

**ORAL TESTIMONY OF DR. JULIE L. GERBERDING**  
**Before the United States Senate Committee on Health, Education, Labor and Pensions**  
**COVID-19: Lessons Learned to Prepare for the Next Pandemic**  
**Tuesday, June 23, 2020**

Chairman Alexander, Ranking Member Murray, and other members of the Committee, thank you for the opportunity to appear today. Reviewing the lessons learned from COVID-19 and other past pandemics and preparing for the next pandemic is critical. Unfortunately, we can't expect this pandemic to be a "once in a century" event; it is a sobering harbinger of things to come. Thank you for your leadership in this critical area.

Experts have predicted for years that a pandemic of this magnitude would occur, and significant progress has been made over the last decade in increasing our capabilities and readiness. Now that we are in the midst of the experience, while we must focus on the immediate task at hand, we can already see some of the vulnerabilities in our system that need to be addressed for the future. We must increase our posture of readiness for future infectious disease threats, with science, capability, and capacity in the U.S. and across the globe. We must ensure there is a robust market for innovation and continue collaboration, partnership, and strategic investments across the public-private continuum.

As one of the very few companies that have continued to invest in both vaccines and anti-infective medicines, at Merck we know we have a special responsibility to help advance both vaccine and antiviral therapies as part of our overall COVID-19 response. We have been fully committed to developing an effective response to the COVID-19 pandemic since it was first recognized, and we know that success will require global collaboration among countries, companies, and other key stakeholders. Despite the unprecedented, rapid collaboration and investment from the biopharmaceutical industry, we will continue to have more lives lost to COVID-19.

The development of a new vaccine is complex, time intensive, and carries no guarantees. It is estimated that only 6% of vaccine candidates get to the finish line and that is why only a small number of companies have continued to operate in this space.

Manufacturing and distributing a vaccine under normal circumstances is exceedingly complex, requiring hundreds of steps, thousands of complex tests, all validated to ensure that every single vial has the identical high quality and safety. When we think about what will be needed to address the pandemic, we are talking about orders of magnitude beyond what we as an industry are currently doing and which truly exceeds the current global capacity.

In order to meet this need, we must all appreciate that the biopharmaceutical collaborators are working at risk. In other words, we are making considerable investments in key elements such as manufacturing capacity before we typically would, before we know whether we even have a successful product – in many cases building a factory before we have fully developed the process at a smaller scale. As a result, we have to think carefully about how these decisions will impact other development programs and allocation of investments, including considering the inevitable opportunity costs.

In the short-term, we can expect many more months of ongoing transmission risk, with many people at risk. This will be further complicated as we expect influenza season to confound the impact of COVID-19 on communities and health systems. Sheltering in place and social distancing have proven effective mechanism to slow the transmission of the virus and protect the health care capacity; however, it comes at a huge price. The economic, individual/family, and community hardships are real. At the same time, communities with less social distancing are beginning to demonstrate more transmission.

I believe we need to find the right evidence-based balance between sufficient social distancing, including masks and avoidance of crowds, with prudent steps to resume business activities and more normal activities of daily life. This is imperative.

We also need to address escalating levels of misinformation related to the pandemic and the public and individual health impact of future vaccines. We are continuously seeing dissemination of information that is inaccurate and/or misguided. This can be quite dangerous as it leads to questioning the safety and efficacy of vaccines, which we know are critical to containing this pandemic and preventing future ones. We have seen the erosion of trust in governments and health care workers, who will be conducting vaccination programs. Ultimately this misinformation and mistrust can lead to a troubling reduction in people choosing to receive vaccines.

The current pandemic has only further emphasized the value of vaccines in preventing illnesses. We know that it is better to prevent an illness rather than treat it, but we are now living a stark example of that principle. As we look forward to a time when new vaccines and treatments are widely available, we must do more to ensure the adequate funding of prevention and immunization infrastructure in our health system more broadly. As this pandemic has shown very clearly, these are critical for health protection but also for national and economic security.

Testing protocols for future pandemics will also be critical. The 6 key priorities for testing are as follows:

1. Test people with symptoms for diagnosis;
2. Test people exposed to known/suspected cases;
3. Test people in “hotspots” where transmission is increasing;
4. Routinely test people in locations known to be or likely to be high risk (nursing homes, health care settings, prisons, meat packing plants, etc.);
5. Test to understand patterns of transmission risk and improve policy decisions (e.g., in daycares, schools, campuses, etc.; using antibody testing) – this is the essence of public health surveillance;
6. Deprioritize other “general” testing to unclog the system, especially until the reliability of tests improves.

Accelerating and enhancing health care surge capacity planning is also essential. This includes a multitude of critical activities, such as:

1. Conducting a thorough supply chain assessment to understand and address vulnerabilities;
2. Examining how to best strengthen the Strategic National Stockpile performance to be the most effective and efficient during a pandemic (e.g., consider expansion of personal productive equipment, ventilators, and other durable medical equipment);
3. Augmenting supplies of antibiotics, intravenous fluids, and other medicines to sustain critical care;
4. Formalizing augmented health care workforce contingency plans (credentials across states, retirees, volunteers, Department of Defense) and updating training;
5. Institutionalizing telehealth and payment reforms; planning for needed in-person primary care, maternal health, mental health, substance abuse, and dental care clinics;
6. Creating an interoperable pandemic health data network (instead of local and state stand-alone networks);
7. Engaging and incentivizing the private sector in planning efforts;
8. Exercising and improving plans with accountability from partners to follow through on lessons learned.

