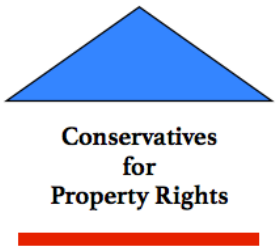

July 10, 2023

U.S. Senate Committee on Health, Education, Labor, and Pensions
428 Dirksen Senate Office Building
Washington, D.C. 20510

Dear Senate Health, Education, Labor, and Pensions (HELP) Committee:

On behalf of Conservatives for Property Rights (CPR), I write to express the coalition's concerns regarding the "reasonable pricing" provisions (Sec. 601 and Sec. 602) of the HELP Committee's reauthorization of the Pandemic and All-Hazards Preparedness Act (PAHPA).

CPR, a coalition of conservative and libertarian organizations, emphasizes the central importance of private property in all its forms—physical, personal, and intellectual. Private property rights rank among the unalienable rights the Founders referenced in the Declaration of Independence. Thus, property rights transcend conservative and liberal politics. CPR considers sections 601 and 602 of the draft legislation to encroach upon private property rights.

Notably, PAHPA has typically been bipartisan and legislated without much controversy. Recent efforts in the U.S. House crafting PAHPA reauthorization language have taken a bipartisan, constructive course. Unfortunately, the "reasonable pricing" measures in the Senate legislation break with that laudable approach. If for no other reason than to ensure that our country adopts timely, important lessons from the COVID-19 pandemic and recent natural disasters, PAHPA should remain clean of controversial, divisive measures, such as sections 601 and 602 of the HELP draft.

These "reasonable pricing" requirements would apply to marketable drug, biologic, or other medical technology that stems from federal research funding from the Centers for Disease Control (CDC) and BARDA. It is virtually guaranteed that the strictures of these provisions would result in less innovation, greater hesitation by would-be grantees and contractors, and fail to achieve the stated goal.

Instead, they would repeat the tried-and-failed CRADA experience of the National Institutes of Health (NIH) in the 1990s, only involving different federal agencies. In

1989, NIH started requiring a "reasonable pricing" provision in its Cooperative Research and Development Agreement federal contracting vehicle as a condition for an exclusive license to NIH-funded technologies. The clause injected uncertainty, diminished intellectual property (IP) value, and undermined property rights over eventual products.

The pricing requirement caused a significant drop in NIH CRADAs, falling from 42 in 1989 to an average of 32 the next six years. This drop-off in CRADAs led NIH to eliminate the provision. CRADAs with NIH immediately rose to about 90 agreements in 1996 and more than 160 in 1997.

When the government price control was removed, NIH Director Harold Varmus said "the pricing clause has driven industry away from potentially beneficial scientific collaborations with [NIH] scientists without providing an offsetting benefit to the public. . . . Eliminating the clause will promote research that can enhance the health of the American people."

Mr Varmus did not mince words in his estimation of the "reasonable pricing" clause: "The [price control] clause attempts to address the rare breakthrough product at the expense of a more open research environment and more vigorous scientific collaborations. One has to have a product to price before one can worry about how to price it, and this clause is a restraint on the new product development that the public identified as an important return on their research investment."

In 2021, NIH reassessed this episode. NIH affirmed that the 1990s CRADA plunge was due to the addition of the "reasonable pricing" clause, and the uptake occurred because of its removal. This shows price controls don't work as intended.

Pegging U.S. government-set prices to the artificially low, government-set prices of other countries would be extremely unwise. It is premised on a simplistic comparison of the means of rapidly, broadly bringing most medical innovations to American patients with the means foreign countries' government-run health systems use. The foreign health systems dictate unreasonably low prices that have little connection to real-world, market-based factors. Those "health systems" keep many new treatments unavailable for much longer—even excluding some new medical products entirely from their health systems. Those systems often ration—even denying access to—newer drugs and medical devices by the most vulnerable patients. Such practices are likely to follow here as sections 601 and 602 compound the adverse consequences beginning, pursuant to the drug price controls in the "Inflation Reduction Act."

In short, CPR urges that the "reasonable pricing" provisions be stricken from PAHPA.

Sincerely,

James Edwards, Ph.D.
Executive Director
Conservatives for Property Rights