



## **RAAP APPLAUDS BIPARTISAN LEGISLATION TO FIX “PILL PENALTY”**

**Washington, D.C. (2-5-24)** – The recently enacted Inflation Reduction Act (IRA), creates different Medicare price negotiation timelines for large and small molecule therapeutics. This difference is now referred to as a “pill penalty” because of the shorter timeframe to negotiate that most small molecule pills will now have as compared to biologics (i.e. larger molecule drugs). The pill penalty provides for the negotiated price to take effect after 9 years of FDA approval which is a major shift from the 13-14 years companies typically had before generic competitors could enter the marketplace. The shorter time frame or pill penalty negatively impacts innovation and disrupts the pipeline of new medicines for rare disease patients. Indeed, already, in the short time since enactment of the IRA, investors are moving away from funding small molecule programs which could have resulted in life saving therapies for rare disease patients.

A major step was taken however with the introduction of legislation entitled, “The Ensuring Pathways to Innovative Cures (EPIC) Act, which was introduced by Representatives Greg Murphy, M.D. (R-NC), Don Davis (D-NC), and Brett Guthrie (R-KY). The legislation will provide small molecule drugs the same period of exemption from price controls as biologics.

“This is a major step towards repairing the harm that the IRA was causing in innovation and the orphan drug pipeline. The change in time periods of 14 years to nine years sent a negative ripple effect through the small molecule drug market, potential investors, and ultimately to care for rare disease patients. This bipartisan legislation is a big step towards fixing a policy that was intended to help reduce costs but missed the mark entirely for the rare disease community. We applaud the bipartisan effort of Representatives Murphy, Davis, and Guthrie for putting patients first and working to restore innovation for small molecule drugs,” said Mike Eging, Executive Director of RAAP.

RAAP, who has been aggressively working to see needed changes made to the IRA to protect rare disease patients, supports the EPIC Act, and will work to advocate for its passage and adoption throughout the process.

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*RAAP, [the Rare Access Action Project](#), is a coalition of life sciences and patient stakeholders that explores 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.*