

Background and Summary of the *Disease X Act of 2023*

Infectious disease outbreaks now occur three times more often than 40 years ago.¹ As noted in the latest Threat Assessment² by the intelligence community, drivers for natural disease emergence persist and are on the rise, and rapid advances in dual-use technology, including bioinformatics, synthetic biology, nanotechnology, and genomic editing, could enable the development of novel biological weapons that complicate detection, attribution, and treatment.

Whether a future pandemic threat is naturally occurring, accidentally released, or deliberately caused, our best defense will be safe and effective medical countermeasures – drugs, vaccines, and diagnostics. Not only do the development of such countermeasures aid in pandemic response, but they also serve as a deterrent against the development of biological weapons by adversaries and bad actors due to the availability of such countermeasures.

Unfortunately, there is no sustained funding, program, or strategy dedicated to accelerating the development of medical countermeasures for previously unidentified infectious disease threats, referred to here as Disease X.³ Viral pathogens with pandemic potential can dramatically affect the American public, military personnel, and our economic and national security.

Existing programs at HHS are primarily directed towards specific, known, high-priority health security threats (including chemical, biological, radiological, nuclear threats, and pandemic influenza). This is in part due to prior statutory priorities and in part due to demand-side incentives through Project BioShield.⁴ Since Disease X medical countermeasures do not have a commercial market that drives private sector investment, it is essential that a sustainable public-private partnership model and dedicated funding be created to share the development risk and incentivize industry to develop platform technologies and new medical countermeasures for viral families with pandemic potential.

The *Disease X Act of 2023* protects Americans by establishing a Disease X Medical Countermeasures Program at the Biomedical Advanced Research and Development Authority (BARDA) in HHS by: (1) clarifying that HHS may award contracts, grants, and cooperative agreements, or enter into other transactions, to promote the development of Disease X medical countermeasures for viral families with pandemic potential; and (2) directing BARDA to accelerate and support the advanced research, development, and procurement of countermeasures and products to address Disease X threats.

¹ <https://centerforhealthsecurity.org/our-work/research-projects/disease-x-medical-countermeasure-program>.

² <https://www.dni.gov/files/ODNI/documents/assessments/ATA-2023-Unclassified-Report.pdf>.

³ <https://centerforhealthsecurity.org/our-work/research-projects/disease-x-medical-countermeasure-program>;
<https://cset.georgetown.edu/publication/viral-families-and-disease-x-a-framework-for-u-s-pandemic-preparedness-policy/>.

⁴ <https://www.medicalcountermeasures.gov/barda/cbrn/project-bioshield>.