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Briefing: "Guardrails to Ensure a Safe and Effective COVID-19 Vaccine"

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Good morning, Chairman Krishnamoorthi and Members of the Committee. Thank you for the work this subcommittee has already done to ensure that the response to the COVID-19 pandemic is guided by the best science and the best scientists.

I am Dr. Bruce Gellin. I currently serve as President of Global Immunization at the Sabin Vaccine Institute here in Washington, DC. Founded in honor of Albert Sabin, the inventor of the oral polio vaccine, our mission is to make vaccines more accessible, enable innovation and expand immunization across the globe. But my entire career spent, largely in government, has been vaccine focused: as Deputy Assistant Secretary for Health and Director of the National Vaccine Program Office at the US Department of Health and Human Service (2002-2017); a medical officer in the National Institute of Allergy and Infectious Diseases at NIH; and a member of CDC's Epidemic Intelligence Service.

We are all too familiar with the startling and deeply disturbing COVID-19-related statistics. The US continues to experience record numbers of infections. Of the more than more than 500,000 deaths that this virus has caused world-wide, one-fourth have occurred among our fellow citizens and we've all been discouraged to see record numbers of infections in several areas of the country.

Beyond the obvious health impacts, no sector of society has been spared and the full economic and societal reckoning will be grim, though difficult to predict. Current estimates project that the pandemic will lead to a drop in global economic growth by 3% to 6% and global trade could be reduced by 13% to 32% in 2020.

While various efforts – "flattening the curve", social distancing, and face coverings are all important in helping to control COVID-19, it is absolutely clear that only population-wide immunity will dampen the virus' ongoing spread and end the pandemic. Let me repeat that: Only population-wide immunity will stop the spread of COVID-19 and end the pandemic.

Consequently, there has been an unprecedented effort to rapidly develop vaccines that can be deployed across the US population and globally. There are upwards of 160 vaccine candidates in the mix. This effort has been extraordinary and marked by collaboration, innovation and speed. The focus of today's hearing is: How do we ensure that all of this results in vaccines that are both safe and effective?

In addition to good science – always the starting point – I would suggest three crucial elements that are fundamental to the success of this extraordinary effort:

1. **No short cuts**
2. **Transparency**
3. **Trust**

Let me briefly describe each and why they are vital.

No short cuts:

The development of a successful human vaccine, from idea to licensure, is a complex and lengthy process and the majority of vaccine candidates that enter the race don't make it to the finish line for a variety of reasons: the immune response or side effect profile isn't what was desired, it may be difficult to manufacture a particular vaccine at scale, and the cost of development and manufacturing are too high. That there are many COVID-19 vaccines in the development pipeline is good news as this gives us more assurance that some will make it to the finish line as it is likely that several in the development R&D pipeline will drop out of the race.

But these timelines reflect both the business and the science of vaccine development. The cost of development increases with each step in the process, so if a product doesn't look like it will be successful, vaccine companies cut their losses and move on. But in response to this public health emergency, there are a number of steps that can be taken in parallel rather than in sequence that can shorten these timelines without sacrificing a thorough assessment of safety and efficacy. The most obvious is proceeding with the huge cost of manufacturing before it is clear that a vaccine candidate is going to work.

FDA Commissioner Hahn is to be commended for publishing the detailed guidance document on the development of COVID-19 vaccines. Guidances like these are critical as they signal to all the key considerations for clinical and non-clinical data, for chemistry, manufacturing and controls and for post licensure safety and effectiveness monitoring. And as the entire US population is at risk for COVID-19 infection, clinical trials should also ensure that vaccines are evaluated in all populations. While the intended purpose of this document is guidance for industry, it also lets all know what is to be expected

of a vaccine that is to be considered for licensure or for use under an Emergency Use Authorization and meet the standards that have made an FDA approval so valuable for companies and consumers. As always, such guidance is based on the best available current thinking and can sometimes evolve with additional science, data and experience – and any changes would be to improve the process by which COVID-19 vaccines will be evaluated to ensure that any vaccine that is being considered.

But there is also a worry that pressured by the rush to bring COVID-19 vaccines to the American people at warp speed there may be well-intended desires to shorten timelines. But such short cuts could short-change the process. We all know that cutting corners comes with a price. Should that happen, it is possible that important signals could be missed that may only be seen in retrospect where they could have been spotted in real time. The consequences of such a misstep are potentially grave – not only do we risk the acceptance of a COVID-19 vaccine that might not meet these standards, but we risk much more – the trust of the American people in the very process we have come here to discuss.

