BIDEN ADMINISTRATION "MARCH-IN" POLICY

Throwing Gas on the IRA Fire That's Burning Rare Disease Patients Hope

Washington, D.C. (12-12-2023) - On December 7th, the Biden administration announced its plans to clarify the Bayh-Dole Act, formally known as the Patent and Trademark Act Amendments, and use the "march-in" clause to re-license high priced drugs that had been a part of a public-private agreement. With this announcement the Biden administration will provide guidelines to federal agencies on how to use "march-in" authority when medications are deemed unavailable to the public on "reasonable terms."

Putting aside for a moment the ambiguous metric "reasonable terms," this announcement to aggressively pursue "march-in" policies, coupled with the uncertainty already generated by the Inflation Reduction Act (IRA), will further cripple the orphan disease drug pipeline by reducing investment into research and raising uncertainty about treatments for rare disease patients.

As an organization whose focus is to advance access to therapies for rare disease patients, the Rare Access Action Project (RAAP) simply cannot support the Biden Administration's "march-in" policy.

"In a world where 95 percent of known rare diseases lack an FDA approved treatment, chasing away future investment in rare disease treatments by raising the specter of having a license revoked after years of research, clinical trials, and millions of dollars in additional investment is just untenable. We must find ways to ensure that patients benefit from access; and there are innovative solutions currently under consideration in Congress, such as fixing the IRA's provisions which erode incentives of the Orphan Drug Act, value based pricing, copay accumulator and maximizer reforms, to name a few," said Mike Eging, Executive Director of RAAP.

Eging continued, "While we applaud the Biden administration for seeking solutions to drug affordability, we would encourage the administration to recognize one size does not fit all and the first order of business is to not make matters worse. We protect rare disease patients and work to stimulate innovation and ensure patient access to rare therapies."

“RAAP has explored policies such as copay accumulator reform, pharmaceutical benefit manager (PBM) transparency, and other areas that can reduce out of pocket costs for rare patients. Lowering prescription drug costs is an important issue, but the solutions simply cannot come at the expense of rare disease patients. We look forward to working with Congress and the Administration on these common sense solutions,” concluded Eging.

For interviews, email Evan@rareaccessactionproject.com or contact Evan Kozlow at 202-731-1275.

###

RAAP, the Rare Access Action Project, is a coalition of life sciences and patient stakeholders that explore creative policy solutions to address structural issues in access and coverage. Our priority is to help ensure rare disease patients have access to the care and treatments they need.