Prepared Statement of Ranking Member Richard Burr

Nomination of Dr. Robert Califf, Commissioner of the Food and Drug Administration

December 14, 2021

Chair Murray, thank you for holding this important hearing today.

With the indulgence of the Chair, I'm going to include your introduction to this Committee as part of my opening statement.

Dr. Califf, last time you were here interviewing for this job, I introduced you to my colleagues as a wonderful father and grandfather, a great doctor, and a great man. All of that remains true today. Welcome back.

Dr. Califf is a distinguished North Carolinian who previously served as Commissioner of Food and Drugs under President Obama from February 2016 until January 2017. Prior to becoming Commissioner, Dr. Califf served as the Deputy Commissioner of FDA's Office of Medical Products and Tobacco beginning in February 2015.

Before joining FDA, Dr. Califf was a professor of medicine and vice chancellor for clinical and translational research at Duke University in Durham, North Carolina. Dr. Califf has spent more than 35 years in leadership roles at his alma mater, including the positions of Director of the Translational Medicine Institute, and the Director of the Clinical Research Institute. He also worked to

move the promising field of translational science forward as the Director of the Clinical Trials Transformation Initiative.

Dr. Califf is currently the Head of Clinical Policy and Strategy for Verily Life Sciences and Google Health at Alphabet, Google's parent company. His experience also includes serving as vice chancellor for health data science and director of Duke Forge and the Donald F. Fortin, MD Professor of Cardiology in the Duke University School of Medicine.

Dr. Califf's unique perspective as a former FDA commissioner coupled with his understanding of partnerships with the private sector and academia that assist in fueling innovation will be vital if confirmed as the next FDA Commissioner.

Dr. Califf, thank you for being here to answer our questions today.

To your family, you should be proud today. All of the criticism he will endure during this process is the result of his success. Thank you for the sacrifice that you are making in allowing him to return to the FDA.

I am thankful to finally have an opportunity to hold a hearing on one of the most significant positions in the Administration, during the worst pandemic in over a century.

This Administration has left the FDA Commissioner position open since January 20th – almost a full year – in the middle of the pandemic.

I'm disappointed that it took them so long, but I am glad to see you again sitting before this committee.

Since you were last here the FDA has made major strides in updating and modernizing their behavior, and now in the midst of the global response to the pandemic, so much more is at stake.

The FDA is responsible for ensuring the safety and effectiveness of medical products in the U.S. and protecting our nation's food supply.

Safety and efficacy is your mission. Is the product safe for use and does it work as intended?

FDA regulates approximately 20 cents of every U.S. dollar spent. The products and practices it regulates are diverse, and there will be more demands on your time than hours in the day.

You are familiar with FDA as an agency, and with its responsibilities, its challenges, and its ability to reach the lives of every American.

Because of FDA's reach, there are infinite things you could do if you are confirmed, but your priorities should align with where FDA can have the greatest impact – supporting the next generation of biomedical science and innovation, and protecting our country from public health threats.

It's been almost five years since you last served at FDA. You will be a newcomer to the agency's pandemic response, and to the ways that FDA has improved over the past two years.

You are filling the shoes of a legend. The nation has been fortunate to have Dr. Janet Woodcock at the helm. The FDA's success is her success, and we need to build on that.

I have significant concerns that FDA could revert to the old way of doing things – go back to the ways before COVID.

You last led the agency during peacetime. We need a wartime Commissioner, who will lead us through the next phase of the response to coronavirus, and build a stronger, more nimble FDA for patients and American consumers.

The past two years have tested FDA. Its authorities and regulatory practices have come under scrutiny as the gatekeeper for medical countermeasures needed to protect against the coronavirus.

The pandemic has exacerbated existing, systemic challenges at the agency, and created entirely new ones that you will face if confirmed.

FDA has made historic progress, the agency finally leaned in to its authorities to move as quickly and as safely as possible.

It worked with manufacturers to develop and rapidly scale up manufacturing of three vaccines, 12 treatments, and more than 420 tests to protect against, detect, and diagnose the virus.

Many of these countermeasures were developed and authorized for use in a matter of months or even weeks without compromising safety and efficacy – a testament to the agency, and its partnerships with innovators.

FDA provided flexibility and certainty, and it made all the difference.

The next Commissioner cannot take their foot off the gas, the agency has come too far.

FDA's regulatory readiness is important for the next threats that we will face, but also for unmet needs for devastating diagnoses, like cancer, Alzheimer's, and ALS.