Transparency:

Ultimately, a decision about licensure will be made by the FDA, as it should be. Sessions like the briefing you've organized today are important to be sure that those charged with important responsibilities are doing all that they can in service of the American people. I feel fortunate that in my time in government almost every day I was able to witness first-hand, the dedication of the best in the world in using their expertise to serve the American people. Because not all are able to view this first hand, that is in part why Congress passed the Federal Advisory Committee Act nearly 30 years ago. Advisory committees enlist our country's best experts who volunteer their time to help provide their advice to the government. And because transparency is an important element in the trust equation, meetings of federal advisory committees are open to the public.

I strongly recommend that any vaccine that is being considered for licensure or use under and Emergency Use Authorization be reviewed in an open public meeting of FDA's Vaccine and Related Products Advisory Committee. Without such public review, there is no doubt stories will appear – especially on social media – about any approved vaccine where decisions were made about things the government didn't want the public to see. Those stories are virtually impossible to stop. The best antidote for that problem is sunshine.

Trust:

While we are here today to talk about the processes in place to ensure that COVID-19 vaccines that make it through the pipeline are safe and effective, we should also acknowledge that we're here today to talk about trust.

In 2015 the **National Vaccine Advisory Committee**, a federal advisory committee that reports to the Assistant Secretary for Health issued a landmark report: **Assessing the State of Vaccine Confidence in the United States**. The findings from that report remain relevant for the successful development and deployment of a COVID vaccine: trust in the research and development process that leads to vaccine licensure; trust in the process that recommends vaccines, trust in the providers who administer vaccines, and trust that once vaccines are used broadly in the population there is a system in place that continues to assess their impact to ensure that they are performing as expected.

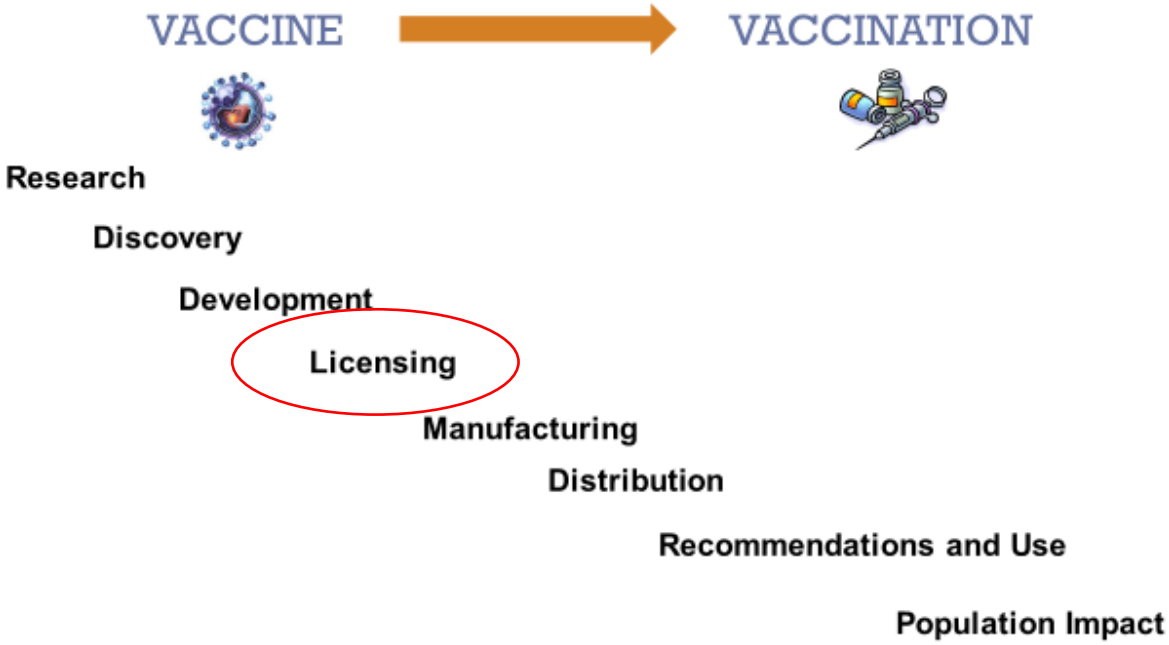
A poll conducted in May by Associated Press-NORC Center for Public Affairs Research found that only half of the US adult population say they will take a COVID-19 vaccine, nearly one-third aren't sure, and approximately 1 in 5 said they would refuse. These results are a window into the confidence that the American public has about this process, which is why it's imperative that all have an opportunity to be witnesses to the process.

