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July 21, 2004



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Congress of the United States
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The Honorable Lester M. Crawford, DVM, PhD
Acting Commissioner
US Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857

RE: Docket No. 2003N-0324 and RIN 0910-AC35

Dear Dr. Crawford:

I am writing to comment on the Food and Drug Administration's proposed regulations to implement Section 17 of PL 107-109, the Best Pharmaceuticals for Children Act of 2002 (BPCA). I had this provision included in BPCA to ensure that consumers know that they have the right to report to the FDA side effects they have experienced from a drug. This provision empowers consumers and gives the FDA more information to help it identify previously unknown adverse events and take necessary action.

Before I comment on the proposed rule, I would like to express my strong disappointment that it has taken the FDA more than two years to issue this proposal, despite language in the law that required a final rule within one year of enactment. This is an important patient safety issue that should not be delayed any longer. The FDA should act expeditiously to implement a final rule, and immediately implement interim measures to inform consumers of the toll-free number.

The FDA's proposed rule requires a side effects statement for all drugs except over-the-counter (OTC) drugs that says, "Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088." The side effects statement is concise and makes it clear that the number is not for medical advice. I also support the agency's decision to use the more consumer-friendly term "side effects" rather than "adverse events." However, I strongly urge the Agency not to qualify the side-effects statement, which would limit the types of events reported. Consumers are not medical professionals or scientists and do not know what "serious" means. By qualifying the statement, FDA will discourage consumers from reporting side-effects and hinder the FDA's ability to identify trends, which is the opposite intent of the law.

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BPCA says the FDA shall promulgate the rule in such a way to "reach the broadest consumer audience." First, I do not agree that OTC drug product labels should have a side effects statement. For prescription drugs, I support the requirement that the side effects statement is in all approved Medication Guides. However, the statement should also be on all package labeling, including refills, to ensure maximum consumer exposure. The alternatives methods for prescription labeling suggested by the FDA, with the exception of pre-printed vial caps, can be thrown away immediately after purchase and are often ignored by the patient.

The FDA should also require the side effect statement on physician labels, which is not included in the proposed rule. In this new information age, consumers can access easily physician labels on the Internet, and consumers looking for answers will turn to these labels as a resource. The side effects statement should be listed there also.

The FDA should also reconsider its proposal to exclude the statement from the patient package inserts (PPIs). PPI's could be the first source of information consumers turn to after experiencing a side effect. The objective of the rule should be that when a consumer experiences a side effect, they will find the side effect statement, wherever they turn to for information first, regardless if it's the bottle, the Internet, or the insert.

Finally, FDA's proposed rule calls for compliance within one year of the effective date. This is too long for consumers to wait. The FDA should require an interim method to notify consumers during the first year after the effective date. Pharmacists should notify consumers of the number immediately, perhaps through the alternative methods listed in the proposed rule (separate sheet of paper, consumer product inserts, pre-printed vial caps). These alternatives can be implemented easily during the first year after the effective date. The side effects statement should be on all packaging, PPI's, Physician Labels, and Medication Guides within one year of the effective date.

Thank you for this opportunity to comment.

Sincerely,



BART STUPAK
Member of Congress

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