



The Honorable Jason Smith
Chairman
U.S. House Committee on Ways & Means
Washington, D.C. 20515

The Honorable Richard Neal
Ranking Member
U.S. House Committee on Ways & Means
Washington, D.C. 20515

Re: Health Subcommittee on Examining Policies that Inhibit Innovation and Patient Access

Dear Chair Smith and Ranking Member Neal:

As the U.S. House Committee on Ways and Means Health Subcommittee examines policies that inhibit innovation and patient access, Incubate is sharing the perspective of the early-stage life sciences ecosystem and private capital. Incubate is a coalition of early-stage life sciences venture capital firms representing the patient, corporate, and investment communities. Our primary aim is to educate policymakers on the role of venture capital in bringing promising treatments to patients in need.

While we are sharing research and views on several topics discussed at the hearing, we urge the Committee and the Congress more broadly to immediately end the Small Molecule Penalty included in the *Inflation Reduction Act of 2022*. Adding disincentives for any type of research and development skews investment, altering the medicines available to patients. Incubate's resources on the "small molecule penalty" are available on our website, <https://incubatecoalition.org/the-small-molecule-penalty/>. This single change will help allow science – not Washington – to pursue the treatments and cures patients are hoping for.

This hearing comes at a critical time. Broader economic pressures are already limiting capital for aspiring bio-entrepreneurs. We need Washington to take immediate and bipartisan action to assure investors, scientists and patients that government will aid, not inhibit the next generation of medicine.

CMS Draft Guidance on Drug Price Negotiation:

Before the Committee, Incubate is reiterating its position that the IRA lacks transparency in the price setting process and disincentivizes small molecule drug development and post-approval research, ultimately sending a perverse signal to the market. The CMS' initial implementation establishes a distorted calculation of the maximum fair price (MFP) and does not mitigate any concerns or address fundamental issues created by the legislation.

For more information, please consider our previous submission to the Centers for Medicare & Medicaid Services' (CMS) on "Drug Price Negotiation Program Guidance: Initial Memorandum,



Implementation of Section 1191 – 1198 of the Social Security Act for Initial Price Applicability Year 2026, and Solicitation of Comments”.¹

CMMI’s Release of New Drug Payment Models:

Incubate is also concerned that the CMMI's proposed demonstration model to change the way drugs approved via the Food and Drug Administration’s (FDA) accelerated approval pathway are reimbursed would place a lower value on certain drugs approved through the pathway despite FDA’s determination that they are safe and effective. This change would also discourage investment in some of the hardest-to-treat diseases and, as a result, undermine the fundamental purpose of the pathway, which is to allow for earlier approval of drugs that treat serious conditions with unmet needs.

CMS NCD:

We believe that the CMS’ Final National Coverage Decision (NCD) on Certain Treatments for Alzheimer’s Disease decision severely restricts patient access to FDA-approved medicines for Alzheimer’s disease and sends a signal to the market that novel therapies in these disease areas are not valued. As a result, we expect companies will alter their research and development of new treatments.

Despite consistent warnings that the coverage decision could undercut the investment needed to bring innovative therapies to patients, CMS doubled down on its efforts to second-guess FDA decision-making - making it even harder for patients to access the medicines their physicians deem appropriate. For more information on our position, please consider our previous submission.²

WTO TRIPS Waiver:

The importance of intellectual property (IP) protections in early-stage life sciences development remains a core belief of Incubate. We strongly agree there will be significant industry repercussions if IP is weakened, which could ultimately lead to decreased investment and fewer new, life-changing or life-saving drugs.

To view additional resources on our perspective, please find Incubate’s testimony and blog in response to the U.S. International Trade Commission’s Investigation No. 332-596, COVID-19 Diagnostics and Therapeutics, Supply, Demand, and TRIPS Agreement Flexibilities.^{3 4}

Small Molecule Penalty:

In its current form, the IRA alters the existing system of patents and exclusivities that ensures successful medicines have, on average, 14 years of profitability for future R&D after the medicines are approved. The law implements price controls after nine years for small molecule drugs while biologics are given 13 years.

¹ <https://incubatecoalition.org/incubate-submits-comment-to-cms-regarding-its-draft-guidance-for-the-medicare-drug-price-negotiation-program/>

² <https://incubatecoalition.org/incubate-comment-on-the-proposed-decision-memo-for-monoclonal-antibodies-directed-against-amyloid-for-the-treatment-of-alzheimers-disease/>

³ <https://incubatecoalition.org/incubate-testifies-at-usitc-hearing/>

⁴ <https://incubatecoalition.org/incubate-takes-the-stand-testifying-on-global-importance-of-ip/>



Resources to help educate policymakers about this "small molecule penalty," are available on our website, including a detailed explainer on the downstream impacts of the penalty on Incubate's podcast, Making Medicine, *The Inflation Reduction Act: A Big Issue for Small-Molecule Medicine*.^{5 6} We call on Congress to fix the IRA's small molecule penalty, as outlined in Incubate Executive Director John Stanford's recent STAT article.⁷⁸

Hearing from the investment community on the impact of the IRA in their quarterly earnings calls, we capture shifts and changes in industry investment in our Life Sciences Investment Tracker to measure the immediate and longer-term impacts of the IRA on the ecosystem.⁹ The tracker follows two key indicators: public shifts in activity specifically due to new price controls and public announcements of decreased R&D activity in the broader investment environment.

Furthermore, BioCentury conducted an industry survey, comprised of 69 biopharma companies and 10 venture capital or other investment organizations, which found that one third (34%) of biotechs and investors expect the IRA to create major changes or existential crisis for their businesses.¹⁰ Similar concerns are reflected in our investment tracker and across our membership.

We would welcome the opportunity to discuss our feedback on any of these topics in greater detail with the Health Subcommittee; please reach out to John@incubatecoalition.org with any questions you may have.

Thank you for the opportunity to comment on these important issues.

Sincerely,

John Stanford
Executive Director
Incubate Coalition

⁵ <https://incubatecoalition.org/the-small-molecule-penalty/>

⁶ <https://incubatecoalition.org/episode-19-the-inflation-reduction-act-a-big-issue-for-small-molecule-medicine/>

⁷ <https://www.statnews.com/2023/03/06/congress-must-fix-ira-small-molecule-penalty/>

⁸ <https://incubatecoalition.org/congress-must-fix-the-iras-small-molecule-penalty/>

⁹ <https://incubatecoalition.org/life-science-investment-tracker/>

¹⁰ https://www.biocentury.com/article/647205?editionId=clfbtldic6cy60ao7evcqyibt&editionType=daily&utm_source=bctoday&utm_campaign=product&utm_medium=email