

Prepared Statement of Ranking Member Richard Burr
Examining Our Covid-19 Response: An Update from Federal Officials

March 18, 2021

Welcome, Dr. Fauci, Dr. Kessler, Dr. Marks, and Dr. Walensky. I am glad to see some familiar faces in the transition to the new administration, we will need your expertise in this important moment of the global pandemic that is still with us. Continuity will be critical as we work through the lessons learned from the COVID-19 pandemic and move into the next phase of our response and, hopefully, our recovery.

This hearing is meant to take stock of our federal COVID-19 response, but I think it is now time to talk about where we are going in the next 30, 60, and 90 days and beyond. America needs to reopen our schools, reopen our businesses, and open up to global commerce. The actions taken by each of your offices affect these goals. Some of you are new to the response, and some of you have been in this fight for the last year alongside members of this Committee. My request of each of you, however, is the same. This pandemic has shown us, very clearly, how we can better prepare for the next threat, and that is by being a better partner to the private sector.

Dr. Walensky, I am going to start with you because you have the hardest job ahead of you. The bottom line is that there is a clear and compelling need for

significant reform at the CDC. Your agency is responsible for communicating to Americans, based on facts, how to return to some form of normalcy, but the guidance documents coming out of the CDC have been two steps behind the data. All that I am asking, is for the CDC's communication to be fast and transparent. Tell the American people what we know, when we know it, and when we don't, so that they can make the best decisions for themselves and their families.

As I mentioned, your best tool to keep pace with the science is the private sector. Last week during this Committee's COVID hearing, I said that CDC can no longer be in charge of all testing in the early days of a novel threat. Let me be blunt: CDC's go-it-alone mentality on testing was arrogant and wrong. Let me propose a solution based on the success that Dr. Hahn at the FDA led last year: lean on your private sector partners – commercial labs, academic centers, and large-scale test makers like BD and Roche to rapidly develop diagnostics that serve as one of the great assets during an outbreak of an emerging infectious disease.

The same is true of your surveillance systems. Last week, Dr. Jha from [Brown University's public health school] said that we need “a new approach” to our surveillance. We discussed leveraging data sets like weather patterns and mobility information alongside traditional de-identified testing and patient data from health care providers. We need a layered surveillance system, in partnership with the private sector, states, and local public health experts to get a true picture

of the threats on the ground. The COVID relief packages have given CDC [billions of dollars] to modernize these systems. CDC must not hoard that money for yourselves, instead use these funds to identify technologies that better equip us. I implore you to not build internal systems that will become obsolete before they are up and running.

Dr. Fauci – welcome back. You and I have worked on these issues together for more than two decades. A lot of what we built worked. The NIH recognized the importance of technology, leveraging existing clinical trial and research networks, extending partnerships with the private sector through the NIH Foundation and other avenues, and establishing programs like RADx in partnership with BARDA to cast the widest net possible for novel technologies in testing. Now, the challenge will be for your center, along with the other institutes and centers at the NIH, to maintain this pace, and apply it to the next challenge or set of health care challenges in the future. Voices at the NIH will be important in determining how can we expand, solidify, and maintain this public-private approach to the biggest health care issues facing our country.

Dr. Marks, this is where you, and your efforts at CBER come in. I can't think of another medical product center at the FDA that will see more of the technologies that will benefit American patients in the next decade – the COVID vaccines come through CBER for review, but so do cell and gene therapies, many

of them relying on new platforms that can be used for multiple devastating diseases and diagnoses.

The pandemic has broken the model at the FDA, and the agency should not go back to its historical approach. Dr. Hahn used his emergency authorities exactly how we envisioned the FDA using them. In my mind he, you, and the dedicated professionals at the FDA are the unsung heroes of the federal response. The EUA standard calls for the benefits to outweigh the risks. Now, as the makers of these products – vaccines, tests, and treatments – apply for full approval, the agency should take this opportunity to use real world information to inform their review, and I hope that you take advantage of the unique opportunity you have here.

Each medical product center at the FDA can apply their practices during the pandemic to the applications that come across reviewers desks. We can accelerate development to the benefit of patients here in the United States, and around the world for more than just COVID but for cancer, diabetes, and more. Stacking clinical trials, receiving rolling sets of data, and coordinating with our global colleagues have been available tools at the agency for a long time. I urge you to continue to use them as you have over the last 12 months.

Dr. Kessler, you were serving as FDA Commissioner when our first conversations about pandemic preparedness began. Now, you are in a position to help use those authorities to their fullest extent. Operation Warp Speed has used

NIH's expertise in early research, BARDA's contracting, advanced development and manufacturing capabilities, and the DoD's logistical muscle to achieve scientific breakthroughs that can rescue the world from this virus. Operation Warp Sped was a huge success and I'm glad that you are planning on building on that success going forward. In the next few months, this project will have made available vaccine for all eligible Americans in record time without cutting any corners on safety or efficacy.

Warp Speed showed us where some of our gaps in countermeasure development existed. We need ways to rapidly identify candidates for tests, treatments and antivirals, and vaccines. This is an area primed for partnership with academia and especially the private sector. We also learned that our manufacturing capabilities came up short. But we saw a remarkable thing when private sector drug makers partnered with their competitors to make more vaccine. It is my hope that you are willing to work with my office to address the gaps that we found during the establishment of Operation Warp Speed, and to uphold the many pieces that worked for the future.

Now, one year into the pandemic, even as the vaccine offers hope that the return to normal will continue and speed up, the offices and responsibilities that each of you hold will become more challenging. Not only will you be required to maintain the pace and urgency of our current response, but to begin to change the

architecture of our public health agencies. The novel coronavirus has irreversibly altered our ability as the federal government to interact with innovators that bring real solutions to the greatest health care challenge in generations. Do not take this moment for granted. Strengthen the relationships and partnerships that have been established during the response. Take stock of the needs that still exist, and how partnerships like these can help to address them. My staff and I will be in the midst of a review with this same goal, and my office is available to you at any time to work together on these efforts.

Thank you for your willingness to serve during such a difficult time for our country. I look forward to working with each of you to reopen our country and memorialize what we have learned along the way.