

Opening Statement of the Honorable Joseph R. Pitts
Subcommittee on Health
Hearing on “Examining Concerns Regarding FDA’s Proposed Changes to Generic Drug Labeling”
April 1, 2014

(As Prepared for Delivery)

One of the great successes in health care in the past 30 years has been the introduction and widespread use of generic drugs, saving patients and taxpayers trillions of dollars.

Today, nearly 85 percent of drugs dispensed in the U.S. are generics.

This success has been possible because consumers and prescribers have confidence that generic drugs are approved by the FDA as the “same” as their brand name counterparts—not only in terms of their chemical composition, but also with respect to their safety and effectiveness.

This principle of “sameness” is the backbone of the 1984 Hatch-Waxman Act, which provided the pathway for generic drugs to come to market. A generic product has the same benefits and risks as the brand name drug and, therefore, the same labeling is required. Ever since enactment, FDA has logically held that this is an ongoing requirement that extends beyond the date of approval.

However, on November 13, 2013, the FDA issued a proposed rule that would allow manufacturers of generic drugs to unilaterally change their safety-related labeling, deviating from the brand. Both FDA’s legal and policy rationale for this change is dubious at best.

Currently, a generic can only change its label when the branded drug does so and FDA approves the change. In that case, all generics are then required to adopt the same new labeling in a timely manner. This system does not obviate the need for generics to bring new safety-related information to the agency as soon as possible.

Ostensibly, the proposed change is designed to help speed newly acquired safety information about drugs to the consumer. However, FDA has not explained how this rule would actually improve communication of drug safety information to prescribers and patients other than establishing a website on which they will post the various labeling proposals.

The only outcome I see if the rule is enacted is mass confusion. The FDA-approved labeling would essentially become just one in a crowd.

The proposed rule undermines the “sameness” requirement in Hatch-Waxman, and will result in situations where multiple FDA-approved, therapeutically equivalent products will have different safety-related labeling prior to the FDA determining whether such changes are even necessary or appropriately tailored.

Not only is the proposed rule in direct conflict with the plain language of the statute, but it directly contradicts numerous FDA statements and assertions over the years that consistent drug labeling is necessary if consumers and prescribers are to have confidence that generic drugs are as safe and effective as the reference brand name product.

Finally, FDA has admitted that the proposed changes will open generic manufacturers up to greater liability under state tort lawsuits. The added costs of litigation will also cause generic prices to rise exponentially.

I thank all of our witnesses for being here today to discuss these important issues, and I look forward to your testimony.

###