



December 20, 2002

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Food and Drug Administration
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RE: Docket No. 02N-0417: Proposed Rule – Patent Listing Requirements and Application of 30-month Stays on Approval of Abbreviated New Drug Applications

The Academy of Managed Care Pharmacy (AMCP) is pleased to comment on the Food and Drug Administration's (FDA's) proposed rule (October 24, 2002, Vol. 67, Number 206, Federal Register, p. 65447) addressing the patent listing and 30-month stay provisions of the Drug Competition and Patent Term Restoration Act of 1984 (Hatch-Waxman Amendments) to the Federal Food, Drug and Cosmetic Act.

The Academy is a professional association of pharmacists who serve patients and the public by the promotion of wellness and rational drug therapy through the application of managed care principles and practices. The Academy has more than 4,800 members nationally who provide comprehensive coverage and services to the more than 200 million Americans served by managed care.

At a time when health care expenditures are escalating at alarming rates, the Academy firmly believes that greater access to generic drugs can aid in restraining the unsustainable increases in prescription drug costs. These rising prescription drug costs are ultimately borne by consumers through increased health care insurance premiums and cost sharing requirements, and/or limitations on benefit coverage. For the over 41 million Americans without health care insurance, the increasing cost of prescription drugs has a profound effect on their ability to purchase the medications they need. Generic drugs, however, have the same active ingredients and are therapeutically equivalent to brand-name drugs but they routinely cost 3 to 5 times less than brand-name drugs. AMCP encourages the use of generic drug products as safe, effective alternatives to brand-name equivalents. Accelerating the entrance of generic drugs into the marketplace facilitates the design and management of pharmacy benefits that provide safe and affordable prescription drug benefits to American consumers.

The Academy applauds the FDA's effort through this regulation to provide consumers with more timely access to generic drugs. We strongly agree with President Bush's statement during the proposed rule's announcement that "generic drugs make American health care far more affordable."¹ We believe the proposed

¹ See press release issued by the Office of the Press Secretary, October 21, 2002: "President Takes Action to Lower Prescription Drug Prices"

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rule takes steps in the right direction by seeking to correct problems in the implementation of current law which have allowed the delay of entry of generic drugs into the marketplace for reasons other than safety and efficacy.

The Hatch-Waxman Amendments established a regulatory framework that sought to balance incentives for continued innovation by research-based pharmaceutical companies and opportunities for market entry by generic drug manufacturers. However, while balance between the generic and brand-name drug manufacturers was the goal of the Amendments, perceived abuses of the Amendments have received significant attention of late by Congress² and by the Federal Trade Commission³ (FTC). Extended market exclusivity and patent extensions, obtained by some pharmaceutical manufacturers after the primary patent for their initial product expired, have been blamed for preventing timely generic competition with brand-name drugs. AMCP supports proposals that would accelerate the entrance of generic drugs into the marketplace and streamline the generic approval process.

The proposed rule attempts to close the loopholes in Hatch-Waxman by:

- Allowing only one opportunity for a 30-month stay in the approval date of each abbreviated new drug application (ANDA);
- Revising the declaration that new drug applicants (NDAs) must provide regarding their patents, to ensure that only appropriate patents are listed, and;
- Clarifying the types of patents that may be listed in the FDA's list of approved drug products with therapeutic equivalents (Orange Book).

The FDA's Orange Book, referenced above, serves as the official repository of drug patent information. The Hatch-Waxman Amendments required that manufacturers submitting applications to the FDA for approval of a new drug or new formulation of an existing approved drug, also include relevant patent information on the drug itself and its method of use, for posting in the Orange Book. The Amendments also required manufacturers to list any other patents they obtain on a drug after the FDA's initial approval. Generic drug manufacturers who seek to market their version of a brand-name drug may do so only after they indicate that they are not infringing a brand-name drug's patents as listed in the Orange Book.

While the proposed rule can mitigate some of the abuses by changing current regulations, other abuses can only be addressed through legislative reform. Specifically there are two provisions in the Hatch-Waxman Amendments that are of particular concern to the Academy: 1) the 30-month stay provision addressed in the

² On May 8, 2002, the Senate Health, Education, Labor and Pensions Committee held a hearing entitled "Closing the Gaps in Hatch-Waxman. Assuring Greater Access to Affordable Pharmaceuticals"

³ See "Generic Drug Entry Prior to Patent Expiration: An FTC Study" Federal Trade Commission, July 2002

proposed rule, and 2) the 180-day exclusivity provision which is not addressed in the proposed rule.

1) 30-Month Stay. The Hatch-Waxman Amendments require that the FDA automatically stay the approval of a generic drug application for 30 months if the brand-name manufacturer sues for patent infringement. The stay was intended to protect valid, proprietary intellectual property normally protected by patents. However, it has become common practice to include frivolous items under patent protection. As a result, there are now patents listed in the Orange Book, and secured through the U.S. Patent and Trademark office for such questionable items as unapproved uses, unmarketed uses, changes to non-active ingredients, patient education kits that accompany the drug, and drug containers. Such activity has generated the interest of Congress and the FTC because each patent listed for a brand-name drug has the potential to delay generic competition for a 30-month period.

