



**Comments on Proposed FDA Regulations**  
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Business for Affordable Medicine (BAM) applauds the Bush Administration's effort to improve the 30-month stay provisions of the Drug Price Competition and Patent Term Restoration Act,<sup>1</sup> and the patent listing requirements under the Federal Food Drug, and Cosmetic Act (FFDCA).<sup>2</sup> BAM believes the President's October 24, 2002 initiative (67 Fed. Reg. 65448) is an important step to improve competition among pharmaceutical manufacturers and provide more timely access for pharmaceutical purchasers to lower-priced generic products.

**About BAM**

BAM was established to help institutional purchasers such as states and corporations contain their rising prescription drug costs through pro-market and pro-competitive strategies. BAM includes 10 Governors, 14 corporations, and three presidents of state chapters of the AFL-CIO.<sup>3</sup>

BAM members collectively spend billions of dollars annually to provide prescription drug coverage to their employees and retirees, and their dependents. For example, BAM corporate members spent \$478 million in 2001 for drugs that face patent expiration before 2006.<sup>4</sup> We estimate savings of 50 percent when generic equivalents become available after patents on the products expire. In addition, state Medicaid agencies paid \$1.2 billion in 2001 for 16 prescription drugs that face patent expiration by 2005, and should also save 50 percent when generic alternatives are available.<sup>5</sup>

<sup>1</sup> 98 Stat. 1585 (1984), referred to as the "Hatch-Waxman Amendments."

<sup>2</sup> 21 U.S.C. § 301

<sup>3</sup> Governors include: Howard Dean, MD. (VT), Bob Wise (WV), Mike Foster (LA), Bill Janklow (SD), Don Siegelman (AL), Gary Locke (WA), Bob Holden (MO), Jeanne Shaheen (NH), Ronnie Musgrove (MS), and Tom Vilsack, (IA). Corporations include Ahold, USA, Allete, Albertsons, Bollinger Shipyards, Constellation Energy Group, Eastman Kodak, General Motors, Kellogg Company, Kmart, Motorola, Sysco, Wal-Mart, Weyerhaeuser, and Woodgrain Millwork. Labor presidents include Ed Maine (UT), William Burga (OH), and Ron Pickering (VT).

<sup>4</sup> Based on an internal survey of BAM members, April 9, 2002.

<sup>5</sup> Based on a survey of 46 state Medicaid agencies, Sep. 2, 2002.

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BAM is concerned that some drug manufacturers increasingly use provisions of the Hatch-Waxman Act and FDCA to unfairly prevent generic competition. As a result, BAM supported the “Greater Access to Affordable Pharmaceuticals Act” during the 107<sup>th</sup> Congress to amend the statutes. We are pleased that the President’s initiative includes two critical provisions contained in the legislation.

### **Problems With Present Law**

The Hatch-Waxman Act was intended to encourage investment in pharmaceutical research and development by protecting any patented product listed with the FDA from competition. It was also intended to ensure timely access to lower-cost generic alternatives when the patents expire. Today, pharmaceutical manufacturers increasingly misuse provisions under the Act to delay generic competition. The proposed regulations address this through the following changes:

- Clarify the types of patents that may be listed with the FDA (in the “Orange Book”).
- Require drug companies to re-certify that their patents qualify to be listed with the FDA.
- Limit stays on generic approvals under the Hatch-Waxman Act to one 30-month period.

While the regulations will improve access to generic drugs, we believe they should be strengthened to prevent other abuses of the patent listing and 30-month stay provisions. For example, the FDA has asserted that it lacks statutory authority to make determinations about the validity of Orange Book patent listings.<sup>6</sup> FDA is likely to assert the same position in court if challenges are made to its role under the proposed regulations. A process should be established to ensure the agency will not allow inappropriate listings in the Orange Book.

We are also concerned that third parties, such as purchasers, have no standing to challenge abusive listings.<sup>7</sup> As a result, consumers, taxpayers, and other purchasers have no regulatory or judicial avenue for relief from unlawful listings. Because of this anomaly, payers are forced to pay millions of dollars more than necessary for prescription drugs that are protected by government-provided market exclusivities that were not intended by Congress.

