

## America's Unaccountable Generic Drug Industry How Legal Immunity Could Be Making You Sick

### Executive Summary

- Generic drugs account for over 80 percent of drugs prescribed today; 94 percent if a generic version of a drug is available.
- When a brand-name drug patent expires - typically after 20 years - the ingredients become available to generic manufacturers, who then attempt to recreate the drug and sell it for less money.
  - Brand-name patents do not explain how a drug is made or put together.
  - Patents on the time-release mechanism can outlast the drug's patent so generic companies may be without information on how the time-release mechanism works.
- Despite what is commonly believed, generic drugs often do not match their brand name counterparts and patients who take them can suffer health consequences due to unsafe design, labeling or manufacturing.
  - **Design.** To keep costs down, the FDA approves generic drugs without independent testing if they believe the generic drug is "bioequivalent" to the brand-name drug, but this determination is sometimes flawed.
    - Generics may contain some lower quality ingredients, which can affect a drug's absorption into the bloodstream.
    - The FDA sometimes approves a strength or dosage that hasn't been tested at all.
    - Even small design differences between generic and brand-name drugs can have health consequences.

- **Manufacturing.** To keep costs down, generic drugs are more likely than their brand-name counterparts to be manufactured overseas, in countries like India and China, where the FDA rarely inspects factories or the supply chain.
  - History shows that generic drugs or ingredients can be manufactured in dilapidated, dirty factories.
  - Wrongdoing in factories can go undetected by the FDA until a whistleblower comes forward – meaning that the FDA sometimes unknowingly allows fraudulent drugs on the market.
- **Labeling.** Current regulations say that a generic drug must maintain the same label as the brand name drug even if it knows that label to be unsafe, inaccurate or out-of-date.
  - Sometimes when the patent on a brand-name drug expires, the company removes the brand-name version from the market altogether and therefore does not keep current as new information about safety risks emerge.
  - The FDA, recognizing that a generic drug’s safety is not guaranteed, has proposed a new rule to place new responsibility on generic companies to immediately update product label to reflect newly acquired safety information.
- Today, whether or not a patient has any legal recourse for injuries depends entirely on whether they have been prescribed a brand-name or generic drug, even though the consumer typically has no choice as to which version they get.
  - In two recent decisions, the U.S. Supreme Court has ruled that if a drug consumer is harmed or killed by a generic drug due to the drug’s inadequate labeling or defective design, the manufacturer cannot be held accountable in court; the injured patient has no recourse.
  - The same immunity does not apply to the brand-name drug industry.
  - To help close this safety gap, the new FDA rule would restore parity between brand-name and generic drug companies when it comes to their responsibilities for maintaining safe and up-to-date warning labels.

A copy of the full White Paper can be found [here](#).