PILL PENALTY PROVISIONS WILL HAVE A CHILLING EFFECT ON THE PRESCRIPTION ECOSYSTEM

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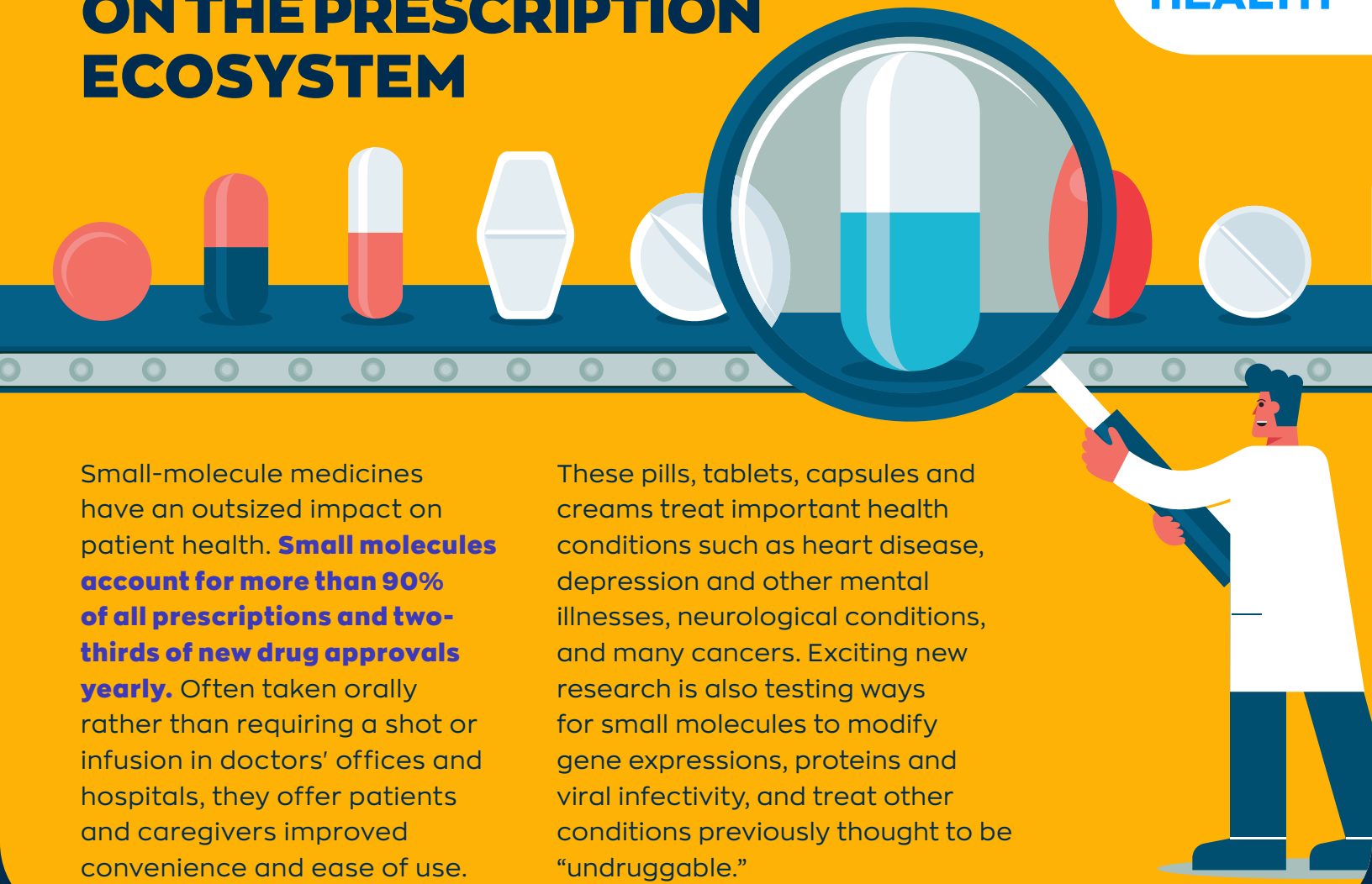

Small-molecule medicines have an outsized impact on patient health. **Small molecules account for more than 90% of all prescriptions and two-thirds of new drug approvals yearly.** Often taken orally rather than requiring a shot or infusion in doctors' offices and hospitals, they offer patients and caregivers improved convenience and ease of use.

