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Nonproliferation
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“Biosecurity for the Future: Strengthening Deterrence and Detection.”

Chairman and Dr. Bera, Ranking Member Chabot, distinguished Members of the Subcommittee, thank you for the opportunity to offer testimony today on the “Biosecurity for the Future: Strengthening Deterrence and Detection.”

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As our country and the rest of the world continue to grapple with the devastating impacts of the COVID-19 pandemic, it is appropriate and important to put surveillance systems and strategies in place to detect in the future the emergence or re-emergence of dangerous viruses with pandemic potential. Because many infectious diseases are contagious and transmit between humans easily, infectious disease threats anywhere can universalize very quickly. We are now seeing firsthand that pathogens no longer travel at the speed of a steam ship; they travel at the speed of a jet. Borders are porous, and diseases seep through them quickly. The U.S. needs to have as comprehensive global situational awareness of infectious disease threats as possible.

As the US government decides how best to invest limited resources in early warning systems for detection of future viral threats, it is critical to prioritize surveillance activities that: (1) are most likely to uncover actual, rather than hypothetical, threats and (2) are practical and add value every day to preparedness, even between outbreaks. Too often, our limited surveillance dollars are funding overly broad surveillance and basic analysis that includes a vast collection of animal samples with the goal of identifying potential infectious diseases emanating from animals in spillover, or zoonotic events. Given the history of viruses such as SARS-CoV2, Nipah, Ebola, and HIV, zoonotic spill over events is an appropriate priority. However, focusing our surveillance efforts on the constant sampling of animals can be like looking for a needle in a never-ending haystack. While this type of surveillance can play a part in early warning systems and it helps us to improve our understanding of disease in animal species, we should be careful not to place an overemphasis on viral cataloging efforts. These are, indeed, essential virological and scientific tasks but should not be construed to be synonymous with early warning or a substitute for pandemic preparedness activities.

We should complement the broad sampling of animal species with a more targeted type of surveillance focused on sampling of viruses present in patients in clinical environments. A microbe most likely to cause a pandemic or a disruptive outbreak is likely one that possesses the ability to infect humans, to some extent, now. These are infections that are occurring in humans by pathogens that have the capacity to do so now. Such a microbe may go

unnoticed, mistaken for other causes, or occur in populations where diagnostic technology is not available. It may be spread via the respiratory route and cause a respiratory infection such as pneumonia. It may also have characteristics that can cause a brain or central nervous system infection like meningitis. And, and critically, it is likely to result in sepsis or septic shock as the final common pathway to severe disease and death.

These types of syndromes occur all over the world every day, even in the US. In some cases, we discover that the cause was a known pathogen such as pneumococcus, influenza, or the like. But the majority of these cases go without identification of the virus and without a specific diagnosis. The empiric treatment either works or it doesn't. This is something I commonly witness in the hospitals in which I round in the Pittsburgh area--it is much more common internationally.

This passive status quo makes us much more vulnerable to infectious disease threats. This vulnerability derives from the fact that we lack full situational awareness of the microbial threats that we are facing now and will face in the future. Testing people already sick to aggressively pursue a specific microbiologic diagnosis is not only practical, but high yield as it is aimed at uncovering, not theoretical threats that have not yet materialized, but ones already present.

I liken the undiagnosed syndromes to biological dark matter which likely contains key information about what is making people sick – some deathly – today, right now, everywhere. The first COVID-19 cases in Wuhan were mixed in with influenza and, because they are clinically indistinguishable, they were missed. This caused weeks delay in digging into more about this emerging novel virus. Imagine having even a few weeks head start on this pandemic. It would have translated to even faster scientific understanding, faster medical countermeasures, less economic disruption. A few weeks would have saved lives. The first U.S. cases of the novel influenza H1N1 virus that sparked the last flu pandemic in 2009 were only identified because the young children who were infected happened to go to a medical facility that was part of a U.S. Navy study that strived to figure out what viruses were making people sick, even mildly sick.

