# Better Medicines, Not "Meaningless Tweaks": Debunking the Product Hopping Myth

Our intellectual property system, including patents, drives manufacturers to continue investing in R&D after initial U.S. Food and Drug Administration (FDA) approval to develop new dosage forms, formulations or delivery mechanisms that are intended to meet unmet medical needs. Advancing these new products can require significant R&D but the payoff can be enormously beneficial for patients.

Critics use the term "product hopping," claiming that drug companies make "meaningless tweaks" to existing products and market a new version just as the original medicine nears generic or biosimilar competition. But these claims dismiss the real patient benefits of post-approval advances, ignore the patent system's own safeguards and misstate a basic fact: **Protections on a new version of a medicine do not block FDA approval of generics or biosimilars of the original version.**

## Post-approval research and development matters

- **180+ daily pills replaced by a single dose** of a long-acting injectable antipsychotic administered every 6 months.
- **$3.3 billion** in **estimated annual net savings** to Medicaid from improved adherence to long-acting injectables, through lower rates of hospitalization and outpatient care.
- **Mortality reduction of 93%** in the **modern antiretroviral era** compared to the pre-combination therapy period. Much of the innovation in antiretroviral treatment has been driven by continued investment in R&D to develop better-tolerated, more potent drug formulations.

## Five things to know

**Drug development doesn't stop at FDA approval.** The IP system rewards post-approval R&D after initial FDA approval, including new dosage forms, formulations and delivery that often address unmet medical needs.

**New dosage forms and formulations deliver real results.** Easier administration, simpler dosing and fewer side effects can improve adherence and outcomes while reducing complications, hospitalizations and health care costs.

**Investment matters.** Developing a new dosage form or formulation can require long and costly clinical trials.

**The patent system doesn't support trivial tweaks.** The USPTO grants patents only for useful, new and non-obvious inventions, a standard that screens out "frivolous" patents.

**Improved medicines don't delay generics or biosimilars of the original medicine.** New dosage forms and formulations carry their own patents and exclusivity periods. They do not extend protection on the original product. A so-called meaningless change wouldn't delay FDA approval of a generic or biosimilar, and if the new version offers no real benefits, the generic of the original medicine is likely to be used instead.

## The Bottom Line

America's IP system rewards research before and after FDA approval. New formulations may qualify for their own patent protections, but they do not extend protections on the original medicine or delay generic or biosimilar competition for the earlier medicine.