

November 10, 2023

The Honorable Charles Schumer  
Majority Leader  
U.S. Senate  
S-221, The Capitol  
Washington, D.C. 20510

The Honorable Mike Johnson  
Speaker of the House  
U.S. House of Representatives  
H-232, The Capitol  
Washington, D.C. 20515

The Honorable Mitch McConnell  
Republican Leader  
U.S. Senate  
S-230, The Capitol  
Washington, D.C. 20510

The Honorable Hakeem Jeffries  
Democratic Leader  
U.S. House of Representatives  
H-204, The Capitol  
Washington, D.C. 20515

Dear Majority Leader Schumer, Republican Leader McConnell, Speaker Johnson, and Democratic Leader Jeffries:

We write to stress the imperative need to retroactively reauthorize the expired Medical Countermeasures (MCM) Priority Review Voucher (PRV) program along with other critical expiring provisions which are pivotal elements of our national health preparedness infrastructure. The PRV program is vital in stimulating the development of innovative products essential for intervening in infectious diseases, whether arising from intentional threats or natural occurrences. Many of these countermeasures, crucial for our biosecurity, face the risk of neglect due to lack of a commercial market. The PRV program is central to overcoming these market failures by incentivizing the creation of these essential medical countermeasures through the expedited review of a subsequent product.

The program's recent expiration and this call for reauthorization coincides with the expiry of other crucial health readiness programs. Funding authorizations for the Biomedical Advanced Research and Development Authority (BARDA), the Strategic National Stockpile (SNS), and the Hospital Preparedness Program are also approaching their sunset. The National Disaster Medical System, which equips our nation with a robust response team of personnel, equipment, and supplies in partnership with hospitals, is at risk. These programs, alongside the MCM PRV, represent the backbone of our ability to respond to health emergencies and must be maintained to assure national resilience. Moreover, there is precedent for including temporary, clean reauthorization of PRVs in a Continuing Resolution (CR).<sup>1</sup>

The reauthorization of the MCM PRV program is a key tool for fostering innovation and addressing unmet medical needs, having significantly shortened the time required for critical new drugs to ensure we are prepared for the next threat. By renewing this program, alongside other expiring provisions, Congress can ensure the sustained momentum of medical innovation

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<sup>1</sup> The FY2021 CR (through December 11, 2020) extended the FDA Rare Pediatric PRV through the duration of the CR. Sec. 2105 of PL 116-159

and preparedness that safeguards our nation. Such decisive action will serve as a reaffirmation of America's dedication to advancing medical treatments and maintaining global leadership in health innovation.

We implore you to act with the utmost urgency in reauthorizing the MCM PRV program and the other mentioned provisions. Together, they form an indispensable framework for our continued progress in combating the world's most pressing health threats.

Yours sincerely,

Aequor Inc.

Anivive Lifesciences, Inc

Atea Pharmaceuticals, Inc.

Battelle

Biotechnology Innovation Organization (BIO)

Humanetics Corporation

Invivyd, Inc.

Medical Countermeasures Coalition (MC2)

Novavax

PharmaJet, Inc.

SAB Biotherapeutics, Inc.

SIGA Technologies, Inc.

Soligenix, Inc.