In many international locations, in which the US government and the Department of Defense have assets, infectious disease diagnosis is largely based on a generic syndrome such as pneumonia and first line medications are prescribed without a specific microbial diagnosis -- which organism is responsible -- but arrived at by local epidemiology (what is common) and clinical presentation. While this is valuable and astute clinicians are extremely valuable it is not enough. For example, during the 2013-2014 West African Ebola outbreak it was often emphasized that West Africa had not seen Ebola before (save one isolated case in the Ivory Coast) but by analyzing blood samples of those thought to have another viral hemorrhagic fever, Lassa Fever, revealed Ebola had been present for over a decade mixed in with Lassa. Imagine how useful that information would have been when health authorities in Guinea took 3 months to realize it was Ebola they were dealing with and not some virulent form of cholera. Lives could have been saved, epidemic curves bent, and spill into other countries prevented by an early warning followed by prompt containment strategies that had been deployed successfully in every prior Ebola outbreak.

Whether what is lurking in the biological dark matter is the first human foray for an emerging pathogen, a change in behavior of a known pathogen, or an ordinary infection that went undiagnosed it is valuable information. We need to commit and spend more time diving deep to understand this dark matter. It is a no regret investment because it is most likely to uncover actual, rather than hypothetical, threats and it is practical and will add value every day to preparedness, even between outbreaks.

The value is five-fold:

1. First, if it is a new emerging pathogen that is obscured because it is causing a familiar clinical syndrome, it's discovery could be an early warning for the entire world to look and prepare for it.
2. Second, if a new property has evolved in a known pathogen, it can be valuable clinical information that can inform care and possibly elevate the threat level of a previously known pathogen.
3. Third, many of these syndromes are treated with antibiotics injudiciously contributing to the world-wide antimicrobial resistance global crisis. Specific diagnoses allow antibiotics to be stewarded – and persevered – more easily.
4. Fourth, even if nothing strikingly new is gained by being aggressive with diagnosis it will add to the epidemiological knowledge of circulating pathogens which could help with public health priorities such as vaccines and also set a more accurate baseline so that aberrations from it could be detected more easily when pathogens change or emerge. The aggregate de-identified data generated alone, would be invaluable to epidemiology and preparedness.
5. Lastly, helping countries improve their infectious disease outcomes and gain epidemiological insight is a method of global health diplomacy.

I believe Congress should prioritize augmentation of diagnostic technologies as part of the international biosurveillance enterprise by specifying that a substantial proportion of funds devoted to these activities be directed towards enhancing every day health care facility diagnostic capacity. Additionally, Congress should direct agencies to view such activities as an integral part of U.S. preparedness for biological threats and not exclusively as humanitarian aid to improve international healthcare infrastructure.

I also want to emphasize that to make these diagnostic capabilities routine does not require sophisticated futuristic machines. The technology and tools exist today and are being used in healthcare facilities every day. In the past several years, technology has improved to such a degree that sophisticated molecular detection techniques such as PCR or the equivalent, can be done at home by an untrained person. Diagnostic panels that check for a multitude of organisms all at once can not only be done in an ordinary hospital lab, but even at the point-of-care. These machines exist now and are used routinely in many hospitals and medical facilities around the globe. Some of them can be used point-of-care with little training. As such, they will not require constructions of fancy labs but could be as simple as just

augmenting diagnostics laboratories that already exist. The Defense Threat Reduction Agency (DTRA) Cooperative Biological Engagement Program (CBEP) had placed a major priority on augmenting host country diagnostic capacity and these programs have had positive impacts, but they should not be narrowly construed as only early warning systems for exotic or biothreat organisms. The ability to improve routine infectious disease care will, as I have argued, naturally, also have major implications for early detection of all infectious disease hazards. The interconnection and dependency of U.S. domestic infectious disease response on international detection and characterization of COVID-19 variants such as Omicron, achieved through ordinary sampling of people ill with COVID-19, concretizes this fact.

When considering how to optimize biosurveillance capabilities internationally and deploy technology and data tools, there is a lot of value in augmenting ordinary clinical diagnostic capabilities. While it may need seem as cutting edge as trapping animals, exploring caves, and searching for gorilla droppings, the cascading benefits that will be realized will not only make clinical care better internationally, but make the US more situationally aware and, therefore, more prepared and ultimately safer.