COUNCIL FOR AFFORDABLE
HEALTH COVERAGE

July 10, 2023

Chairman Bernie Sanders
Ranking Member Bill Cassidy
Sent to: PAHPA2023Comments@help.senate.gov

Dear Chairman and Ranking Member:

The Council for Affordable Health Coverage (CAHC) appreciates your solicitation of comments on the draft legislation to reauthorize the Pandemic and All-Hazards Preparedness Act (PAHPA), which expires on September 30.

We write to specifically address Sections 601 and 602 (CDC and BARDA Reasonable Pricing Requirements) and Section 611 (Priority Review to Encourage Treatment for Agents that Present National Security Threats). We encourage the Committee to remove Sections 601 and 602 and include Section 611 in the final PAHPA reauthorization.

Section 601 and 602, Reasonable Pricing Requirements

CAHC opposes the inclusion of these provisions because they impose international price controls on all drugs, biological products, devices, or other biomedical technology that stems from contracts, grants, and cooperative agreements, and in entering into licenses or other transactions with either the CDC or BARDA. These sections require all BARDA and CDC-supported products to be sold at the lowest price among G7 countries (Canada, France, Germany, Italy, Japan, and the United Kingdom). These price controls will harm the ability to bring new products to the market that are critical for combatting public health and emerging threats. We urge you to remove the section for three reasons:

1. **This approach has been tried (and failed) before.** The NIH adopted a reasonable pricing provision for Cooperative Research and Development Agreements (CRADAs) in 1989, and the number of CRADAs cratered, and did not increase to pre-1989 levels until after the contracting provision was jettisoned in 1995. Rather than encourage new pandemic-related countermeasures, the proposal would have the opposite effect. It would be a major step back for pandemic preparedness.

2. **Europe doesn't know best.** There is ample evidence from many countries who have adopted price controls, including G7 countries, that importing their pricing systems here would result in fewer products overall, fewer new products, and worse access to care. For years, European policymakers have imposed strict price controls on new pharmaceuticals – and those price caps have delayed patients' access to cutting-edge medicines.

   The same story played out with COVID-19 vaccines. Four months after the first COVID vaccine earned authorization, large portions of Europe struggled to inoculate their populations. In Germany, Italy, and France, only about 15 percent of patients received at least one vaccine dose. Such massive delays led to another wave of cases, hospitalizations,

and deaths in Europe, and a fresh round of lockdowns. One major factor was the European Union's obsession with prioritizing negotiating over new drugs and immunizations over access to countermeasures. Whereas Israel – by far the world leader in COVID-19 vaccinations – agreed to pay $25 for each dose, and the United States paid $20, the EU held out for a discount, ultimately paying $15 to $19.

The EU's price negotiations wasted valuable time at a critical moment in the vaccination campaign. While EU countries got a lower price, they paid more in other ways. According to one analysis, each dollar the EU shaved off the price of its vaccines provided $1 billion in savings, but that figure is dwarfed by the economic cost of the vaccine's slow rollout. A study found that the delayed rollout cost the European economy almost $107 billion. That's more than four times what the EU paid for its vaccines. And this says nothing of the suffering and death caused by the latest wave of infections.

Sadly, this isn't the first time Europe's price-obsessed bureaucracy has delayed access to lifesaving new medicines. It's routine for agencies like Germany's Federal Joint Committee and France's Economic Committee for Health Products to set prices for breakthrough drugs at below-market rates. It's because of these tactics that new medicines generally take far longer to reach European patients. There were 290 new active pharmaceutical substances released worldwide between 2011 and 2018. Of those, German patients had access to just under two-thirds, and about half were offered to French patients. Meanwhile, in America – where policymakers have so far eschewed European-style price controls – patients had access to nearly 90 percent of these new treatments.

The trade-off between lower prices and access to new medicines, especially those to counter fast-moving pandemics, is simply too great.

3. **Lessons learned: Politicizing pandemic preparedness is a mistake.** Finally, because the provision applies broadly to all CDC and BARDA contracts, the section is unrelated to pandemic preparedness in general. Because PAHPA expires in September, we encourage you to reject this approach so as not to threaten the passage of the reauthorization bill prior to the expiration of the law.

Section 611, Priority Review to Encourage Treatment for Agents that Present National Security Threats

CAHC supports the inclusion of this section because it will expand available products to address emerging pandemics quickly, reducing disease, hospitalizations, death, and the costs associated with not aggressively promoting a public health response.

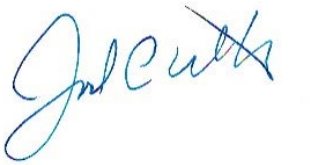
As GAO noted in their January 2020 report[1] on the issue, “Drug sponsors—facing a lengthy and expensive drug development process—may be reluctant to develop treatments for these diseases or conditions given the small markets or potentially limited profitability for them. Other challenges can make drug development for…medical countermeasures more difficult than for other drugs. Medical countermeasures treat high-priority threats that affect health security, making it difficult to test the drugs because exposing study volunteers to such threats would be an unethical and unacceptable risk.”

[1] GAO-20-251 Priority Review Vouchers

Considering the number of priority review vouchers is least for medical countermeasures (6.5 percent of all PRVs), efforts to expand incentives for new products in this area are sorely needed. Expanding medical countermeasures will lower costs by preventing illness and hospitalization. We encourage the inclusion of Section 611 in the PAHPA reauthorization.

Thank you for considering our comments. Please do not hesitate to reach out should you wish to discuss this or if you have any questions.

Sincerely,



Joel C. White