

# Why C4IP Opposes the Drug Competition Enhancement Act (S. 1040)

**The <u>Drug Competition Enhancement Act</u>** targets <u>the perceived issue</u> of "product hopping," a term inaccurately suggesting innovators attempt to block competition by making tiny modifications to existing products while ceasing production or marketing of prior versions. This narrative misrepresents how innovation — and progress — happen.

# The Myth of "Product Hopping"

The term "product hopping" unfairly casts improvements, or follow-on innovation, as anti-competitive. In reality, follow-on improvements deliver profound consumer benefits and are essential to progress in all sectors.

We do not find fault with automakers for phasing out older models in favor of safer, more efficient versions. The same logic should apply to biopharma. Follow-on innovations — like chewable medicine tablets, transdermal patches, and extended-release formulations — offer real clinical value: greater safety, easier use, and improved adherence. And they don't block the entry of generics.

Yet under S. 1040, companies could face Federal Trade Commission (FTC) action simply for launching an improved drug — even when the original remains available. That would set a troubling precedent, disincentivizing investment to improve technology and eroding U.S. competitiveness.

### What the Data Actually Shows

A <u>2025 report</u> from the Information Technology and Innovation Foundation (ITIF), a non-profit, nonpartisan research institute, debunks the myth of product hopping.

Key takeaways from the report include:

- **Innovation is <u>cumulative</u>**. After a treatment receives approval, researchers continue working to reduce side effects, improve delivery, and enhance patient experience.
- Follow-on drugs comprise over 60% of the World Health Organization's (WHO's) Essential Medicines List, underscoring the value of ongoing innovation to global health.
- Patents on follow-on innovations do not prolong the original drug's exclusivity. Once the original
  patent expires, generic versions can and do enter the market. A recent U.S. Patent and Trademark
  Office (USPTO) study confirmed this.

## Real-World Examples of Follow-On Innovation

- <u>Insulin Delivery Advances</u>: Ultralong-acting insulin has helped stabilize blood sugar for over 24 hours, improving outcomes and adherence for diabetes patients.
- <u>Alzheimer's Treatment Improvements</u>: Oral disintegrating tablets and patches have made medication safer and easier for cognitively impaired patients to take reliably.
- Rheumatoid Arthritis Treatment Advancements: A biologic initially available only via clinic infusion was reformulated into a self-injectable option reducing clinic visits, cutting costs, and increasing patient autonomy.

#### How the Bill Will Harm the Innovation Ecosystem

- Discourages continuous innovation: The bill would subject innovators to potential FTC penalties and lawsuits for introducing improved versions of drugs, even when the original product remains available. By presuming anti-competitiveness, the bill would chill investment in next-generation therapies.
- Destabilizes the broader IP system: The bill's vague legal standards create uncertainty around legitimate patents, making it riskier to pursue high-cost R&D in biopharma and across IP-intensive sectors.
- Erodes U.S. competitiveness: By weakening IP protections, the bill would slow economic growth, diminish America's global competitiveness, and hand a strategic advantage to foreign manufacturers from China and other countries.

#### **Bottom Line**

**S. 1040** is a solution in search of a problem. It mischaracterizes progress as misconduct - jeopardizing improved treatments and threatening the very system that delivers medical breakthroughs. Congress should reject this bill and protect the innovation pipeline that keeps America at the forefront of global health care

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