Everyone wants a safe and effective vaccine to be available as soon as possible to provide the individual and community protection that will allow us to go about all of the things that constitute our society. And it's in no one's interest to rush a vaccine that isn't ready to go.

In the end, Americans want to know and understand what the process is. They want to be assured that the process is being followed, not short-circuited. They need to have all this to build the trust and confidence that has been eroding over vaccines and vaccination for some time so that they will actually choose to be vaccinated when a vaccine becomes available.

The title of today's briefing would imply a focus only on the critical role of the FDA in reviewing all of the available data about any vaccine being considered for broad use in the population – under an Emergency Use Authorization (EUA) or as a licensed vaccine. But I would like to highlight that reaching that goal is built on the larger vaccine enterprise that includes the research and development, the assessment of safety at every step in the vaccine development process (including continued monitoring of the impact of vaccines when vaccines are used more broadly in the population).

The figure below is a high level representation of the process and I've circled where we are primarily focusing today with a particular emphasis on the evaluation of the range of data that will reviewed and scrutinized to ensure that any vaccine that is considered for use by the American public has been vetted. It is a rigorous process because all know what's at stake. That's especially the case for vaccines. In contrast to drugs and other therapeutics that are given to people who are ill, vaccines are given to people who are well to protect them from a future exposure to a bacteria or a virus. Because of this, the standard for safety of vaccines are higher than they are for any other medical product, as they should be.



While this picture outlines the elements of the process (and provides some insight into the timelines) what it doesn't adequately depict is the interconnectedness of the many pieces of this ecosystem.

Finally, it is important to note that the vaccine approval process – what we are talking about today – is only one part of the broader vaccine ecosystem. Think of this system as gears in an engine. The gears must all mesh to ensure optimal performance of the engine. So, too, for the development of a safe and effective vaccine – of any type.

Mr. Chairman and members of this Committee, in your role as you continue to oversee the system to be sure that all of the gears in the engine are meshing to bring about safe and effective COVID-19 vaccines as expeditiously as possible, I would encourage you to examine the other parts of the vaccine and vaccination system as well. Even though vaccines are still in development and a handful are being examined as parts of clinical trials, vaccines don't deliver themselves and there are many outstanding questions about plans for the vaccination program.

There are important, but as yet unanswered questions about the specifics of the COVID-19 vaccination program. Some of these were touched on in a Senate hearing earlier this month (before the Senate Appropriations Committee Subcommittee on Labor, Health and Human Services, Education, and Related Agencies).

Among the many questions not addressed in the HHS Operation Warp Speed fact sheet that was released on June 16, 2020 are:

- When will an actual plan be developed?
- How will we ensure that all have access to COVID-19 vaccines?
- Early in the vaccination response, how will we allocate this scarce but valuable resource in an equitable way when demand outstrips supply? And who makes this decision?

- What "infrastructure" is needed to be built for vaccine distribution? Who is doing it and how will it leverage our national immunization program?
- What specifically is DoD's involvement "to enable faster distribution and administration than would have otherwise been possible?"
- Should we need a two-dose COVID-19 vaccination program – and especially should we have more than one vaccine available, how will we keep track of who got which vaccines as we should assume that these vaccines are not interchangeable?

The future COVID-19 vaccination will be the part of the system that will be very visible to all Americans. Given some of the frustration and delays with critical elements of the pandemic response to date, it's not too late to put a plan in place and communicate it to all who want and need to know. People are tired of hearing "we're building the ship as we're sailing it." Let's build it, then sail it. Nobody wants it to sink.

Finally, HHS is currently updating the National Vaccine Plan. Last updated in 2010 under my direction, the National Vaccine Plan represents the blueprint for the vaccine and vaccination enterprise. The broad goals of the National Vaccine Plan are:

- Foster Innovation in vaccine development and related technologies
- Continue to leverage the vaccine safety system
- Enhance knowledge of and confidence in routine vaccines and the immunization system
- Optimize access to and utilization of routinely recommended vaccines across the lifespan
- Promote global immunization

Every aspect of the **National Vaccine Plan** is in play as part of the country's vaccine response to COVID-19. This massive effort provides an opportunity to leverage our current investments in the COVID-19 vaccination response to strengthen the Nation's vaccine and vaccination enterprise for the long term.

In conclusion, Mr. Chairman, in my view – based upon my extensive experience in the field – the guardrails to ensure a safe and effective COVID-19 vaccine go beyond compliance with rules and regulations. Compliance alone will not result in a successful COVID-19 vaccine campaign. There must be transparency in the vaccine development process – from day one. There must be no short cuts in that process, and trust must be built (or re-built) among government, vaccine developers and the public.

We need to get started on all of these right now.