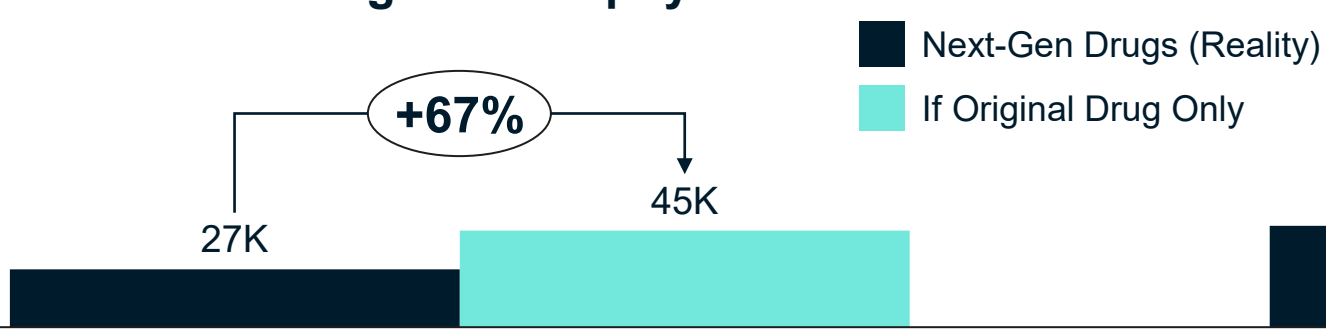
IRA Threatens Access to Safer Anticoagulants that Prevent Strokes and Cardiovascular Disease

Anticoagulant therapies are widely used to reduce risks associated with blood clots, such as stroke. For example, without anticoagulant treatment for irregular heartbeat (atrial fibrillation), more than half of people with Afib would die within five years of symptom onset. Next-generation anticoagulant therapies are commonly used by older adults because of their clinical benefits, reduced side effects, and ease of use compared with first generation therapy. Pills and other small molecule medicines offer a convenient way for people to manage clotting risks and get the additional protective benefits. However, their widespread use subjects them to Medicare price setting. With lower prices set by Medicare, manufacturers are not incentivized to continue further research and development in anticoagulant therapies.

Key Points

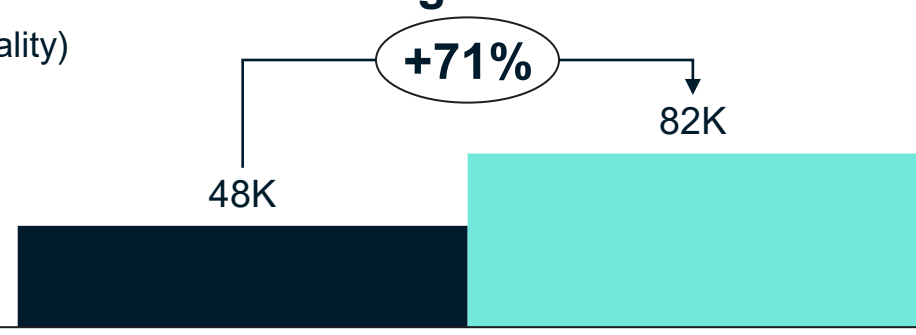
- Allowing Medicare to set the price of small molecule medicines 9 years after FDA approval may discourage investment in critical treatments for common conditions like stroke and heart disease.
- Health inequities are common: these conditions are more prevalent in Black and Brown Americans, who also have worse outcomes in part because of poor access to treatments.
- Post-approval R&D – which takes place after a medicine's first FDA approval – is particularly important for testing new uses for existing medicines. But the shorter timeframe for price setting imposed by the IRA on small molecule medicines puts this type of resource-intensive R&D at risk.
- Since the clinical trials for cardiovascular diseases are notably long and costly, the IRA's shorter timeline for pricing may disincentivize this necessary research.

Annual Incidence of Stroke for Patients on Anticoagulant Prophylaxis



Stroke and Systemic Embolism

Annual Incidence of Anticoagulant-Related Bleeding Adverse Events



Drug-Related Major Bleeding

Continued R&D Leads to New FDA-Approved Uses That IRA Timeline Puts at Risk

Time after 1st FDA approval	*0-2 years*	*3-6 years* R&D decisions account for potential price setting	*7-8 years* Price setting selection
Additional FDA Approvals	**4 approvals** Next-gen drug A: +3 indications Next-gen drug B: +1 indications	**6 additional approvals** Next-gen drug A: +1 indications Next-gen drug B: +2 indication Next-gen drug C: +3 indications	**1 additional approvals** Next-gen drug B: +1 indications

Next generation anticoagulant drugs are estimated to **prevent 18,000 strokes and avoid 34,000 major bleeding** adverse events each year