national down syndrome society
ndss

May 27, 2025

The Honorable John Thune
511 Dirksen Senate Office Building
Washington, DC 20510

The Honorable Chuck Schumer
322 Hart Senate Office Building
Washington, DC 20510

The Honorable John Barrasso
307 Dirksen Senate Office Building
Washington, DC 20510

The Honorable Dick Durbin
711 Hart Senate Office Building
Washington, DC 20510

Dear Majority Leader Thune, Majority Whip Barrasso, Democratic Leader Schumer, and Democratic Whip Durbin:

The National Down Syndrome Society (NDSS) empowers individuals with Down syndrome and their families by driving policy change, providing resources, engaging with local communities, and shifting public perceptions. Today we write in strong support of the *Ensuring Pathways to Innovative Cures (EPIC) Act* (S. 832/H.R. 1492). If passed, this bill would ensure that small-molecule drugs such as pills, tablets, and patches receive equal priority in research and funding compared to more invasive treatment options.

President Donald Trump's recent executive order directs Health and Human Services Secretary Robert F. Kennedy Jr. to work with Congress to fix the "pill penalty," a provision in the Inflation Reduction Act (IRA) that disincentivizes research into small-molecule drugs. [1] The bipartisan EPIC Act does just that.

The Inflation Reduction Act (IRA), which was signed into law in 2022, included pricing controls for certain drugs and therapeutics. However, before these price controls go into effect, new medicines get a "grace period" which gives developers time to earn a return on their investments and further incentivizes the drug development that individuals with Down syndrome and other disabilities benefit greatly from. For large-molecule drugs, which are often administered in hospitals and physicians' offices, the IRA grants a 13-year period after FDA approval before the new drugs and treatments would be subjected to the pricing caps. However, small-molecule drugs, such as pills, tablets, and patches, only get a 9-year grace period before they are subjected to government pricing caps.[2] The implications of that four-year gap are profound and misaligned with the needs of patients and families. It is estimated that over the next 20 years, this penalty on the development of small-molecule drugs will result in 188 fewer small-molecule treatments reaching patients.[3]

The EPIC Act would correct this imbalance by extending the Medicare negotiation exemption period for small-molecule drugs from nine years to 13 years, aligning it with the timeline already

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[1] https://www.whitehouse.gov/presidential-actions/2025/04/lowering-drug-prices-by-once-again-putting-americans-first/
[2] https://www.kff.org/medicare/issue-brief/explaining-the-prescription-drug-provisions-in-the-inflation-reduction-act/
[3] https://ecchc.economics.uchicago.edu/2023/10/09/policy-brief-the-potentially-larger-than-predicted-impact-of-the-ira-on-small-molecule-rd-and-patient-health-2/

granted to biologics. This simple, targeted fix would help ensure that both types of treatments have equal opportunity to reach the patients who need them.

Individuals with Down syndrome often rely on and benefit greatly from small-molecule drugs. Traveling to hospitals isn't always accessible for individuals with disabilities, especially in rural areas. Furthermore, small-molecule drugs that can be administered at home alleviate the cost and inconvenience of travel, allowing patients to maintain daily activities. For individuals with Down syndrome, who may already struggle with invasive medical procedures and unfamiliar environments, the additional complexity that more intensive treatments pose can be overwhelming.

Beyond the increased accessibility that small-molecule drugs can provide to individuals with Down syndrome, these drugs are also at the forefront of addressing some of the most critical health needs of the Down syndrome community. The Down syndrome community has an over 90% chance of developing Alzheimer's disease over their lifetime, a much higher rate than for the general population.[4] Small-molecule drugs represent one possible treatment option that could have a profound impact. Unlike large-molecule drugs such as biologics, these medications can cross the blood-brain barrier, targeting the root causes of dementia.[4] People with Down syndrome also suffer from hypothyroidism, heart anomalies, blood disorders, infections, and epilepsy at higher rates than the general population – all areas that could benefit from small-molecule research.[5] [6] [7] [8] [9] [10]

President Trump's executive order affirms the urgency of this issue. We urge you to take swift action to pass the EPIC Act.

Thank you for your continued leadership and commitment to improving the lives of individuals with Down syndrome and other disabilities.

Sincerely,

Kandi Pick

Kandi Pickard
President and CEO
National Down Syndrome Society

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[4] https://pmc.ncbi.nlm.nih.gov/articles/PMC9387748/
[5] https://www.pnas.org/doi/10.1073/pnas.0904506106
[6] https://pmc.ncbi.nlm.nih.gov/articles/PMC5866956/
[7] https://www.bmc.org/news/new-small-molecule-could-treat-sickle-cell-disease-adults-dont-respond-hydroxyurea-alone
[8] https://pmc.ncbi.nlm.nih.gov/articles/PMC8609069/#:~:text=The%20concept%20of%20%E2%80%9Cprecision%E2%80%9D%20treatment,ion%20channel%20or%20neurotransmitter%20receptor)%2C
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