



The Alliance for Biosecurity (Alliance) appreciates the Trump Administration's efforts to increase U.S. manufacturing of "essential drugs," medical countermeasures (MCMs), and other medical supplies. However, the Alliance is concerned that, despite the intention behind President Trump's Executive Order on Ensuring Essential Medicines, Medical Countermeasures, and Critical Inputs Are Made in the United States (Executive Order), without appropriate safeguards the impact of the Executive Order as signed by the President could be to impede America's preparedness efforts and ability to innovate.

As you know, the Alliance is a coalition of biopharmaceutical companies and laboratory/academic partners that promotes a strong public-private partnership to ensure MCMs are available to protect public health and enhance national health security. The Alliance advocates for public policies and funding to support the rapid development, production, stockpiling, and distribution of critically needed MCMs.

To that end, as the Department of Health and Human Services (HHS) seeks to implement this Executive Order, the Alliance is concerned about the impact that an approach requiring solely domestic manufacturing for specialized MCMs might have on U.S. preparedness and innovation. Moreover, the Executive Order is likely to have an outsized impact on smaller biotech companies. For example, one Alliance member company has raised concerns about the challenges the Executive Order would pose for establishing a domestic manufacturing and supply chain for a certain antibiotic, which is formulated into its final drug product. Currently, the company does not have the capacity to produce the antibiotic, nor can the antibiotic be sourced in the United States. This threatens to limit innovation in the antibiotics space, which is currently being driven by small biotech companies, and puts potentially devastating constraints on U.S. preparedness efforts.

Moreover, as HHS considers the specifics of implementing the Executive Order, the Alliance believes that HHS should first provide additional information about various of its provisions to allow for proper consultation with industry to ensure that the goal of increasing U.S. manufacturing capacity of "essential drugs," MCMs, and other medical supplies is accomplished without negatively impacting American preparedness and innovation. Specifically, the Alliance urges HHS to provide clarity about: (1) the waiver process, including the timing of when that process will be implemented and logistics of how the process will work; (2) whether the Executive Order would apply to options on existing contracts; (3) how U.S. manufacturing will be defined; and (4) what MCMs will be classified as essential.

Finally, the Alliance suggests that HHS consider that there is a need moving forward, if the Executive Order is to be fully implemented, to establish manufacturing capacity in the United States that can be utilized by product developers and to provide financial assistance/incentives for them to transition their manufacturing capacity to the United States, such as the reestablishment of tax incentives that spur domestic manufacturing and plant construction. Without the domestic capacity, there are in some instances, no viable options for product developers to make this change.

Alliance for Biosecurity

As you know, the Alliance considers itself to be a partner with the U.S. Government in securing our nation from biosecurity threats and looks forward to working with you to strike an appropriate balance between incentivizing domestic manufacturing and at the same time moving forward U.S. preparedness and innovation.

Sincerely,

A handwritten signature in black ink that reads "Jack Kingston". The signature is written in a cursive style with a large initial "J" and "K".

The Honorable Jack Kingston
Squire Patton Boggs
Secretariat, Alliance for Biosecurity