

# IRA Compromises Access to Medicines to Treat Mental Illness

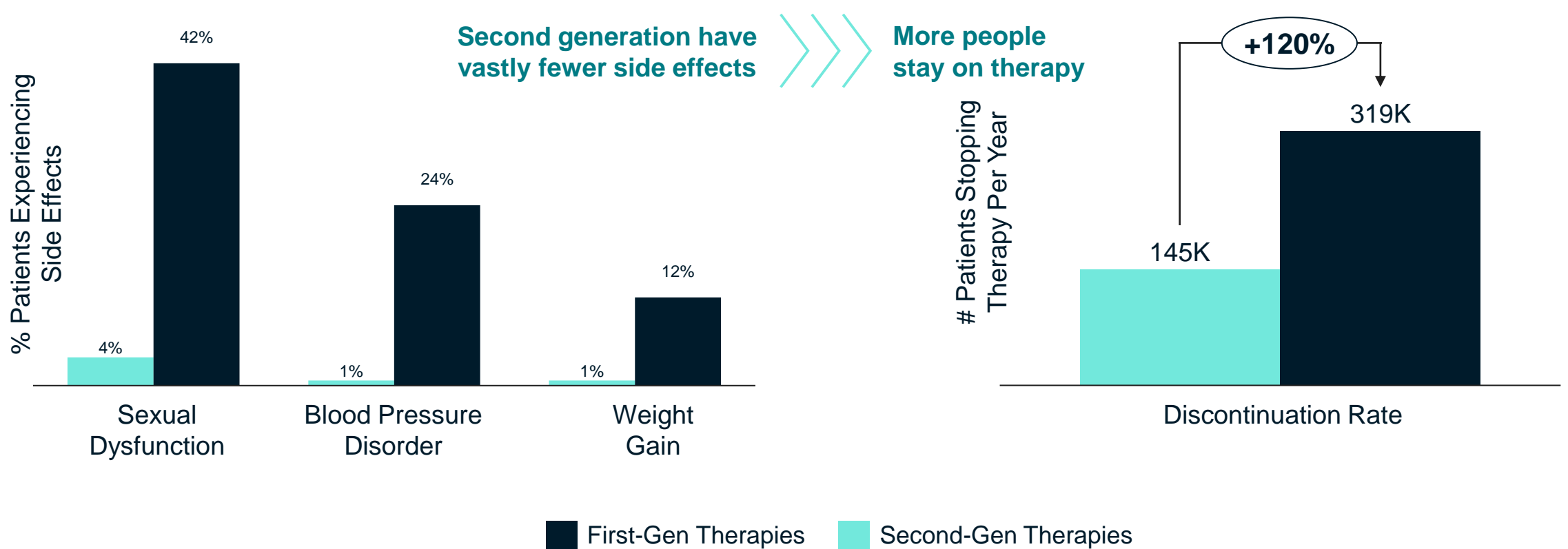
Almost one in five adults in America report being diagnosed with depression during their lives and women are disproportionately affected<sup>1</sup>. Depression is one of the most burdensome illnesses, negatively affecting people’s daily activities, quality of life, employment status, and productivity<sup>2</sup>.

Treating depression and other neurological diseases requires getting medicines past the protective blood-brain barrier and into the brain for the most impact. Pills and other small molecule medicines offer the best way to do just that, but the IRA penalizes their development and threatens patient access to them.

## Key Points

- Allowing Medicare to set the price of small molecule medicines 9 years after FDA approval discourages investment in critical treatments for mental health conditions.
- R&D for medicines to treat mental illness is incredibly challenging: it takes 20% longer to develop a drug treating the central nervous system and 38% longer to receive regulatory approval.
- Particularly in disease areas with approved generics, price controls harm the economic viability of new medicines, discouraging research into additional new treatments to lower side effects, improve efficacy, or address other unmet needs. For example, second generation treatments for major depression significantly reduced people stopping treatment because they had vastly fewer side effects
- Additionally, post-approval research, which takes place after initial FDA approval, is particularly important for mental illness. The short timeframe for price setting imposed by the IRA on small molecule medicines puts this type of resource-intensive R&D at risk.

## Therapies at Risk After IRA: Next Generation Antidepressants



**ONE IN FIVE** people treated for depression would have stopped taking their medicines because of side effects but for the development of second-generation anti-depressants.

**Abbreviations:** IRA=Inflation Reduction Act; R&D=Research and Development