

Removing the pill penalty could reduce healthcare spending

Published on: March 04, 2025

SO WHAT Last week, the EPIC Act was reintroduced. This bill seeks to create parity between the time clocks for Medicare drug price negotiation so that both small molecules and biologics would have 13 years before the negotiated price sets in. Currently, the Medicare Drug Price Negotiation Program looks at small molecules and biologics differently. [...]

SO WHAT

Last week, the [EPIC Act was reintroduced](#). This bill seeks to create parity between the time clocks for Medicare drug price negotiation so that both small molecules and biologics would have 13 years before the negotiated price sets in.

Currently, the Medicare Drug Price Negotiation Program looks at small molecules and biologics differently. Selected small molecules have 9 years and selected biologics have 13 years before the negotiated price sets in.

Historically (i.e., pre-Medicare drug price negotiation), investors and innovators have expected around a [14-year period](#) to be paid back for their innovation based on patent protection periods. In a world with Medicare drug price negotiation, there is another time clock that comes in.

For biologics, there is now this other 13-year time clock, but 13 years and 14 years don't seem all that different. However, for small molecules, the other time clock is 9 years. Nine years is very different from 14 years; and 9 years (small molecule time clock for Medicare negotiated price to set in) and 13 years (biologic time clock for Medicare negotiated price to set in) are very different from one another.

Understandably, many people in the industry are focused on what signal this sends to investors and innovators of pre-clinical and in-development small molecule drugs. Will this disincentivize the development of some small molecules? Will the different time clocks shift investments to biologics? Evidence is building on the potential impact of the Inflation Reduction Act (IRA) on small molecule investment and development. [Work from the University of Chicago](#) suggests that over the next 20 years, we could miss out on 79 potential small molecule drugs.

As a health economist, I am concerned with what fewer small molecule drugs could mean for healthcare spending. We know that small molecules have the potential to become very low-cost after the patent period, so signals away from their development (or shifting investments to biologics versus small molecules due to the longer time clock that biologics currently have) could lead to higher spending on drugs

Point #1: Small molecule generics tend to be much cheaper than biosimilars.

When a drug first launches, the price is high (for a short period of time) because we are paying back the investment. After the appropriate protected period/payback period, competition enters and the price should drop to something closer to its cost of goods sold with a small profit margin to

ensure supply, quality, etc. over the long term. This eventual drop in price frees up our healthcare resources for other new innovations in their protected period/payback period and encourages innovators to develop new products. That's how we get closer to an efficient market that incentivizes ongoing innovation.

Small molecules tend to be easy and relatively cheap to genericize and manufacture. Because of this, we have seen many small molecules [drop in price to near pennies](#) once competition enters the market. [Research shows that small molecule generic competition](#) enters the market very quickly after patent expiration.

Rep. Jake Auchincloss stated [on The Biocentury Show with Steve Usdin](#), "There is nothing more equitable in healthcare than a small molecule drug that goes generic, because it becomes available to everybody for pennies."

Let's contrast this with a biologic. [Biosimilars are much more difficult and much more expensive to develop and commercialize](#). It takes longer for biosimilars to enter the market, and the cost of a biosimilar has remained in the thousands of dollars each year (not pennies). Biosimilars exist and have been effective at reducing pricing, but they are still relatively expensive to develop and manufacture. The cost of goods sold and the cost to develop are simply higher for biosimilars.

Point #2: Small molecule branded drugs tend to be cheaper and more cost-effective than biologics.

Biologics tend to be significantly more expensive than small molecules. [Recent research](#) reported the median cost for a biologic was more than \$90,000 per year, as compared to a median cost for a small molecule drug of \$33,000 per year.

Despite being less expensive, [research by Katherine Clifford and colleagues has shown](#) that small molecule drugs and biologic drugs offer similar amounts of health gains. Thus, the cost-effectiveness of small molecule drugs tends to be more favorable than the cost-effectiveness of biologics. In a health system where efficiency is necessary, small molecules are extremely important.

I am not arguing against biologics or biosimilars by any means, rather I am shining a light on the current disparity in time to Medicare Drug Price Negotiation between biologics and small molecules and the disparity in time between the patent period for small molecules and the current time to Medicare Drug Price Negotiation for small molecules.

