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Negative impact of the IRA on patient access to innovative treatments

By Victor Bulto | Aug 15, 2024

At Novartis, we are constantly pushing the limits of science to develop and deliver transformative medicines that fight disease and help people live life on their terms. Last year alone, we invested \$11.37 billion in research and development. We received approval for 22 new medicines. And we reached more than 250 million people worldwide with our therapies. Offering people the chance to share more moments with their loved ones by delivering life-changing treatments is the heart of everything we do.

We know our work only makes a difference if the people who need our medicines can get them. It is why we are dedicated to finding solutions that help patients access their prescriptions.

While we agree the US healthcare system must evolve to help more people afford their medicines, we do not believe that letting the government set the prices of these medicines via the Inflation Reduction Act (IRA) will guarantee lower costs for patients. This is because Medicare Part D insurance plans decide what Medicare patients pay at the pharmacy counter. We are also concerned that the IRA will limit our ability to discover and develop life-saving medicines for people who need them most.

How would this happen? We put great care in ensuring that anyone who can benefit from our medicines can get them. One of the ways we do this is by providing discounts on our medicines to payer organizations – like health insurance plans, Medicare and Medicaid. The government just announced the government-mandated price for one of our medicines (Entresto). Entresto is a life-saving medicine with no comparable alternative and it has helped more than 2 million heart failure patients in the US alone. Entresto is recommended in guidelines developed by medical societies specializing in the treatment of heart conditions (American Heart Association / American College of Cardiology / Heart Failure Society of America) to help physicians decide which treatments to use for patients with heart failure. Entresto has transformed the standard of care for people living with heart failure.

Today, 98% of people on Medicare who take Entresto can get their prescription without needing prior approval from their insurance plan. They also pay on average \$29 per month for Entresto. This low out-of-pocket cost did not happen by accident. Instead, it is an example of our commitment to get our medicines to the people who need them most.

We're concerned that the government price setting will disrupt this process. Patients could face higher out-ofpocket costs and more limited access to medicines. And, if Novartis did not accede to the government's price, we risked catastrophic fines or patients on Medicare and Medicaid not being able to receive any Novartis medicines, not just Entresto.

In addition to these short-term consequences, the IRA will limit future innovation and hold our industry back from making progress against treating, and even possibly curing, our country's most challenging health issues. At Novartis, we have already had to make difficult decisions about studying some potential new treatments because of the IRA price controls. For example, we've stopped some early-stage cancer drug trials because we would not have enough time on the market to recoup our investment in them before price controls were implemented. The IRA price controls would inhibit our **pp**ility to both bring new medicines to patients in need

and also fuel our future research and development.

There are too many diseases that still don't have adequate treatments. And it is those who desperately need the next medical breakthrough who will suffer if we cannot support ongoing innovation. For these reasons, we will continue to press for an environment that supports patient access and protects the ability to discover and develop life-changing medicines for patients now and in the future.

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