



Inflation Reduction Act to Harm Rare Disease Innovation

RAAP Supports Legal Efforts Targeting Price Setting Provisions

Washington, D.C. (7-11-23) - The recently passed Inflation Reduction Act (IRA) was hailed by supporters as a major milestone for reducing costs across a range of sectors, including prescription drug prices. The Rare Access Action Project (RAAP) was involved in the debate from the beginning warning that certain provisions could have detrimental effects on innovation, particularly in the orphan drug space.

“RAAP conducted a study in 2021 that modeled the impact of provisions that include increased costs for participating in Medicare Part D, the costs of punitive provisions to force acceptance of government price setting, and the erosion of incentives to pursue indications in smaller populations. The impact of these provisions were found to be both inflationary and costly. In fact, our research based on earlier legislation with the same provisions saw an increase in company costs in Medicare Part D of between 400 and 800 percent.⁽¹⁾ Such increases in costs, coupled with price controls and incentives that make rare disease investments even less certain, have combined to have a devastating effect on rare disease innovation,” said RAAP’s Executive Director Michael Eging.

Other studies, including one from the Biotechnology Innovation Organization (BIO) entitled “Orphan Drugs 2023-2028, A Flattening Curve?” explained that the IRA could hurt growth of orphan drugs. The new law “exempts orphans with just one approved indication from the price controls that will hit other high-cost Medicare drugs.” says BIO’s report. This means that drugs treating more than one disease will be subject to price controls.

As a result, patients are already missing out on potential cures. Alnylam, for example, stopped researching whether their nerve damage drug Amvuttra also treats Stargardt, which impacts children’s vision, Evaluate says.

“That is why RAAP supports the lawsuits filed in federal court by multiple companies targeting price setting provisions based on constitutional concerns with government price setting. Specifically, provisions that would essentially force companies to accept government price setting by imposing punitive penalties if the company doesn’t agree with the price that the government demands. This and the mechanism for government price setting of multiple indication orphan products will make investment in products with multiple uses uncertain and create an incentive to only invest in the largest diseases, leaving the smallest to languish.

RAAP supports efforts to review these and other provisions in federal court prior to IRA being able to create enormous inflationary pressure and enact policies that will erode continued

investment incentives. Such policies will damage the therapy pipeline for the next generation of 21st Century rare disease patients and is more important in light of CMS' recent issuance of its final Negotiation guidance which did not change the most harmful provisions for orphan drug development," concluded Eging.

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((1) Changes in the Medicare Part D Benefit Design can Impact Availability of Future Treatments, Xcenda, research sponsored by RAAP, 11/02/21, <http://rareaccessactionproject.org/wp-content/uploads/2021/11/Wyden.Pelosi-Proposal-MEK.pdf>)

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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. RAAP is a registered 501 c4 non-profit organization.