The FTC's July 2002 report acknowledged that the 30-month stay provision was susceptible to strategies that, in some cases, may have prevented the availability of generic drugs. The report cites the following emerging trends:

- The number of 30-month stays per ANDA are increasing.
- The average time to obtain a court decision has increased because of additional patents to be litigated. This is particularly evident in the case of block-buster drugs.
- There has been an increase in the number of additional patents listed by brand-name companies in the Orange Book *after* a generic company has filed an ANDA which causes generic companies to re-certify the newly listed patent(s) and notify the brand-name company of its re-certification.
- In eight instances, brand-name companies have listed later-issued patents in the Orange Book *after* an ANDA has been filed for the product. Out of those eight instances, six have occurred since 1998.

The proposed rule limits brand-name manufactures to one 30-month stay. While the Academy appreciates the FDA addressing this provision, we support the total elimination of the 30-month stay. Because the brand-name manufacturer can secure an additional 30-months of market exclusivity just by filing suit, the automatic 30-month stay invites litigation, regardless of the merits of the suit. If the 30-month stay provision was eliminated, there would be no financial gains derived from improperly listed patents and litigation would be reduced. Legislation aimed at eliminating the 30-month stay should also include statutory provisions to ensure the timely resolution of reasonable patent disputes. Since the FDA does not have the authority to eliminate the 30-month stay provision through the rulemaking process, we strongly urge the Administration to support legislation to eliminate the 30-month stay provision of the Hatch-Waxman Amendments.

Alternatively, if the 30-month stay provision is not eliminated and manufacturers are limited to one 30-month stay, the ability to delist frivolous patents becomes critical to ensuring timely generic drug entry into the marketplace. Although the proposed rule does define the types of patents that may be listed in the Orange Book and strengthens the declaration that patent holders must provide to list their patents, the FTC has noted that:

...currently, the FDA does not review the propriety of patents listed in the Orange Book, and courts have ruled that generic applicants have no private right of action to challenge those listings. As a result, there is no mechanism to delist an improperly listed patent from the Orange Book. The lack of such a mechanism may have real world consequences in that the Commission is aware of at least a few instances in which a 30-month stay was generated solely by a patent that raised legitimate listability questions.⁴

The Academy believes that if the FTC's understanding that the FDA cannot review the propriety of patents listed in the Orange Book, and the 30-month stay provision is not entirely eliminated, there must be a process in place to delist frivolous patents so that generic drug entry to the marketplace is not unduly delayed.

2) 180-Day Exclusivity Provision. Under the Hatch-Waxman Amendments, generic drug manufacturers are encouraged to enter the market with the reward of a 180-day market exclusivity that is granted to the first generic applicant to file an application with the FDA, certifying that the patents on a brand product are either invalid or will not be infringed. Entry into the market for other generics challenging the brand patent is therefore frozen until the 180-day period runs out on the first to file.

The 180-day market exclusivity provision has led some brand-name and generic manufactures to exploit the law. By entering into secret arrangements with brand-name drug manufacturers, generic drug manufacturers, who have filed an application for approval and obtained the 180 days of exclusivity, have agreed not to market their generic product which blocks other generics from entering into the market and extends the brand-name manufacturer's exclusivity for an additional 180 days. The FTC study notes those occasions in which the Agency has challenged such settlements.

With regard to the 180-day market exclusivity provision, AMCP supports the language of the Greater Access to Affordable Pharmaceuticals Act (S. 812) as passed in the Senate in July 2002. S. 812 allowed the 180-day exclusivity period granted to the first generic applicant to roll to the next generic applicant where that applicant

⁴ See "Generic Drug Entry Prior to Patent Expiration: An FTC Study." Federal Trade Commission, July 2002.

was the second to challenge the patent, has successfully done so, and can immediately come to market. This action would be triggered if the previous applicant:

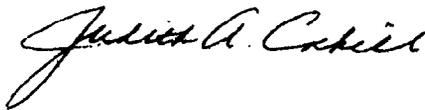
- reaches a financial settlement with the brand-name manufacturer to stay out of the market until the patent(s) have expired,
- fails to go to market within 90 days once their application is effective,
- does not get FDA approval within 30 months,
- fails to challenge a new patent within 60 days,
- withdraws their application, or
- is determined by the Department of Health and Human Services in consultation with the Federal Trade Commission, to have engaged in anti-competitive activities.

We understand that the FDA cannot address the 180-day exclusivity provision of the Hatch-Waxman Amendments through the rulemaking process, therefore we strongly urge the Administration to support legislation to this end.

The Academy appreciates the opportunity to submit these comments on the proposed rule regarding patent listing requirements and application of 30-month stays on approval of abbreviated new drug applications. AMCP applauds the Administration's leadership in addressing the need to assure access to generic drugs. The Academy looks forward to working with the Administration on legislative reform necessary to codify and strengthen this proposed rule.

If you have any questions, please do not hesitate to contact me at 800-827-2627, ext. 313, or at jcahill@amcp.org.

Sincerely,



Judith A. Cahill
Executive Director