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Bonnell: Prescription drug board threatens development of rare disease drugs

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For those of us who have loved ones living with a currently incurable disease, our hopes of finding a cure are at risk due to the unintended consequences of policy changes by lawmakers in Lansing and Washington, D.C.

These proposals, some already in place, others moving rapidly through our state Legislature, have the potential to halt the innovation that patients count on for new treatments and cures.

Let's start in Lansing.

Healthcare costs are of course something that impacts everyone — but so is disease, Bonnell writes. *James Yarema, Unsplash*

While it sounds sexy for lawmakers to pass bills that claim they will cut costs of prescription drugs and put money back in patient's pockets, the legislation to form a Prescription Drug Affordability Board (PDAB) will do neither. Instead, it will put research and development that Michigan patients need in jeopardy and help insurance companies make more money.

Putting limits on what medications will be covered in the state means patients like my daughters could be denied medications now or in years to come to help them live with cystic fibrosis, which they were both diagnosed with as infants.

I recently attempted to testify against the PDAB during a short window of time allotted for public comment, and I was not able to speak, although my letter was put on the record. Instead of offering the rare disease community more time to share its concerns, the Senate passed the PDAB on to the full Senate, who also quickly passed the legislation.

Before the legislation goes any further, more time is needed to understand how it could impact future treatment research.

Poorly crafted policy on the state or federal level will disincentivize the investment in research and development that is so needed.

In Washington, it's not any better.

Congress and the Biden administration, in an effort to get the economy back on track, set forth a huge package of initiatives that included language that instructs government agencies to set prices for certain pharmaceuticals.

See any similarities? Congress needs to make fixes to this legislation to preserve investment in research and development.

Bringing a rare disease treatment to the market is already daunting — costing years of research and billions of dollars. Often known as "orphan drugs" because they treat only one condition. This class of medicine has historically been protected and incentivized via the Orphan Drug Act of 1983.

This legislation has been a game changer for research and development of treatments and spurred a major uptick in the number of new treatments being brought to market. However, the new policies will only allow orphan drugs to be exempt from price setting if they only treat one disease.

Often, drugs that have an FDA approval for treating one disease get another look from researchers for other treatment options — this has led to breakthroughs in scores of diseases — rare and otherwise.

The U.S. is the world leader in medication development, accounting for more than half of the FDA approved medications from 2011 to 2020. But government price setting could vastly change that.

By some estimates more than 130 new medications may not make it to market in the next decade because of the changes that companies will have to make to their research and development budgets.

An additional concern is with what's come to be known as the "pill penalty." Treatments that come in pill or capsule form that treat everything from cancer to mental illness. Without a change from Congress, the time that these treatments become eligible for price negotiations is seven years — roughly half the time of other medicines. This simply will make treatment harder for patients, while also disincentivizing investment of medication in this form.

Without action to reverse all of these initiatives, new treatments could potentially never be brought to market because price restrictions will not allow for a solid return on investment for the companies or private equity funding.

Healthcare costs are of course something that impacts everyone — but so is disease. Lawmakers need to find an approach that doesn't put the future of so many potential treatments, and the hope of patients, at risk.

Laura Bonnell is a former radio news reporter in Detroit that now uses her voice to raise awareness about cystic fibrosis through The Bonnell Foundation.