

“Facing 21st Century Public Health Threats: Our Nation’s Preparedness and Response Capabilities, Part 2”

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Before the Senate Health, Education, Labor and Pensions Committee

January 23, 2018

Introduction

Good morning Mr. Chairman, Ranking Member Murray, and members of the committee. My name is Brent MacGregor and I am the Senior Vice President of Commercial Operations for Seqirus. I appreciate the opportunity to appear before you today as you prepare to consider the second reauthorization of the Pandemic and All Hazards Preparedness Act (PAHPA). I would like to focus my remarks on the importance of preparedness against pandemic influenza and the critical role played by the Biomedical Advanced Research and Development Authority (BARDA) and its industry partners.

Seqirus is a global leader in the development and manufacturing of influenza vaccines. With extensive research and production expertise and facilities in the U.S., U.K. and Australia, Seqirus is a committed partner in pandemic preparedness and a major contributor to the prevention and control of influenza globally. Seqirus' influenza vaccine business comprises a workforce of over 3,000 employees, significant manufacturing capacity, a commercial presence in twenty countries, and product and geographic diversity. We are the only influenza vaccines manufacturer with the flexibility of two scaled up production technologies, including, cell-based vaccines.

Our long-established parent company, CSL Limited, has a rich heritage in influenza dating back to the Spanish flu pandemic. As you may know, this year marks the 100th anniversary of the 1918 pandemic, which killed more than 50 million people and represents one of the deadliest natural disasters in human history. It is especially timely for this committee to be considering how the U.S. can be better prepared against pandemic influenza in the future.

I would like to highlight Seqirus' state-of-the-art vaccine production facility in Holly Springs, North Carolina. Thanks to the leadership of Senator Burr, members of this committee, and the dedicated team at BARDA, we believe the Holly Springs facility is one of the best examples of a public-private partnership envisioned by the authors of PAHPA when it was originally signed into law in 2006.

I would also like to highlight Seqirus' proprietary adjuvant MF59® which boosts response, and broadens vaccine match as well as enabling dose-sparing of vaccine antigen. MF59® is a

cornerstone of broader access to pandemic influenza vaccines and part of BARDA's pandemic preparedness and response stockpiling strategy. We believe it is critical to manage MF59 as a long term asset within the pandemic preparedness enterprise which means that it needs a life cycle management strategy consistent with industry standards.

We are currently working with BARDA to manufacture candidate vaccines against the H7N9 strain circulating in China. Last week, testifying before this committee, the Assistant Secretary for Preparedness and Response, Dr. Kadlec, highlighted his concern with the ominous trends that they are seeing with the evolution of the H7N9 strain.

Seqirus believes it is critical that PAHPA be reauthorized in a timely manner to ensure BARDA has the resources it needs to continue its unique national security mission at the Department of Health and Human Services (HHS). We also strongly believe that the committee's reauthorization of PAHPA should finally include an authorization of BARDA's pandemic influenza program. Despite representing the "P" in PAHPA, authorized funding for pandemic influenza preparedness has never been included in this legislation.

Similar to medical countermeasures against chemical, biological, radiological, and nuclear (CBRN) threats, there is no commercial market for pandemic influenza vaccines. Seqirus relies on our partnership with the U.S. government to make continued investments in research, development, infrastructure, and vaccine production. Authorizing BARDA's pandemic influenza program and providing robust, sustained annual funding for the program would send a clear signal to the private sector that the United States is committed to preparedness against pandemic influenza.

Seqirus also supports the PAHPA reauthorization priorities identified by the Alliance for Biosecurity, to which I am privileged to be a Co-Chair, and by the Biotechnology Innovation Organization (BIO). These priorities include multi-year funding for the Project BioShield Special Reserve Fund (SRF) and increased funding for BARDA's advanced research and development programs, including for emerging infectious diseases and antibiotics. Finally, I would like to thank the members of this committee for all the work they have done to support HHS'

preparedness enterprise since the last PAHPA reauthorization, including making important changes to BARDA's contracting process in last year's 21st Century Cures Act.

PAHPA has been a success since it was first passed by Congress in 2006. The biodefense enterprise created at HHS over the last 12 years has greatly improved our nation's security. From the perspective of a manufacturer, this enterprise has made it more attractive to invest in partnerships with the U.S. government. However, there are areas where the medical countermeasure (MCM) enterprise could be improved.

