

May 22, 2023

Dear Members of the Massachusetts congressional delegation:

We, the undersigned entrepreneurs, investors, and leaders representing the early-stage life sciences ecosystem, urge Congress to swiftly end the Small Molecule Penalty included in the *Inflation Reduction Act (IRA) of 2022*.<sup>1</sup>

The IRA fundamentally changed the existing, proven and successful system of patents and exclusivities that ensures approved medicines have, on average, 14 years to recoup investment and generate a return that can be reinvested into future drug discoveries. Instead, the law imposes European-style price controls after a specified number of year post FDA approval: nine years for small molecule products and thirteen years for large molecules, or biologics. This Small Molecule Penalty must be addressed by aligning the negotiation timelines for both small and large molecules to 13 years.

Small molecule products are generally pills, tablets, or capsules that patients can easily pick up at the pharmacy and take at home, enabling broad accessibility for those in need. Because they can penetrate cell membranes, including the blood-brain barrier, they often provide important treatments for cancer, neurological conditions, and more. Small molecules also become low-cost generics after intellectual property (IP) protections expire. Biologics are generally infused or injected treatments for serious health conditions, and typically require administration in a doctor's office, hospital or clinic.

Fixing the IRA's small molecule penalty is of the utmost importance - the impact is already being felt. We are seeing market shifts in value for small molecule drugs.<sup>2</sup> More specifically, there is less interest and less investment in this space, which ultimately means fewer treatments for patients. Without a change to align the negotiation timelines to 13 years for all drugs, the IRA will force investors to make a simple choice between a thirteen-year return or a nine-year return, which is especially impactful since 50% of revenues from a drug come in years nine through thirteen. Capital always flows to the best risk-adjusted return, and the IRA's arbitrary prioritization of biologics means investors will follow suit.

A recent BioCentury survey of 69 biopharma companies and 10 venture capital or investment organizations found that one third (34%) of biotechs and investors expect the IRA to create major downshift changes or existential crises for their businesses.<sup>3</sup> Ending the Small Molecule Penalty will help allow science – not Washington – to lead us away from crisis and towards the treatment and cures patients need.

Thank you for your consideration of this important issue.

Sincerely,

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<sup>1</sup> *H.R.5376, Inflation Reduction Act of 2022*. <https://www.congress.gov/bill/117th-congress/house-bill/5376/text>

<sup>2</sup> *Incubate Life Sciences Investment Tracker*. <https://incubatecoalition.org/life-science-investment-tracker/>

<sup>3</sup> Fishburn, C. S. (2023, March 16). *Ira survey: Biotechs bracing for impact*. BioCentury. [https://www.biocentury.com/article/647205?editionId=clfbtldic6cy60ao7evcqyibt&editionType=daily&utm\\_source=bctoday&utm\\_campaign=product&utm\\_medium=email](https://www.biocentury.com/article/647205?editionId=clfbtldic6cy60ao7evcqyibt&editionType=daily&utm_source=bctoday&utm_campaign=product&utm_medium=email)

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*Electronically Delivered To:*

Senator Elizabeth Warren (MA)  
Senator Ed Markey (MA)  
Representative Richie Neal (MA-1)  
Representative Jim McGovern (MA-2)  
Representative Lori Trahan (MA-3)  
Representative Jake Auchincloss (MA-4)  
Representative Katherine Clark (MA-5)  
Representative Seth Moulton (MA-6)  
Representative Ayanna Pressley (MA-7)  
Representative Stephen Lynch (MA-8)  
Representative Bill Keating (MA-9)