

The Risks of Transplant Drug Carve-Out Laws

Attempts Persist to Block Effective Generic Immunosuppressant Drugs

Every day there are millions of Americans who must take immunosuppressant medication to prevent the rejection of transplanted organs. Nearly half of these patients get their prescriptions filled with a generic version of the drug their doctor prescribed.¹ Yet despite the proven safety and effectiveness of generic immunosuppressants, attempts persist in some states to prevent the substitution of lower cost, FDA-approved generics. This is especially unfortunate because there are no published studies or scientific evidence to show that the interchangeability of a generic for a brand name immunosuppressant presents any danger to the patient.

FDA Assesses Approval Guidelines for Generic Immunosuppressants

FDA has carefully evaluated the validity and reliability of current bioequivalence guidelines for approving generic immunosuppressants, as evidenced by the Agency's issuance of specific guidance describing the requirements for their review.² FDA has determined that immunosuppressants require no special status, specific rules or requirements to establish "sameness" between a generic and the name brand product. In fact, several post-approval versions of brand immunosuppressants have been approved by FDA based on exactly the same rules and guidelines that are used for approval of generic drugs. Thus, according to the FDA, there is no reason why generics should be approved based on rules different than those that have been proven valid for brand name immunosuppressants. The FDA has reiterated this position in letters to the National Association of Chain Drug Stores, the National Association of Boards of Pharmacy, and others.³

The Adverse Consequences of Immunosuppressant Carve-Out Laws

In recent years, it has become an often used strategy of brand name drug companies to advocate for state carve-out laws intended to limit generic substitution for transplant drugs that are due to lose patent protection. This is especially true for immunosuppressants because brand companies believe they can justify the anti-generic tactic on the incorrect notion that generic transplant drugs are not as effective as brand versions.

But enactment of carve-out laws has the effect of extending brand product monopolies well beyond patent expiration, at a high cost to patients, insurers and state programs. One example is the brand immunosuppressant Prograf, which faces generic competition when its patent expires this year.⁴ The patent holder has launched a multi-state effort to enact legislation that would prohibit the substitution of generic immunosuppressants.⁴

Carve-out laws also add a new duplicative prescription approval layer, which typically requires pharmacists to call physicians to confirm what is already designated on the written prescriptions. This adverse consequence is particularly evident on state Medicaid programs, which typically require pharmacists to dispense generics unless the prescriber expressly indicates on the script pad that a brand must be dispensed. If these laws take effect, consumers would be denied the choice of lower cost generics, which would threaten their access to vitally needed medicines.

Lawmakers Should Just Say No to Immunosuppressant Carve-Out Legislation

Lawmakers faced with immunosuppressant carve-out legislation must recognize who is lobbying for such anti-consumer, anti-competitive laws. Manufacturers who promote carve-out laws are focused on protecting soon-to-expire monopolies or recently expired monopolies by squelching generic competition and limiting consumer access to lower cost, FDA-approved generics—medicines that generate billions of dollars in savings every year for consumers and state-sponsored drug benefit programs.

1 IMS Health, accessed February 2008.

2 Food and Drug Administration

(www.fda.gov/cder/guidance/bioequivalence/recommendations/Tacrolimus.pdf).

3 April 2007 FDA letter to National Association of Chain Drug Stores; April 1997 FDA Letter to National Association of Boards of Pharmacy.

4 Based on state-by-state research of lobbying reports from California, Florida, Idaho, Illinois, Indiana, Massachusetts, Michigan, Nebraska, Nevada, New Jersey, Oklahoma, Pennsylvania and Texas.

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