

The Independent Information Center



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RxHealthValue

December 23, 2002

Dockets Management Branch
HFA-305
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Re: Docket No. 02N-0417 -- Proposed Rule on Applications for FDA Approval to Market a New Drug: Patent Listing Requirements and Application of 30-Month Stays on Approval of Abbreviated New Drug Applications Certifying that a Patent Claiming a Drug Is Invalid or Will Not be Infringed, 67 Fed. Reg. 65448 (October 24, 2002)

To Whom It May Concern:

RxHealthValue appreciates the opportunity to submit comments on the above-captioned proposed rule. RxHealthValue is a broad and diverse coalition of more than 20 national organizations representing consumer organizations, purchasers of pharmaceuticals, health benefits sponsors and health plans including AARP, Families USA, Ford, General Motors, DaimlerChrysler, Verizon, the United Auto Workers, the AFL-CIO, the Academy of Managed Care Pharmacy, the Alliance of Community Health Plans, the Blue Cross Blue Shield Association, and Kaiser Permanente. RxHealthValue is committed to research, education and both public- and private-sector solutions to assure that Americans receive the full health and economic value from their prescription drugs.

Achieving full economic value for prescriptions drugs entails, among other things, assuring that high quality generics are made available in a timely fashion. Abuses of the current regulations implementing the Drug Price Competition and Patent Term Restoration Act (Hatch-Waxman Amendments) prevented timely generic approval of a number of drugs, as outlined in the FTC's July 2002 report on the subject. In response, RxHealthValue members have taken an acute interest in legislative and regulatory efforts to return the Hatch-Waxman Amendments to its proper position balancing the public interests in promoting true innovation of new drugs and assuring reasonably prompt availability of generics.

We applaud the Administration and FDA for acknowledging the need to update its regulatory approach to implementing Hatch-Waxman because of the abuse of the 30-month stay

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requirement and late listing of patents. The Administration has taken an important first step to right the balance that Hatch-Waxman originally sought to achieve.

However, FDA is constrained by the limitations of the current statutory language. As such, it may be impossible for FDA, on its own, to achieve all that is necessary to assure that the balance of interests can be retained while it updates the regulations. To achieve its goals within the scope of its authority, FDA would have to modify the rule to incorporate several important protections. We believe such modifications to be crucial for the approach envisioned in the proposed rule to be effective.

Establishing a Single 30-Month Stay

As a matter of legislative policy, RxHealthValue continues to question the need for the automatic 30-month stay. As long as the 30-month stay remains a part of the Hatch-Waxman Amendments, however, we believe that the Administration's position that branded manufacturers should be limited to a single 30-month stay per abbreviated new drug application (ANDA) is the most reasonable and appropriate interpretation of the current law. The FDA's recitation of the relevant legislative history provides important support for this view. A revision of the FDA's rule is particularly appropriate given the post-1998 conduct by the brand name industry described in the FTC report, which conflicted with Congressional expectations that, based on representations by the branded industry association, evergreening and stacking multiple patents were not likely to occur. Congress did not expect the Hatch-Waxman amendments to lead to multiple 30-month stays on a single drug.

Any attempt to limit brand-name drug companies to a single 30-month stay must include safeguards to avoid collateral damage and ensure that the patent litigation and FDA review occur simultaneously so that affordable generic drugs reach consumers as soon as possible. The Greater Access to Affordable Pharmaceuticals Act (S 812) took the approach of requiring NDA holders to list all patents within thirty days or lose the right to bring suit against generics challengers and additionally requiring that suits against generics by NDA holders must be filed within 45 days of a challenge to their patent. We urge the FDA to include such safeguards to the extent they were within the Administration's statutory ability and to support legislation to enact such safeguards to the extent they were not. Therefore, RxHealth Value believes that the single 30-month stay provision in the proposed rule must be augmented with measures to ensure the timely resolution of patent disputes. To the extent that such augmentation is beyond the scope of the administrative authority, RxHealth Value encourages the FDA to support legislation to effectuate timely market entry of generic drugs.

Without such augmentation, the basic process under Hatch-Waxman could break down, with brand manufacturers being able to initiate actions to slow or stop generic entry at virtually any time.

Implementation

In regard to the FDA's request for specific comments on implementation of the proposed rule, we would observe that there seems to be no manifest unfairness for branded manufacturers to have the rule applied to all NDA holders since branded manufacturers would still be entitled under the rule to full litigation of their claims.

Possible Litigation

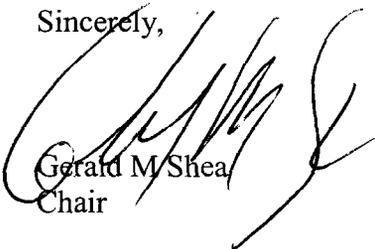
We would further comment on the importance of the FDA's taking note of the widespread questioning of the Administration's statutory authority underling this proposed rule. We would support proceeding with this rule in the modified form suggested above. Prudence would seem to dictate, however, that the Administration support enactment of appropriate legislative remedies at the same time. In this respect we are on record as strongly supportive of the regime embodied in S812, at least, and would hope the Administration could support such a statutory proposal in the 108th Congress.

Conclusion

RxHealthValue is a strong supporter of intellectual property protection. Effective protection of patents is essential to assuring an incentive to develop innovative new drugs. We believe that such protection, including the Hatch-Waxman amendments, created an environment of remarkable innovation in the 1980s and early 1990s that led to the development of many effective new drugs, improving health care and quality of life for many Americans. We believe that a properly updated Hatch-Waxman can achieve the same thing again in this decade, as drug manufacturers will once again have a strong incentive to innovate by developing new drugs, rather than finding new ways to protect market exclusivity on old ones.

Thank you for your consideration of the views of RxHealthValue.

Sincerely,


Gerald M. Shea
Chair

RxHealthValue

RxHealthValue is a national coalition of large employers, consumer groups, labor unions, health plans, health care providers and pharmacy benefit managers that, through its members, represents almost 100 million Americans. RxHealthValue is committed to research, education and both public- and private-sector solutions to assure that Americans receive the full health and economic value from their prescription drugs.

Participating Organizations

AARP
Academy of Managed Care Pharmacy

AFL-CIO
AFSCME
Alliance of Community Health Plans
American Academy of Family Physicians
BlueCross BlueShield Association
Caremark Rx
DaimlerChrysler
Families USA
Ford
General Motors Corporation
International Union, UAW
Kaiser Permanente
Midwest Business Group on Health
National Consumers League
Pacific Business Group on Health
Verizon
Visteon

RxHealthValue
625 Indiana Avenue, Suite 200
Washington, D.C. 20004
202-393-0557