



May 7, 2025

Via Electronic Submission

Mr. Eric Longnecker
Deputy Assistant Secretary for Technology Security
Bureau of Industry and Security Department of Commerce
1401 Constitution Ave. NW
Washington, DC 20230

**Re: Notice of Request for Public Comments on Section 232 National Security
Investigation of Imports of Pharmaceuticals and Pharmaceutical Ingredients**

[Docket No. 250414-0065] XRIN 0694-XC120

Emergent BioSolutions Inc. (Emergent) is a global life sciences company, headquartered in the United States (U.S.), whose mission is to protect and save lives. Our approximately 900 employees develop, manufacture, and deliver medical countermeasures (MCMs), as well as lifesaving opioid overdose reversal medications. For more than 25 years, we have been partnering with the U.S. and allied governments to protect warfighters and civilians from man-made and naturally occurring health threats like anthrax, botulism, smallpox and opioid overdoses, including those caused by fentanyl. Our partnership with the U.S. government is foundational to the country's national security.

Emergent shares the administration's national security goals, including the urgent need to reduce dependence on foreign adversaries by reshoring and "friendshoring" key elements of the pharmaceutical supply chain. Emergent proudly manufactures most of our medicines in the U.S. and stands ready to fulfill the needs of the U.S. government in protecting the public and the military.

MCMs are explicitly designed to address national security challenges. These medicines protect Americans from the dangers posed by chemical, biologic, radiologic or nuclear threats and emerging infectious diseases. High-priority, category A threat agents identified by the U.S. government include smallpox, anthrax and botulism. All of Emergent's manufacturing facilities are either based in the U.S. or are U.S.-Mexico-Canada Agreement (USMCA)-compliant. We manufacture our anthrax and smallpox MCMs in facilities in Michigan and Massachusetts and remain committed to maintaining our U.S. footprint. Additionally, we have lab-scale development and large-scale commercial manufacturing capabilities and sites that we can use to support onshoring for companies looking to increase U.S. manufacturing.

EMERGENT®

Emergent manufactures four FDA-approved anthrax medicines. In 2001, Americans were killed in a bioterrorist attack when anthrax spores were mailed to U.S. government and media buildings, including the U.S. Senate office buildings.¹ In response to this deadly attack, U.S. defense health leaders invested in countermeasure development and stockpiling. National security experts agree the threat of weaponized anthrax remains a top national security concern.² Anthrax is especially dangerous because it can survive for long periods of time, is easily dispersed, and can cause fatal infections when inhaled.³

Emergent also manufactures a primary smallpox product designated for use in a bioterrorism emergency and has supplied millions of doses to the U.S. Strategic National Stockpile.⁴ With a 30 percent mortality rate, smallpox is considered by the U.S. intelligence community to be one of the most significant biological threats.⁵ While smallpox was eradicated in 1980, the virus continues to exist in research laboratories in certain countries and can be synthetically developed for use as a bioweapon.⁶ Funding challenges have slowed replenishment of the smallpox national stockpile, intended for use in a mass outbreak event.^{7,8} Many biodefense experts agree the country is not adequately prepared to respond to a large-scale outbreak.⁹

Opioids, including synthetic ones like fentanyl, are well known for their heartbreakingly lethal toll on America's communities. Emergent makes NARCAN® Nasal Spray, the market leading naloxone product to rescue opioid overdose patients. Fentanyl and its analogues have been investigated as incapacitating agents by a number of governments, including the U.S. Department of Defense (DOD). While fentanyl has not been declared a weapon of mass destruction, National Defense University experts agreed in 2019 that fentanyl compounds could be used as chemical weapons.¹⁰

Most MCMs have a limited or nonexistent commercial, or private, market, and government agencies are the sole purchasers. The importance of the U.S. government as a partner and purchaser to companies developing and manufacturing MCMs cannot be overstated. It takes approximately 10-15 years to develop a new medicine, and the average cost of developing a new drug is estimated at between \$1 billion¹¹ and \$2.3 billion.¹² Companies must have a market to ensure there is a return on this significant investment and a sustainable business

¹ [National Defense University - Anthrax in America](#)

² [CSIS – Twenty Years of Project BioShield](#)

³ [FDA – Anthrax](#)

⁴ [Emergent BioSolutions' ACAM2000®, \(Smallpox and Mpox \(Vaccinia\) Vaccine, Live\) Receives U.S. FDA Approval for Mpox](#)

⁵ [Smallpox as a Weapon for Bioterrorism](#)

⁶ [Bipartisan Commission on Biodefense- Smallpox remains a threat](#)

⁷ [U.S. FDA – Smallpox Preparedness and Response](#)

⁸ [Smallpox vaccines: past, present and future](#)

⁹ [20 Years after the anthrax attacks, We're still unprepared](#)

¹⁰ [National Defense University - Fentanyl](#)

¹¹ [ASBMB Today: 90% of drugs fail in clinical trials](#)

¹² [Deloitte: Measuring Return from Pharmaceutical Innovation](#)



model. For most medicines, that solution is the commercial market; however, for MCMs, that solution is government partnership and procurement.