The pandemic demonstrated that medical products can be developed more quickly without compromising FDA's gold standard.

The time it takes to develop a new drug increased from an average of seven years in 1997 to nine years in 2017. According to NIH, it can take up to seven years to develop a diagnostic. We need to go the other way.

We developed treatments and vaccines for COVID-19 in under 1 year, and diagnostic tests in less than a few months.

Many vaccines and treatments used during COVID leverage platform technologies that can be adapted to address new targets.

I think that one of the best ways to accelerate development at FDA is to work with innovators to streamline the development and review of new products built on these cutting-edge platforms – whether for a new pathogen or for a life-changing disease.

Next year, this committee will be charged with evaluating FDA's user fee programs and consider their reauthorization.

I have strong, deeply held feelings about these important programs.

I have served in Congress for all but the first user fee process.

Since their creation, the user fee programs have grown to enormous sizes. Over the last decade, PDUFA program fees collected have roughly doubled, and the MDUFA program fees have more than quadrupled.

This growth in user fees from industry weakens FDA's accountability to Congress, and to the patients we serve.

The purpose of the user fee programs is to *supplement* the money FDA receives from Congress for the review of medical products to bring treatments and therapies to Americans as quickly as possible

Today, after all the agency has been through with the pandemic response, our approach to the user fees will undoubtedly look different.

As FDA and industry work to finalize the commitment letters for congress to review next year, I expect that each agreement will take stock of lessons learned over the last 2 years.

Dr. Califf, should you be confirmed, I look forward to working with you during the most important user fee cycle that this Committee has faced.

I have spent almost 30 years working to hold FDA accountable so that Americans benefit from innovative medicines.

The best way for the agency to achieve this goal is to provide clear, predictable pathways for products to come to market.

FDA has made progress on this for some of the products it regulates – approving life-saving drugs and medical devices every year.

FDA has issued specific guidance for rare diseases, cell and gene therapies, and complex generic drugs, but more work remains to speed the slow gears of regulation.

FDA also still has much to do to provide a clear and predictable path to market for tobacco products and diagnostic tests.

Leadership, vision, and an understanding of the innovation of products are critical to a fair, predictable regulatory pathway for *any* product regulated by FDA.

The Center for Tobacco Products receives the second highest user fee dollars of any center at the agency except for the drug center.

More than a decade after receiving authority from Congress, FDA just recently issued the foundational rules to provide a regulatory roadmap for new, and potentially less harmful, tobacco products.

Can you imagine if FDA did not have foundational regulations for the review of new drugs, while still requiring products to submit applications?

Despite 13 years and more than $7.5 billion, it has authorized under the premarket pathway only *one* vapor product – a class of product that can provide a new, potentially less harmful alternative for life-long smokers.

CTP is charged with the regulation of tobacco products, which includes a mission to regulate these products for the protection of public health.

It's not meeting that mission either.

According to data FDA gave me in 2019, CTP spent millions more on advertisements than it spent on enforcement actions to find bad actors.

Dr. Califf, should you be confirmed, I would ask you to take a hard look at the tobacco center and get your house in order.

Enormous innovation is occurring in the area of diagnostic tests.

We have experienced this innovation throughout the pandemic response – the laboratory community rapidly developed tests to detect, diagnose, and surveille for the coronavirus.

There was confusion early on in the response as to whether these tests were under FDA's regulatory purview, and if so, what was required of them to be available to Americans.

Public health officials, test developers, providers, and patients need the law to provide regulatory certainty and predictability that allows for innovation to continue on the same trajectory we are experiencing during the pandemic.

Dr. Califf, I hope you can agree that Congress needs to speak to resolve this decades-old issue once and for all.

If you are confirmed as Commissioner, you will be responsible for maintaining FDA's mission as we enter a new era of biomedical innovation.

This new era will require FDA to recruit, hire, and retain the right talent.

FDA has long faced systemic hiring challenges, and it will be one of the top challenges you face as Commissioner. If you're confirmed, I look forward to working with you to help address it.

You will be responsible for policy decisions to help Americans as they safely return to normal life, to prepare to respond to future pandemics, and to build upon successful policies that enable more medical innovation to reach patients more quickly.

Effective and accountable leadership at FDA is paramount.

My questions today are intended to make sure that you are up to the task of leading the FDA while we are still battling a once in a life-time pandemic.

I urge you to focus on what matters most. To not lose sight of all of the ground gained, and to use the tools we have given you to their fullest extent.

I look forward to our conversation today and hearing your plan for returning to the agency to address the many challenges you may face.

I yield back.