



Weekly Checkup

Squeezing Bitter Juice

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The **ill effects** of the **Inflation Reduction Act (IRA)** will be with us for **quite some time**, but they are also being matched by newer pricing and regulatory schemes abroad, as American Action Forum Director of Health Care Policy Laura Hobbs highlights in **a new insight**. Let's dive into her key takeaways and ultimately why this all matters.

Hobbs starts by reminding readers of the regulatory ridiculousness of the IRA's drug price-setting scheme (a.k.a. "negotiation"). For those who don't recall, the Centers for Medicare and Medicaid Services (CMS) is setting a maximum fair price (MFP) that Medicare will pay for negotiated drugs. Small molecule drugs are exempted from the MFP for nine years, while biologics are exempted for 13 years. Additionally, orphan drugs are only exempted if they have a single indication, meaning they only treat one condition. Hobbs notes one of the more critical flaws: CMS selected the first 10 drugs for price setting back in August, based on the total cost to Medicare *before rebates and other discounts were applied*. Not only that, but by selecting the drugs Medicare spent the most money on before rebates, CMS is effectively punishing the drugs with some of the highest volumes of utilization among Medicare beneficiaries. **Hobbs cites KFF reporting that showed six of the 10 selected drugs had a median copayment of \$47 per month for Part D beneficiaries. In short, CMS is penalizing drugs that seniors use the most – not drugs that cost seniors the most.** This author has covered the fallout in previous **Weekly Checkups**: Manufacturers are already shifting investments away from small molecules and multiple-indication orphan drugs (or **away from orphan drugs** altogether).

Hobbs writes that the United Kingdom (UK) and the European Union (EU) aren't doing any better. The UK is updating its Voluntary Scheme for Branded Medicines Pricing and Access, which Hobbs notes is expected to increase rebates above the current 26.5 percent. Notably, manufacturers are also penalized for rising volumes of drug sales: If a branded product exceeds a set growth in total sales, the manufacturer must pay an additional financial penalty. On top of this, the UK won't cover a drug if it costs more than £20,000–£30,000 per additional **Quality-Adjusted Life Year**, an arbitrary measure of the quality of a given additional year of life that results from a drug, and **some** in the UK are even calling for that limit to be *decreased*. The EU has some equally dodgy ideas. **Hobbs reports that draft legislation this past April would reduce market exclusivity for new drugs from 10 to eight years unless manufacturers can get those drugs to all 27 member states within two years. That's all well and good, until one notices that while Germany, Austria, and Denmark had over 100 new drug approvals between 2015 and 2017 that launched in 2018, Latvia had just 11.** The pricing and reimbursement process is different for each nation, and the EU requires medicines to become available within 180 days of pricing and reimbursement approval. That's hard to meet for small manufacturers already, but it will become impossible for anyone when pricing and reimbursement approvals take between 127 days (Germany) to more than 823 days (Poland). **The short of it is this: Manufacturers will have significantly decreased incentives to bring new and innovative drugs to the UK and EU markets.**

The big takeaway from Hobbs' insight is that the United States, the UK, and the EU are all attempting similar pricing schemes, which will all likely have the same effects of fewer new drugs and reduced access to those drugs. It should also be noted that none of these policy changes is occurring in a vacuum — all will interact with each other, compounding the negative impact on innovation and access. Pharmaceutical manufacturers are being squeezed on both sides of the Atlantic, and the juice we'll end up getting — potentially **hundreds fewer new cures — is surely too bitter to be worth it.**