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Strengthening REMS for patient safety and faster access to generics

By David Gaugh

Let's take a moment to separate the campaign season rhetoric from the facts on drug prices. As brand and specialty pharmaceutical prices continue to rise, one thing is increasingly clear:

Generic drugs drive savings, not costs.

Generics today are 88% of prescriptions dispensed in the United States but account for only 28% of total pharmaceutical spending. Now consider the inverse: 12% of brand drugs are responsible for nearly three-quarters (72%) of total U.S. pharmaceutical expenditures. In addition, 1% of prescriptions dispensed are branded specialty medicines and these drugs alone account for more than 30% of total drug costs.

More can be done to improve patient access to generic drugs, a proven way to grow patient and health system savings. Policymakers and stakeholders alike are calling to reduce the backlog of 3,400 generic applications waiting for Food and Drug Administration (FDA) approval.

Remarkably, certain brand drug companies are actively pursuing tactics to block patient access to generic drugs, even as the public outcry over rising brand drug costs reaches fever pitch. These anti-competitive business practices must stop.

Such maneuvers by brand drug manufacturers include the misuse of FDA-mandated Risk Evaluation and Mitigation Strategies (REMS) patient safety programs or other drug distribution programs, some of which are voluntarily created by brand companies to make generic competition more difficult. Some brand companies engage in multi-year tactics to block generics by denying generic manufacturers access to the product samples needed to conduct the bioequivalence studies required for FDA approval.

Some brand drug company-funded coalitions assert that generic manufacturers seek to weaken drug safety programs like REMS. To be clear, GPhA strongly supports FDA-mandated REMS programs, and many of our members companies actively participate in them. These are critical programs designed for patient safety. Not only do they serve a clear public health purpose when used as intended, but they also need to be strengthened so that brand drug companies can no longer exploit regulatory loopholes to block generic competition and impede patient access to more affordable medicines.

Matrix Global Advisors estimates that curbing this misuse could save the health system more than

$5 billion annually and the need for a remedy is heard from regulators, stakeholders and others.

The Federal Trade Commission has raised concerns about the anti-competitive nature of REMS exploitation. And, the FDA itself acknowledged, through draft guidance and public testimony, that abuse of programs like REMS restricts competition. During a January 2016 Senate HELP hearing, Janet Woodcock, Director, FDA Center for Drug Evaluation and Research, said, “[brand drug companies] feel it’s their duty to their stockholders to delay competition as long as possible.”

Further support for stopping these unscrupulous tactics was expressed to the Senate Aging Committee by leading healthcare stakeholders in a letter that stated, “Companies that exploit restricted access programs delay generic competition and undermine the intent of Hatch-Waxman at the expense of America’s patients.”

FDA and others recognize that abuses cannot simply be curbed through regulation. Legislation providing the FDA with specific authorities is needed. Fortunately, such a legislative solution is within reach.

GPhA urges Congress to pass H.R. 2841, the Fair Access to Safe and Timely (FAST) Generics Act, a bipartisan bill that strengthens REMS by closing the loopholes that make these costly and anti-competitive abuses possible.

The FAST Generics Act aligns with the Hatch-Waxman statute’s generic drug application pathway and provides a reasonable window for negotiations between manufacturers; limits the extent to which companies can delay competition; minimizes the burden on FDA, which has spent hundreds of hours refereeing disputes between companies; and would limit abuse rampant in both FDA-mandated REMS and the self-imposed restricted distribution programs that brand companies like Turing decide to establish for generic and biosimilar drugs.

With so many signs pointing toward unsustainable brand and specialty drug costs, steps must be taken to prioritize and improve patient access to safe and affordable medicines. Passing the FAST Generics Act is one piece of the cost savings puzzle that could save consumers billions and expedite access to safe, effective more affordable generics.

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