

THE SMALL MOLECULE PENALTY

WHAT THEY ARE SAYING

By placing price controls on small molecule drugs after only nine years following FDA approval – compared to 13 years for biologics – the Inflation Reduction Act changes America’s tried-and-true system for research and development of much-needed medicines. Here’s what leading voices have to say about how the small molecule penalty will impact the future drug development pipelines and, ultimately, harm patients in need of new therapies.



Offering biologic drugs 13 years of protection from IRA price setting is close enough to the 14-year average investors have long counted on, but giving oral tablets just nine years harms patient-centric innovation.”

– Paul Hastings,
President and CEO of
Nkarta Therapeutics¹



Because they usually become quite cost effective to manufacture, small molecule therapies provide an opportunity for more affordable pricing with the entry of generic competition. We’re hopeful that this “small molecule penalty” will be fixed in the IRA and won’t stifle innovation in small molecule programs, which have made a significant positive impact on healthcare globally.”

– Stephen Brady, CEO of Tempest
Therapeutics²



Small-molecule drugs are important in rare disease treatment. But the penalty means drug companies might steer research dollars away from this medicine class and towards biologics. Biologics are usually administered in a clinical setting, so it’s more difficult for vulnerable groups to access them. These two provisions threaten to rob millions of rare-disease patients of future breakthroughs.”

– Jenifer Ngo Waldrop,
Executive Director of the Rare
Disease Diversity Coalition³

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As a small biotech drug developer, here's the most toxic: It's forcing me to choose to develop a drug for kids instead of a drug for their grandparents, when I could be developing both."

- **Steve Potts, Founder of Serpass Biologics and Redrock Science**⁴



Now, Washington wants to pick "winners and losers" by shortening exclusivity periods for small molecules, which only makes discovery more difficult."

- **John "CZ" Czwartacki, Chairman and founder of Survivors for Solutions**⁵



There is no scientific reason for this distinction, and it will have a real and detrimental impact on drug discovery and patient care. Nine years is not enough time to recoup the deep investments into small molecule R&D before government price controls take effect. As a result, companies will deprioritize small molecule programs, lowering the potential to create drugs using these technologies.

- **Daniel M. Skovronsky, Chief Scientific and Medical Officer, Eli Lilly & Company**⁶



The solution is simple. Amend the IRA in a bipartisan way to give small molecule drugs the same 13-year protection before price controls set in as has been given to biologics. That way, science – not lawmakers – attract capital and bring the next generation of medicines forward."

- **John Stanford, Executive Director of Incubate**⁷

1. Hastings, Paul. [How Will Industry Work With Congress To Make The Inflation Reduction Act \(IRA\) Workable?](#) *Life Science Leader*. April 3, 2023.

2. [Interview with Stephen Brady](#). *Investment Reports*. March 7, 2023.

3. Ngo Waldrop, Jenifer. [Waldrop: Inflation Reduction Act undermines rare disease research](#). *Boston Herald*. February 28, 2023.

4. Potts, Steve. [Saving money for Medicare by abandoning new drugs for Medicare patients](#). *Rapport*. September 21, 2022.

5. Czwartacki, John. [Hands Off Our Cures](#). *Real Clear Health*. March 9, 2023.

6. Skovronsky, Daniel. [The IRA's nonsensical distinction between small- and large-molecule drugs](#). *STAT*. May 9, 2023.

7. Stanford, John. [Congress must fix the IRA's small molecule penalty](#). *STAT*. March 6, 2023.