At the beginning of this process, industry partners with the National Institutes of Health (NIH) to conduct basic research and discovery. These public and private investments often yield promising MCM candidates which can progress to advanced development with BARDA. While BARDA has improved its communication with industry partners to ensure smooth transitions, better coordination and communication within the government could improve the ability to provide end-to-end certainty to government partners. In recent years, BARDA has focused on the promise of platform technologies which can speed up development timelines and provide rapid response capabilities in an outbreak.

Because there is no commercial market for MCMs, the procurement funding provided by the Project BioShield Special Reserve Fund (SRF), the Strategic National Stockpile (SNS) and BARDA's pandemic influenza program provides manufacturers with market certainty after investing for many years in research and development. However, the lack of multi-year funding has created uncertainty in the long term sustainability of some medical countermeasures programs. And importantly, the Food and Drug Administration's (FDA) dedication to addressing the unique challenges of MCM development has given companies confidence that MCM candidates can ultimately gain licensure. FDA approval is an important milestone for companies and a key public health goal for the government.

Of course, this process is not perfect and can certainly be improved. The overall structure created by PAHPA has enabled dynamic public-private partnerships to thrive, but these partnerships must be sustained over time through a demonstrated commitment by the federal government.

Seqirus is just one example of how a partnership with BARDA could be successful in the pandemic influenza space. There are dozens of other companies – both large and small – that have committed to BARDA’s mission and made significant new investments in MCM development. Reauthorization of PAHPA’s authorities and a renewed commitment to MCM development funding will ensure these investments yield even more approved MCMs.

The Threat of Pandemic Influenza

As members of this committee know well, one of the most urgent public health threats we face as a nation is pandemic influenza, a constantly changing global viral threat. It is often forgotten that the 2009 H1N1 pandemic, a relatively mild pandemic, killed more than 12,000 Americans and hospitalized 300,000 more. The cost to our citizens, our economy, and our security was incredibly high. It is not a matter of if, but when, the next pandemic strikes.

Pandemic influenza is not just a public health threat; it is indeed a national security threat. Ensuring we are prepared to respond to an influenza pandemic is critical to our national and economic security. The World Bank has estimated that a severe global influenza pandemic could cost nearly five percent of global GDP.

To be ready when a pandemic is declared, we have to invest in R&D for new and better influenza vaccines, to invest in, and sustain, the manufacturing surge capacity to rapidly produce more than 600 million doses of matched virus – two for every American, and we have to maintain stockpiles of vaccine against circulating pre-pandemic strains so we can protect first responders and essential personnel during the time it takes to manufacture matched vaccine.

Pandemic influenza is related to seasonal influenza, but is also different in many significant ways. Most importantly, new pandemic influenza strains show up across the globe in real-time, emerging from animal to human transmission of strains new to our immune system. Because there is no commercial market to develop vaccines against these new pandemic strains, the U.S. government must work with private sector partners to ensure vaccines against these strains are

available if an outbreak occurs. This process of developing pandemic influenza vaccines requires a robust partnership between the government and the private sector. We are proud of our decade-long partnership with BARDA to ensure the United States is prepared to respond to a pandemic influenza outbreak.

Unfortunately, funding for preparedness against pandemic influenza threats has been episodic since 2009. The vast majority of funding provided to the Department of Health and Human Services (HHS) for pandemic influenza was in emergency supplemental legislation during the 2004, 2005, and 2009 outbreaks. These emergency funds helped stand up critical response efforts at HHS, but are now fully exhausted. Since that time, annual funding for HHS' pandemic influenza readiness programs have dramatically declined. It is critical that our domestic influenza manufacturing capabilities are strengthened and sustained, and private sector partners see a renewed commitment from Congress and HHS.

Seqirus' Pandemic Influenza Partnership with BARDA

In 2007, BARDA partnered with Seqirus (then Novartis) in the construction of a new influenza vaccine manufacturing facility in Holly Springs, North Carolina. Seqirus currently has several contracts with HHS to (1) complete advance stage development of antigen-sparing capability for pandemic influenza vaccination; (2) facilitate domestic vaccine capability with more rapid response and with greater surge capacity in the event of an influenza pandemic; (3) stockpile pandemic vaccine supplies; and (4) develop a synthetic influenza seed process for rapid pandemic response.

