in guidance issued by the White House Office of Science and Technology Policy for HHS to develop review mechanisms for

oversight of the study of "potential pandemic pathogens." The guidance was referred to as Potential Pandemic Pathogen Care and Oversight (P3CO). According to the P3CO framework, the operative definition of GoF research is research that results in "enhancement" of the function of a "potential pandemic pathogen." "Enhancement" refers specifically to the experimental enhancement of a pathogen's transmissibility (its ability to spread from person to person) and/or pathogenesis (its ability to cause severe disease). The P3CO framework defines a "potential pandemic pathogen" as follows:

> A *potential pandemic pathogen* (PPP) is one that satisfies both of the following: 2.2.1) It is likely highly transmissible and likely capable of wide and uncontrollable spread in human populations, and 2.2.2) It is likely highly virulent and likely to cause significant morbidity and/ or mortality in humans.

The viruses studied under the NIAID-funded EHA sub-award to WIV had never been shown to infect humans, much less to cause high transmissibility or significant morbidity and mortality in humans. Their study, therefore, could not and did not constitute GoF research according to the operative P3CO definition, which is the definition I have always used.

Moreover, even if those viruses had previously been shown to infect humans (for which there was no evidence) the design and objective of the WIV experiments was not to "enhance" the transmissibility or pathogenesis of the viruses in humans or any other species, nor were the anticipated outcomes of these experiments expected to alter those attributes of the viruses. Therefore, according to the P3CO framework, which provided the then-operative and regulatory definition of GoF research, those experiments clearly were not GoF research.

Also, my response to the ultimate question regarding the origins of SARS-CoV-2 has received considerable attention: Was it a lab leak or a natural spillover from an animal reservoir? I have repeatedly stated that I have a completely open mind to either possibility and that if definitive evidence becomes available to validate or refute either theory, I will readily accept it.

As of now, however, it is important to point out that the information currently available and that has been carefully examined and published in reputable peer-reviewed journals by highly respected virologists strongly suggests that the virus spilled over from an animal reservoir in the Hunan Seafood Market in Wuhan, leading to the COVID-19 pandemic (Worobey M, et al: The Hunan Seafood Wholesale Market in Wuhan was the early epicenter of the COVID-19 pandemic. *Science* 377: 951-959, Aug. 26, 2022; Pekar JE, et al: The molecular epidemiology of multiple zoonotic origins of SARS-CoV-2. *Science* 377:960-966, Aug. 26, 2022; Holmes EC, et al: The origins of SARS-CoV-2: A critical review. *Cell* 184: 4848-4856, September 16, 2021; Holmes EC: The emergence and evolution of SARS-CoV-2. *Ann Rev Virol* 11:2.1-2.22, 2024) Since this information is not *definitive* proof of a natural spillover, I maintain a completely open mind as to the origin of COVID-19.

Two other issues that have been brought to public attention deserve addressing. Dr. David Morens, whose title during my tenure as NIAID Director was Senior Advisor to the NIAID Director, has recently been investigated for conduct unbecoming a government official. Naturally, given his title, a connection is made to me. I knew nothing of his actions in assisting Dr. Daszak and EcoHealth Alliance or his conducting NIH business on his personal e-mail account or deleting emails to avoid FOIAs.. Several years ago, Dr. Morens was transferred from a scientific division at NIAID to help me write scientific papers and review the scientific literature on infectious diseases. Following his transfer, we needed a title for him and the empirical title of "Senior Advisor to the NIAID Director" was chosen. It is important to point out for the record that, despite his title, functionally Dr. Morens was not an advisor to me on institute policy or other substantive issues. He is a scientist, science writer and historian. At NIAID we had a weekly executive committee meeting of the institute leadership, which to the

best of my recollection he did not attend. We had a daily morning meeting of the immediate Office of the Director leadership staff, which to the best of my recollection he did not attend. Furthermore, his office is located in a different building from that of the NIAID Director.

Finally, in a Majority Staff Memorandum of May 22, 2024, there is a statement: "Dr. Fauci may have conducted official business via personal e-mail". Let me state for the record that to the best of my knowledge I have never conducted official business via my personal email.

Thank you for your attention and the opportunity to appear before the Select Subcommittee. I would be happy to address any of these issues or others in the discussion period.