As we look forward, it is important to understand the key lessons that can and should be applied to help us better prepare for and respond to future pandemics. Vaccine development is complex and carries no guarantees; for this reason, we need to support the pursuit of multiple approaches.

While the first step is clearly finding the one or more effective vaccines, we can't underestimate the challenges of successfully deploying those vaccines. The complexity of the situation on the ground and challenges faced by vaccinators in the Democratic Republic of Congo (DRC) with our Ebola vaccine have been unparalleled. The scope and scale of the vaccine distribution, delivery, and administration challenges for COVID-19 will be significantly greater and will require unprecedented partnerships amongst manufacturers, supply chain and logistics professionals, governments, community leaders, health care workers, and individual citizens.

Key lessons we learned through our experience with Ebola that we can leverage moving forward include:

1. Public-private partnerships can be very powerful and effective, but also exceptionally complex and resource intensive. Bringing a diverse set of collaborators together requires trust and an "eyes wide open" effort with clear roles, expectations, and accountability defined for each collaborator.
2. Regulatory requirements and regulatory-manufacturing interplays are highly complex, requiring approval of both the product and the manufacturing process at each manufacturing facility for licensure. Accounting for these complexities requires more standardization and rightsizing specifically for preparedness goals, as well as better pre-work and harmonization when moving forward.
3. Numerous non-regulatory policies, such as trade, GMO, and BSL requirements can act as barriers to the free flow of raw materials and other component parts needed for vaccine

manufacturing and quality testing. If these can be identified in advance, manufacturers and government officials can work actively to address them before they result in manufacturing delays.

Preparing for tomorrow's pandemic requires a new health security doctrine. For the past two years, I have co-chaired with former Senator Kelly Ayotte the Center for Strategic International Studies (CSIS) Commission on Strengthening America's Health Security. Senators Murray and Young are part of the Commission. Other Congressional members include: Representatives Bera, Brooks, Cole, and Eshoo, in addition to several security experts. In November 2019, the Commission released the *Ending the Cycle of Crisis and Complacency* report. The report lays out several key steps that the Administration and Congress should take to create a sustainable basis for strengthening the health security of Americans.

We began the Commission's work with a simple understanding: health security is national security, in a world that is increasingly dangerous and interdependent.

Biological threats – outbreaks from natural, intentional, and accidental causes – are occurring more often and at the same time, the world is increasingly insecure, violent and disordered, and it is exactly in these danger zones where an increasing number of biological outbreaks occur.

Globalization and the rise of international trade and travel mean that an outbreak in a disordered setting with a compromised health system can quickly become a pandemic, threatening the United States and the rest of the world. Policymakers increasingly recognize these threats can undermine the social, economic, and political security of nations.

Unfortunately, this recognition occurs when a health crisis strikes – COVID-19, measles, MERS, Zika, dengue, Ebola, pandemic flu – and U.S. policymakers rush to allocate resources in response. Yet all too often, when the crisis fades and public attention subsides, urgency morphs into complacency. Investments dry up, attention shifts, and a false sense of security takes hold.

That realization led us to conclude: the U.S. government needs to break the cycle of crisis and complacency and replace it with a doctrine that can guarantee continuous prevention, protection, and resilience. The Commission advocates for a package of strategic, affordable actions to advance U.S. health security.

First and foremost, we recommend permanent health security leadership as a central pillar of the National Security Council (NSC) by a credentialed and qualified expert.

Second, we need to invest directly and consistently, over the next decade, in the capacities of low-income countries. The best approach to protect the American people is to stop outbreaks at the source. The Global Health Security Agenda has a proven track record in building health systems and health security preparedness in low- and middle-income countries, financed through a \$1 billion Ebola emergency supplemental funding. We recommend sustaining that success, not disrupting or curtailing it.

Create a new non-discretionary budget authority that assures sustainable investments independent of budget caps or the necessity of annual budget trade-offs.

We recommend that the U.S. government expand DTRA's geographic authorities to operate in all continents where health security threats exist. Furthermore, support for military overseas infectious research laboratories should be sustained. DOD biological research and development programs often focus on diseases not studied in other venues and result in medical countermeasures that would otherwise be delayed or not developed at all.

Congress should require national, state, and local governments to conduct regular preparedness exercises with updates to Congress on strengths and identified gaps in capacity.

The Commission also advocates that the U.S. government strengthen and adapt programs and capacities to deliver health services in fragile settings that meet the special needs of acutely vulnerable populations, elderly, women, and children.

It is also important to prioritize a "one health" research agenda, including significantly augmenting research to understand the intersection of human, animal, and ecosystem factors that promote the emergence and spread of infectious diseases and how to reduce and contain these threats. This would include expanding the investment in animal and environmental health surveillance for infectious diseases, modernizing global public health infectious diseases data systems and tools, and seeking predictive insights and preemptive interventions, not just countermeasures and emergency response capabilities.

The last area of priority concern is to plan strategically, with strong private-sector partners, to support targeted investments that will accelerate the development of new technologies for epidemic preparedness and response. We assert that the U.S. government should directly invest in the Coalition for Epidemic Preparedness Innovations, or CEPI, an international alliance that finances and coordinates the development of new vaccines to prevent and contain epidemics.

Again, thank you for the opportunity to testify in front of you today, and it is my sincere hope that we can work closely together to advance the U.S. health security agenda, so we are better prepared for the next pandemic.