

July 12, 2023

Via Electronic Mail – Hannah.Berner@Hickenlooper.Senate.gov

Re: CBSA Letter Regarding PAHPA Concerns

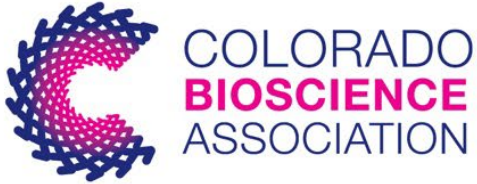
Dear Senator Hickenlooper:

On behalf of Colorado BioScience Association (CBSA), I am writing to express the Colorado life sciences community's concerns with and opposition to several provisions included in the Senate HELP Committee's draft of the 2023 Reauthorization of the Pandemic and All-Hazards Preparedness Act (PAHPA).

The PAHPA Reauthorization discussion draft included several concerning provisions, outside of bipartisan agreement, that could undermine the purpose and intent of the program to protect our country, were they to be advanced. Specifically, we are opposed to Sections 601 and 602 in the Chairman's proposal that require all Biomedical Advanced Research and Development Authority (BARDA) and Centers for Disease Control (CDC) - supported products be sold to the Federal Government or in the U.S. commercial market at the lowest price among G7 countries and at a "reasonable price." If enacted, these provisions would effectively shut down private sector investment and the type of public-private partnerships that are vital to the development of life-saving medical countermeasures (MCMs). This is especially true for many MCMs that have a limited commercial market or no commercial market and rely on these partnerships. This means that our nation's intelligence, defense, and healthcare agencies will lack the tools they need to defend all Americans from chemical, biological, radiological, and nuclear threats, including threats from our adversaries, and to be better prepared for future pandemics. History has shown us that "reasonable pricing" clauses at National Institutes of Health (NIH) have been attempted but quickly failed. These attempts resulted in rapidly reduced private investment and engagement across the agency. As a result, the Clinton Administration revoked these provisions in 1995. Once this happened, critical partnerships resumed and increased.

CBSA is supportive of Section 611 of the proposal, which would incentivize the development of more MCMs by extending the Priority Review Voucher (PRV) program through the duration of PAHPA. This provision would provide a new, non-transferrable priority review voucher to companies that develop new MCMs on top of the transferrable voucher they currently receive. In addition, the provision would be expanded to include threats to the Armed Forces. The MCM PRV program creates a powerful incentive for industry to develop products on the material threat list. These products have limited or no commercial market, and this incentive is key to the development of these products. As drug development takes an average of 10+ years, eliminating the 5-year sunset date for the MCM PRV program would stabilize and strengthen the incentive by providing a signal to spur and support earlier stage innovation. Thus far, this program has been a success and has led to the issuance of 7 vouchers at zero cost to the government, according to the Congressional Budget Office (CBO). Reauthorizing the MCM PRV Program and eliminating the sunset are crucial to preserving this incentive for research and development.

CBSA supports the reauthorization of this historically bipartisan legislation and the addition of certain new polices in the discussion draft, but we are very concerned that the above-mentioned provisions would be detrimental to the public-private partnerships that are vital to developing MCMs necessary to protect citizens



303.592.4073
info@cobioscience.com
cobioscience.com
600 Grant Street, Suite 306
Denver, CO 80203

in Colorado and across our nation.

Thank you for considering our feedback and we look forward to working with your staff to support the passage of a timely and bipartisan PAHPA Reauthorization bill. If you have any questions or would like to discuss any of this further, you can reach me by email at eb blazevich@cobioscience.com or by phone at (303) 592-4072.

Sincerely,

A handwritten signature in black ink, appearing to read 'Elyse Blazeovich'.

Elyse Blazeovich
President and CEO
Colorado BioScience Association