The Holly Springs facility will quickly surge domestic production capacity of pandemic influenza vaccine to combat public health emergencies. The facility has been designed to provide pandemic vaccines to protect one third of the US population, within six months of the declaration of a pandemic.

The facility employs approximately 500 high-skilled workers to produce both pandemic and seasonal influenza vaccines using innovative cell culture-based manufacturing technologies. We

believe Holly Springs is one of the most successful public-private partnerships between industry and BARDA. The total investment in the facility committed by both Seqirus and BARDA has now surpassed \$1 billion. The innovations developed at Holly Springs – like new, cell-based flu vaccines – are critical to improving U.S. preparedness.

Seqirus is a Leader in the Development of Innovative, Cell-Based Vaccines Technologies

How well flu vaccines work can vary from season to season. One of the main factors that impact flu vaccine effectiveness is the “match” between the viruses that the flu vaccine is designed to protect against, and the flu viruses spreading in the community.

How closely the vaccine is “matched” to circulating strains can be impacted by changes in the circulating viruses between the time the influenza vaccine was manufactured and the public is vaccinated, as well as changes that can take place in the influenza vaccine production process.

The majority of currently available influenza vaccines globally are manufactured using egg-based technology, and work reasonably well. However, the viruses used by manufacturers to start the production process can undergo changes when optimized for growth in eggs. When this occurs, the resulting vaccine may not be as closely matched to the circulating virus as would be preferred, which can reduce the level of protection against influenza infection.

The influenza vaccine industry is pursuing several new technologies to improve vaccine effectiveness. One of the new technologies used by Seqirus is a cell-based influenza vaccine manufactured in the United States. Cell-based influenza vaccines are not subject to egg-adaptation issues, and may therefore be more closely matched to circulating viruses. We believe the use of cell-based influenza vaccines in future flu seasons and flu pandemics has the potential to significantly improve vaccine effectiveness, and as a result, save more lives.

PAHPA reauthorization Must Include BARDA’s Pandemic Influenza Program

Over the last 13 years, Congress has passed three separate emergency supplemental bills providing \$13.2 billion in funding to respond to the threat of pandemic influenza. This funding sustained HHS programs to develop and purchase flu vaccines, antivirals, and necessary medical supplies. The funding also supported the construction and renovation of manufacturing facilities for the production of pandemic influenza vaccines to secure sufficient supplies for the U.S. population.

For more than a decade, HHS has relied on and drawn down balances from supplemental appropriations bills to fund pandemic preparedness. These balances are now exhausted. Since the passage of these three emergency supplemental bills, sustained resources for HHS' pandemic flu readiness programs have dramatically declined. This has led to an aging stockpile that doesn't match currently circulating strains, critical adjuvants such as our MF59 that are expired, domestic manufacturing capabilities that must be sustained, and private sector partners who aren't sure if HHS is committed to this partnership that is so critical to the nation's readiness.

In order to successfully prepare against a future influenza pandemic, Seqirus believes Congress should finally enact a permanent authorization of BARDA's pandemic influenza program in the reauthorization of PAHPA. This authorization is necessary to support research and development of new influenza technologies, regularly test and evaluate rapid response capabilities for known and new pandemic threats, and maintain influenza stockpiles of vaccine and therapies. Having a program authorized by Congress will also provide a clear signal to the private sector that the U.S. government is committed to preparing against pandemic threats.

BARDA's most recent five-year budget outlined \$630 million in pandemic influenza funding needs for Fiscal Year 2019 alone. We believe an annual authorization level of at least \$535 million is needed to support HHS' most critical pandemic influenza activities. These activities include pandemic vaccine stockpile maintenance, diagnostic research, infrastructure improvements, universal flu vaccines research, and flu therapeutic research.

Conclusion

We believe tremendous progress has been made to ensure Americans are better protected against the threat of pandemic influenza, and Seqirus is excited about the future of our partnership with BARDA.

I would like to thank members of this committee, and in particular Senator Burr, for their commitment to reauthorizing PAHPA in a timely manner. This is a critical opportunity for Congress to ensure BARDA has the resources it needs to prepare against of the most predictable threats we face as a nation.

I look forward to serving as a resource for this committee during the PAHPA reauthorization process, and I am happy to answer any questions you may have today. Thank you.