These pills, tablets, capsules and creams treat important health conditions such as heart disease, depression and other mental illnesses, neurological conditions, and many cancers. Exciting new research is also testing ways for small molecules to modify gene expressions, proteins and viral infectivity, and treat other conditions previously thought to be "undruggable."

But these products differ in another way due to price-setting provisions in the Inflation Reduction Act (IRA).

YEARS AFTER INITIAL U.S. FOOD AND DRUG ADMINISTRATION (FDA) APPROVAL	SMALL MOLECULES	BIOLOGICS
Selection for Price-Setting	7 years	11 years
Price-Setting Begins	9 years	13 years

This pill penalty has unintended consequences and undermines the Hatch-Waxman Act and the ecosystem that encourages generic competition.

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UNINTENDED CONSEQUENCES OF THE PILL PENALTY

- **Fewer New Drugs —** Researchers project between **79-155** fewer small-molecule medicines will be developed over the next 10 years.[1,2]
- **Less Post-Approval Research and Fewer New Indications —** Post-approval research is critical to learn more about other ways drugs can help patients. More than **50%** of all small-molecule medicines (including 61% of all cancer products and 63% of medications with orphan indications) receive at least one post-approval indication.[3] These indications occur on average **7.5 years from the initial FDA approval** — after these products would be eligible for price controls.[4] In other words, if a small molecule has already been selected for price-setting, there is less incentive under the IRA to explore other indications.
- **Missed Opportunities to Improve Health —** Experts estimate the public will lose **116 million life years** due to the development of fewer small-molecule medicines and reduced post-approval research.[2]
- **Less Investment in Small Molecules — 63%** of biopharmaceutical companies expect to shift investments away from small molecules as a result of the IRA.[5]

The IRA Pill Penalty Undermines the Carefully Balanced System Created by the Hatch-Waxman Act to Encourage Innovation and Generic Competition in the Market

The Hatch-Waxman Act ensured a period of market exclusivity for new drugs and the opportunity to recover research and development costs before lower-cost generic products can be approved and marketed. Generic products typically enter the market after 13-14 years of exclusivity.[6] By making small molecule drugs eligible for price setting just 7 years post-FDA approval, the IRA significantly reduces the window for recouping a sufficient return on the investment. These provisions can threaten the vital drug ecosystem for patient access.

We Work For Health advocates for **policies and initiatives** to support medical innovation, address concerns and reverse the pill penalty, including ***the Ensuring Pathways to Innovative Cures (EPIC) Act.***

1 Vital Transformation. IRA's Impact on the U.S. Biopharma Ecosystem. June 1, 2023. https://vitaltransformation.com/wp-content/uploads/2023/10/VT-BIO_IRA_v14.pdf.

2 Philipson TJ, Ling Y, Chang R. The Impact of Price Setting at 9 Years on Small Molecule Innovation Under the Inflation Act. October 5, 2023. https://ecchc.economics.uchicago.edu/files/2023/10/Small-Molecule-Paper-Final-Oct-5-2023.pdf.

3 Phar. Implications of the Inflation Reduction Act Price Setting Provisions on Post-Approval Indications for Small Molecule Medicines. June 2023. https://www.pharllc.com/wp-content/uploads/2022/11/Clinical-Benefits-of-Post-Authorization-Research-Brief.pdf.

4 Patterson J, Motyka J, O'Brien JM. Unintended Consequences of the Inflation Reduction Act: Clinical Development Toward Subsequent Indications. American Journal of Managed Care. 2024; 30(2). https://www.ajmc.com/view/unintended-consequences-of-the-inflation-reduction-act-clinical-development-toward-subsequent-indications.

5 Longo, N. Inflation Reduction Act Already Impacting R&D Decisions. PhRMA, January 17, 2023. https://catalyst.phrma.org/wtas-inflation-reduction-act-already-impacting-rd-decisions.

6 Grabowski H, Long G, Mortimer R, Bilginsoy M. Continuing Trends in U.S. Brand-name and Generic Drug Competition. Journal of Medical Economics. 2021;24(1):908-17. https://doi.org/10.1080/13696998.2021.1952795.

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