#### 30-Month Stays

The Hatch-Waxman Act prevents FDA approval of a generic drug for 30 months (or until a court decision) upon a challenge by the patent holder. By providing the equivalent of an automatic injunction against generic competitors, the provision establishes monopoly protections for brand manufacturers in addition to those granted by patent laws. Because the Hatch-Waxman Act does not require patent holders to prove their claims in order to obtain a stay, the provision provides

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<sup>6</sup> See 59 Fed. Reg. 50338, 50343 (Oct. 3, 1994), which states, “FDA does not have the expertise to review patent information. The agency believes that its resources would be better utilized in reviewing applications rather than reviewing patent claims.” and 54 Fed. Reg. 28872, 28910 (July 10, 1989), which states, “In deciding whether a claim of patent infringement could reasonably be asserted . . . the agency will defer to the information submitted by the NDA applicant.”

<sup>7</sup> Two recent court decisions have held that there is no private right of action under FDCA to de-list Orange Book listings (see *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).

brand companies with a powerful incentive to sue generic competitors in order to prevent timely generic approvals.

In addition, because the Act provides stays only against products that are alleged to infringe listed patents, the law presents brand companies with “a considerable incentive to cause the FDA to list patents,” according to the courts.<sup>8</sup>

BAM supports the proposed limit of one 30-month stay against generic products. We believe the Administration’s clarification of congressional intent on this point—that multiple stays were not contemplated under the Hatch-Waxman amendments— provides a critical step toward improving access to lower-cost medicine.

We remain concerned, however, that the limit will not prevent the use of “late-listed” patents—those filed after generic applications are submitted—to obtain additional stays. Litigation under the Hatch-Waxman Act is increasingly tied to patents that have been listed after the filing of generic applications. The Senate-passed version of GAAP addressed this problem by restricting the patents that could trigger 30-month stays to those that were listed prior to the filing of the related generic application, a provision we encourage be adopted in the proposed regulations.

We also are concerned that the proposed regulation may encourage drug manufacturers to intentionally delay litigation on other patents until the end of any 30-month stay. This will further delay generic sales, leading to reduced competition in contradiction to the intent of the Hatch-Waxman Act, and resulting in millions of dollars in lost savings to consumers, taxpayers, and other purchasers.

#### Unlawful Patent Listings

Manipulation of the Hatch-Waxman Act is further encouraged by the fact that FDA does not determine whether patents submitted for listing are in compliance with the agency’s listing requirements.<sup>9</sup> As a result of this inaction and prohibitions against third-party challenges, the present system actually encourages drug companies to unlawfully list patents in order to delay generic competition.

BAM is concerned that the proposed regulations provide no mechanism by which FDA may refuse to list unqualified patents, or remove patents that are improperly listed. We believe it is critical that FDA establish an administrative process to prevent such listings, and to remove them when necessary.

We are encouraged by the Administration’s proposal to clarify which patents are eligible for listing. While it is a critical step, it is not likely to completely prevent inappropriate listings

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<sup>8</sup> *Mylan Pharmaceuticals, Inc. v. Thompson*, 139 F.Supp.2d 1, x (D.D.C.), *rev’d* 268 F.3d 1323 (Fed. Cir. 2001).

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given FDA's refusal to enforce its listing criteria. Further, because the FDA already requires drug companies to certify that their patent listings are lawful, it is unlikely that the "recertification" process in the proposed regulations will provide added protection against unlawful listings.

## **Conclusion**

The Administration's proposed regulations represent an important shift away from protectionist interpretations of the Hatch-Waxman Act that stifle pharmaceutical competition and toward proactive efforts to improve the act for the benefit of consumers and other purchasers.

BAM appreciates the Administration's action as an important step to address failures in the Hatch-Waxman Act and FFDCA, and believes its proposed regulations focus on the two most important failures of the present regulatory system. Purchasers will save billions of dollars annually as a result of changes proposed by the regulations; namely, the prevention of multiple stays on generic product approvals.

We believe, however, that legislation is necessary to ensure more effective and comprehensive reform. Legislation is also necessary to provide statutory authority to FDA to enforce its patent listing rules, to provide avenues for challenging unlawfully listed patents, and to address other shortcomings in the present law.