CHIMERIX

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July 11, 2018

Congress of the United States
House of Representatives
Committee on Energy and Commerce
2125 Rayburn House Office Building
Washington, DC 20515-6115

Re: Reauthorizing the Pandemic and All-Hazards Preparedness Act

Dear Mr. Butler:

In response to the questions submitted by the Energy and Commerce Subcommittee on Health on June 26, 2018, please find the attached responses.

Very truly yours,

M. Michelle Berrey, M.D., M.P.H.
Chimerix, Inc.
President and Chief Executive Officer

Q: Do you all believe that current law puts some constraints on how BARDA is able to partner new companies and new technologies?

a. Follow up: Can you explain to me the limits of BARDA's authority to work with companies developing non-therapeutic technologies to counter antibiotic and antimicrobial resistance?

b. Follow up: Do you believe giving BARDA the flexibility to work with companies more broadly would be beneficial to BARDA as they work to achieve their mission to counter anti-biotic and antimicrobial resistance?

A: Given the growing public health and economic burdens posed by antimicrobial resistance (AMR), there is an urgent need to reinvigorate the antimicrobial pipeline. This is particularly critical given the long development times (10-15 years) for new medicines and vaccines. There is a consensus among stakeholders worldwide that multifaceted solutions are needed to reinvigorate antibiotic development and other approaches to addressing AMR. As such, the Alliance for Biosecurity supports measures for novel market based incentives that are sustainable and will adequately strengthen the research and development pipeline. Such incentives through BARDA will advance innovation in, and accelerate and support the advanced research, development, and procurement of, countermeasures and products to address, among other threats, AMR.

Q: In your written testimony you discussed how the passage of the Project Bioshield Act, then PAHPA, created a market for medical countermeasures for the first time that created incentives for companies to develop countermeasures. In your view, do you believe this legislation will help industry research and develop the therapies necessary to combat the biomedical threats facing this nation? In your past experiences, what have been some of the challenges your company has faced to develop countermeasures?

We absolutely believe that this legislation will help industry to develop new therapies. There is no commercial market for smallpox countermeasures. If the Project BioShield Act and PAHPA had not created incentives and a government market for medical countermeasures, companies like ours (small cap, pre-revenue) would not be able to invest the time and resources in developing these products. The business of identifying and developing new drugs is a risky and capital-intensive proposition. With no commercial revenue streams, we rely on outside investment to fund the advancement of our product pipeline. It is the promise of a government market that attracts this investment. Putting these pieces together, it is the promise of a governmental market that makes our development of a medical countermeasure possible.

Perhaps even more importantly, BARDA's direct investment has helped bridge the drug development "valley of death" and attract private investment at a stage when committing resources is particularly risky. The draft legislation's support for increased, multi-year funding for the Project BioShield Special Reserve Fund and increased funding for BARDA's research and development efforts will help ensure that this record of success continues into the future.

With respect to our past experiences, we have faced two primary challenges. The first is one that is common to all small companies developing medical countermeasures—the availability of capital. As noted above, our business has extremely long timelines and is highly capital-

intensive. We confront this issue on a daily basis and it affects everything that we do. While this legislation will not resolve all of our capital issues, restoring multi-year funding for Project BioShield will send an important signal to investors, and we commend Congress for taking this step. The second issue that is more specific to our company and our lead compound is the challenge of developing a drug for dual use: Brincidofovir is currently being developed not only for a biodefense indication (treatment of smallpox infection) but also for a commercial medical indication (treatment of a life-threatening viral infection in transplant recipients). Pursuing a dual-use helps leverage scarce federal dollars by procuring private sector investment as well as helping to ensure our continued viability as a company. However, this approach also brings certain regulatory and administrative challenges that we are working to address.

Q: What assistance has Chimerix received from the federal government in the development of your product, brincidofovir?

A: (see below)

Q: How much of the research and development costs related to brincidofovir have been secured from private sources?

A: To date, $655 million has been secured from private sources for the research and development of brincidofovir for the treatment of adenovirus, cytomegalovirus, BK virus and other viral infections. For our smallpox program, we have been fortunate to receive $92 million in funding from the U.S. National Institute of Asthma and Infectious Diseases (NIAID) and the U.S. Biomedical Advanced Research and Development Authority (BARDA), which represents about 12 percent of the total investment made to date in the brincidofovir development program.

Q: Do you believe that providing stable, advance appropriations for medical countermeasure development and procurement would be a sufficient incentive to encourage other manufacturers to enter the biodefense space?

A: Yes. Stable government funding is absolutely critical to the development and procurement of medical countermeasures, and the original ten-year advance appropriations for Project BioShield was very helpful in this regard. The transition of the program to annual appropriations introduced substantial uncertainty for private sector partners and decreased the average scope and size of awards. We believe that the return to advance appropriations will help enable and sustain long-term investment in the research and development of medical countermeasures, and we thank the Committee for including this provision. Having the ability to report on future cash flows would encourage small, pre-revenue companies like ours to enter this space and attract additional investment from the private sector.