The EPIC Act that was re-introduced by House lawmakers would change the Medicare Drug Price Negotiation time clock of small molecules to be equivalent to that of biologics. If passed, both small molecules and biologics would have 13 years before the Medicare negotiated price would set in.

This would remove the disparity in time to Medicare drug price negotiations between biologics and small molecules and would reduce the gap in the time between the initial expected protected period and the time to Medicare Drug Price Negotiation.

[Ed Silverman wrote a great piece in STAT](#) summarizing the different perspectives. It includes a quote from me in support of removing the “pill penalty” that says, “We know that small molecules have the potential to become very low-cost after the patent period, so signals away from their development—or shifting investments to biologics versus small molecules due to the longer time clock that biologics have—could have negative impacts [i.e., could increase] the long-term spending on drugs.

THE OTHER NEW SONG

Last week, we released [a new episode of our podcast](#). [Frank S. David, MD, PhD](#), Managing Director of Pharmagellan and Professor of the Practice at Tufts University and I had a nerdy conversation on the use of models to inform decision making—and how economic models used to estimate cost-effectiveness in the world of pharmacoeconomics differ from the financial models used for biotech valuation in the world of healthcare investing and development.

We talked about why models are built, what inputs go into them, how all models are wrong, and how the provisions within the Inflation Reduction Act impact pharmacoeconomic and financial models.

There are details that we couldn't dive into during a 30-minute episode (e.g., I focused mostly on cohort models for cost-effectiveness analysis rather than patient level simulations, budget impact models, etc.), and generalizations that we made (e.g., I said cost-effectiveness analysis keeps drug pricing static) when of course there are nuances and unique considerations. However, I hope you still enjoy the episode and learn something new—even if it is that there are really two people in this world who are passionate about building models.

Hopefully it can give investors and innovators a glimpse into the world of pharmacoeconomics, and hopefully it can give pharmacoeconomists a glimpse into the world of healthcare investment and development. Collectively, I hope both worlds find synergies and learn how to work together. That's the only way I see possible for us to be a society that prioritizes healthcare innovation and dynamic efficiency.

In the spirit of me trying to be a bridge between the two worlds, I am going to recommend opportunities for each.

For pharmacoeconomists:

- Include expected impacts of competition in your models (e.g., price changes over exclusivity period, price changes after exclusivity period) rather than keeping the prices of drugs static to bring the estimates of cost closer to reality.
- Use a product “lifetime” time horizon rather than a time horizon of a person starting the drug at launch to inform decisions for patients beyond those who start at launch.
- Include costs and consequences outside the healthcare system, including such things as productivity and caregiver impact, to inform societal welfare rather than a narrower focus on only the health system.
- Estimate the *total* long-term societal net benefit rather than per-person estimates if judging a drug’s price and the “reward” the manufacturer receives. A single price per person is not the “reward” for an innovation. The reward is a function of price, volume, and margins.

For innovators:

- Explain the impact of your innovations on people and society. A lot of the dialogue is around price and profit for obvious and understood reasons, but then public criticisms are also around price and profit. We can’t forget to explain the impact that innovations have.
- Lean into the use of economic models and the [generalized cost-effectiveness analysis \(GCEA\) framework](#) to explain the impact your innovation is expected to have on patients, caregivers, the health system, and society. I am not suggesting you must price your drug in direct alignment with these estimates. I suggest using them to extrapolate and synthesize evidence to explain impact.
- Bring pharmacoeconomists into the conversation during early phases of your work. Pharmacoeconomics can be used to differentiate treatments. Some drugs are marginal improvements, while others are curative. Both have value, but pharmacoeconomics provides a structure to differentiate based on a magnitude of benefit.
- Be transparent. Check out [Brian Reid’s February 28th newsletter](#) where we explains that “‘price’ shouldn’t be a dirty word”. Healthcare innovations do great things. As Brian says, “be willing to defend the prices” and “explain the value that they deliver”. Economic models can be an extremely helpful tool to explain the value that innovations deliver.

We need an efficient market-based system that incentives ongoing healthcare innovation.

Collaboration between pharmacoeconomists, investors, and innovators moves us in that direction.