

**Opening Statement of the Honorable Fred Upton**  
**Subcommittee on Health**  
**Hearing on “Examining Concerns Regarding FDA’s Proposed Changes to Generic Drug Labeling”**  
**April 1, 2014**

*(As Prepared for Delivery)*

In a bicameral letter sent earlier this year, my colleagues and I raised important questions and concerns regarding the Food and Drug Administration’s recent proposed rule on generic drug labeling, and today I hope we can learn more about the agency’s rationale. There are significant concerns regarding the legal basis for the proposed rule and its consequences on patients and providers.

First, there is the question of whether FDA has the authority to even make this proposal. Since the passage of the Hatch-Waxman Act three decades ago, the agency has adamantly asserted that a generic drug must have the same labeling as the brand-name product and that this ongoing requirement is based in statute. In 2011, the Supreme Court agreed. With this proposed rule, FDA is taking a different view of the statute. If the law does actually need to be changed for whatever reason, the authority to do so belongs to Congress.

Second, we want to find out why the FDA proposed this rule and who was involved in the decision-making process. FDA stated in the proposal that the generic market has matured and that manufacturers no longer have sufficient incentives to conduct post-market surveillance, evaluation, and reporting. They cited the need to get new safety-related information to patients faster and that allowing generic companies to change their labeling prior to FDA-approval would ensure that such companies actively participated in the process. Yet in their response to our letter from January, FDA cited no evidence that generics are not actively participating already and no evidence that there are public health concerns justifying such a fundamental shift in well-established policy. The agency made very contradictory statements in its brief to the Supreme Court just three years ago. What changed?

Finally, and most importantly, we need to understand how this proposal would impact patients and providers both in terms of confusing warnings and raising the costs of generic drugs. Generic drugmakers like Perrigo in southwest Michigan provide medicines that countless Americans depend on. In fact, more than 80 percent of prescriptions are currently filled with generic drugs. But the FDA’s proposed rule could drive the costs up for the drug manufacturers, patients, and the government.

Simply, this proposed rule reverses years of successful practice and is built on questionable legal terms.

I look forward to hearing from FDA and understanding the need for and rationale behind this proposed rule.

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