The Medication Affordability and Patent Integrity Act (S.2658)

the campaign for SUSTAINABLE Rx PRICING

Brand name drug manufacturers game the patent system and drug approval process by presenting one narrative to the U.S. Food & Drug Administration (FDA) and another to the U.S. Patent and Trademark Office (USPTO).

While both agencies receive the same core information during the approval process – such as a drug's composition and chemistry – brand name manufacturers abuse gaps in agency coordination by withholding key information from the USPTO. This deceptive strategy enables Big Pharma to secure secondary patents long after a drug's original approval, artificially extending its market exclusivity.

The result is the creation of overlapping or contradictory patents that unfairly prolong a product's market dominance, blocking biosimilar and generic drugs from market entry, years after the drug's original patent expired.

The Medication Affordability and Patent Integrity Act (S.2658) has a simple goal:

Stop brand name pharmaceutical manufacturers from gaming the system by certifying that submitted information to the FDA and USPTO does not conflict.

$115M

The Congressional Budget Office (CBO) projects this legislation will boost generic competition, delivering **$115 million in taxpayer savings over 10 years** – with potential additional out-of-pocket savings for patients.

The pharmaceutical industry is making false claims about what the impact of this bill would be because they want to keep drug prices high and block competition. **Get a dose of reality on their false rhetoric here:**

Big Pharma Claim:
The bill will expose industry trade secrets.

DOSE OF REALITY:

The legislation includes explicit trade secret protections that were negotiated with industry itself. The USPTO and FDA already have protocols in place to protect sensitive information.

Big Pharma Claim:
The bill forces drug companies to send an overwhelming amount of sensitive clinical trial data to the USPTO.

DOSE OF REALITY:

That's false. The legislation was revised to exclude sensitive clinical trial data entirely and only includes information sharing provisions directly related to patentability.

Big Pharma Claim:
The bill gives the FDA too much power over patents.

DOSE OF REALITY:

The FDA's role stays the same. This legislation only requires manufacturers to certify that they are submitting the same information to both the FDA and USPTO. The FDA isn't adjudicating patents. It's just accepting an attestation in the normal drug approval process.

> "For too long, Big Pharma has been abusing the patent process to block generic competition and keep prices for patients artificially high. Granite Staters deserve better than a system that allows Big Pharma to exploit our patent system at the expense of families struggling to afford their medications. This bipartisan bill would help close a key loophole and bring down prescription drug costs for families across New Hampshire and the country."
>
> **– U.S. Senator Maggie Hassan (D-NH)**

> "Big Pharma companies have been driving up their profits by gatekeeping select drug information and exploiting our bloated bureaucracy. But their habit of gaming the U.S. patent system means delaying Americans' access to affordable medications. This bipartisan legislation would require manufacturers to disclose critical drug information across agencies, so Congress can finally begin to upend Big Pharma's anticompetitive practices."
>
> **– U.S. Senator Josh Hawley (R-MO)**