Business for Affordable Medicine

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June 24, 2003

The Honorable Dennis Hastert
Speaker
U.S. House of Representatives
Washington, D.C. 20515

Dear Speaker Hastert:

We urge you to pass legislation as part of Medicare reform that will improve the Drug Price Competition and Patent Term Restoration Act, and the patent listing requirements under the Federal Food Drug, and Cosmetic Act (FFDCA).[2]

States spend billions of dollars annually and provide prescription medicine to residents, state employees, and retirees. Tax payers are forced to pay hundreds of millions of dollars in excess costs for the medicine because of loopholes in the Hatch-Waxman Act that restrict timely access to lower-cost generic pharmaceuticals. As a result, BAM members, including states, companies, and labor groups, support changes to the Hatch-Waxman act that will provide greater pharmaceutical competition and more timely access to generics.

Compromise legislation passed by the Senate last week will provide all purchasers with greater access to generics, and will produce hundreds of millions of dollars in savings for federal and state programs. We urge the House to adopt similar legislation as part of the effort by Congress to add a prescription drug benefit to Medicare, and urge you to resist changes or amendments that would weaken the most important cost-savings provisions

98 Stat. 1585 (1984), referred to as the "Hatch-Waxman Amendments."

the Hatch-Waxman Act is increasingly tied to patents that have been listed after the filing of generic applications, resulting in the need for legislation to restrict the use of 30-month stays to only those patents listed in the Orange Book prior to the filing of related generic applications. We also support changes to provisions in the law that allow drug manufacturers to intentionally delay litigation on certain drug patents until the end of any 30-month stay.

In addition, we are concerned that consumers, taxpayers and institutional purchasers have no standing under current law to challenge abusive listings.[3] As a result, all purchasers have been forced at times to pay millions of dollars more than necessary for products that should have faced more timely competition from generics. We support efforts to ensure generic manufacturers will be provided with the most effective avenues possible for relief from unlawful listings.

BAM is committed to working with all members of Congress to restore balance to the Hatch-Waxman Act and improve pharmaceutical competition. We look forward to assisting your efforts.

Sincerely,

[3] Two recent court decisions have held that there is no private right of action under FFDCA to de-list Orange Book listings (s*ee Andrx Pharm., Inc. v. Biovail Corp.*, 276 F.3d 1368, Fed. Cir. 2002; and *Mylan Pharm., Inc. v. Thompson*, 268 F.3d 1323, Fed. Cir. 2001).