Importantly, Emergent strives to provide our products to the U.S. government at the lowest price. Companies that provide medicines in a commercial marketplace may have flexibility to pass costs associated with tariffs to other stakeholders in the supply chain. Emergent, however, supplies critical MCMs to the U.S. government through fixed-price contracts, which cannot be unilaterally modified. As the importer, Emergent would bear the full cost of tariff-associated increases.

Emergent is proud that most of our products are manufactured in the U.S. using technology developed here. While it may be feasible to restructure pharmaceutical supply chains to move an entire manufacturing supply chain to the U.S., time and money are significant barriers. Transferring a single product to a different manufacturing site has significant time and cost associated with it, heavily dependent on dosage form, the complexity of the manufacturing process, and other factors. Transferring large numbers of products would require either major retrofits of existing facilities or new facilities to be built. Building a new manufacturing facility can cost up to \$2 billion and it can take five to ten years before it is operational.¹³

For a medium-sized company, like Emergent, which relies heavily on U.S. government partnership to purchase its MCMs, government funding to cover the costs of this type of transfer would be critically important, especially given the often inconsistent and opaque demand patterns for these products. Additionally, a longer-term timeline to allow for careful planning would be helpful in considering implementing changes to our supply chain.

Emergent urges a strategic and phased approach to protecting U.S. manufacturing that enhances public-private collaboration. Emergent has certain products, or a key component of its products, that rely on a portion of the manufacturing process in an allied country, which would be negatively impacted by tariffs on the sector. Emergent respectfully urges the administration to consider keeping USMCA-compliant products tariff-free.

Emergent receives no meaningful incentives from other nations to bolster its supply chain. Increased costs throughout the manufacturing process could potentially disrupt Emergent's ability to sustainably provide MCMs to protect Americans from potential chemical and biological threats. This could be mitigated via the inclusion of FAR 52.229-3, which enables key products such as these MCM products to be exempt from potential tariffs.

¹³ [PhRMA – Biopharmaceutical Manufacturing](#)



NARCAN® Naloxone HCl Nasal Spray 4 mg, which is approved by the FDA as an over-the-counter treatment for lay people to restore breathing in victims of suspected opioid overdoses, including those caused by fentanyl¹⁴, is manufactured in the U.S.; however, certain device components are manufactured by suppliers in Europe. In particular, the actuator, which is the key element in ensuring proper dose delivery, is manufactured by the accepted industry leader in France. That supplier is working to move some manufacturing capacity to the U.S., but it might not be enough to fully supply the U.S. market.

TEMBEXA® (brincidofovir) Emergent is under contract with the U.S. government to manufacture and supply two forms of TEMBEXA®, which is indicated for treatment of smallpox virus in humans, including pediatric and neonatal indications.¹¹ The Active Pharmaceutical Ingredient is manufactured in Canada, the tablet dosage form is manufactured in the UK, and the suspension dosage form is manufactured in the U.S.

Blood PLASMA-Derived Therapeutics Emergent is under contract with the U.S. government to manufacture and supply two Plasma-derived therapeutics for the treatment of botulism and potential complications resulting from a smallpox vaccine (BAT® and VIGIV®) and has previously supplied a third product (AIG®).¹¹ The most important component, with the largest cost, of the BAT® and VIG® production is the plasma collection effort, which is conducted entirely within the U.S. via commercial and academic partnerships. The manufacturing process is performed in an Emergent-owned, state-of-the-art, plasma fractionation facility in Canada.

It is critical that the U.S. government maintains its ability to safeguard the public and the warfighter against high-priority threats. Medical countermeasures are foundational to enhancing national security. Emergent is proud of its longstanding commitment to manufacturing most of its medicines in the U.S. and would be pleased to use its development and manufacturing capabilities and capacity to partner with companies looking to increase their U.S. manufacturing. Imposing tariffs without financial support, or a relevant tariff exemption, from the U.S. government could jeopardize Emergent's ability to sustainably provide cost-effective MCMs to the U.S. government and worldwide, potentially endangering preparedness, a critical component of national security.

¹⁴ [Emergent BioSolutions Product Information](#)