



**Statement of Coco Jervis, J.D., Program Director
March 27, 2015**

Food and Drug Administration (FDA) Public Meeting on Supplemental Applications Proposing Labeling Changes for Approved Drugs and Biological Products

The National Women's Health Network is a nonprofit advocacy organization that works to improve the health of all women. We bring the voices of women consumers to policy and regulatory decision-making bodies. We are supported by our members and do not take financial contributions from drug companies, medical device manufacturers, insurance companies, or any other entity with a financial stake in women's health decision-making.

Requiring all prescription drugs to carry current and adequate safety warnings is essential for improving the safety and efficacy of all FDA approved drugs as well as for shoring up needed consumer safeguards and protections. As it currently stands, a woman may have no idea that the generic drug that she is taking could cause devastating complications as generic drug manufacturers are not legally permitted to update drug product labels to accurately reflect known side effects or health risks. Accurate, up-to-date generic drug labels would provide the necessary information women need to ensure that they are accurately dosing and administering a drug at the appropriate levels, are aware of drug-drug interactions with other medicines they may be taking, and have access to critical warnings and precautionary recommendations alongside known side effects and adverse reaction related information.

As the health care decision-makers, not only for themselves but often for family members as well, women have a keen interest in ensuring that drug labels provide them with the most up to date information. It is for this reason that the NWHN strongly supports FDA's proposed rule regarding the *Supplemental Applications Proposing Labeling Changes for Approved Drugs and Biological Products*. This new rule will give women access to better and more accurate information about the risks and benefits of the medications they are taking - regardless of whether a drug is brand-name or generic.

We believe that brand and generic drug manufacturers must have both the authority and the requirement to update drug labels expeditiously. The NWHN has previously supported initiatives to increase the availability and transparency of medical information, including clinical trial demographic information and drug labeling safety information. We support this rule as an initiative to increase and improve the accuracy and transparency of drug label information for informed health care decision making.

Background

Generic drugs account for the majority of prescriptions filled in the United States. In fact, after the introduction of lower cost generic drugs, the market share of the brand name drug may drop significantly. Generic drugs, which are similar in quality, performance, strength, and safety to reference listed or brand name drugs, offer consumers therapeutically equivalent medical products often at significantly lower



prices. Consumers, health providers, and insurance companies have come to rely on generic drugs as a safe and economically sensible alternative to brand name drugs for life-saving pharmaceutical needs. Without labeling authority parity between brand and generic manufacturers, consumers and prescribers of generic drugs face a significant disadvantage in the accuracy and reliability of the information available to them.

In 2011, the Supreme Court ruled that generic manufacturers may not unilaterally update drug safety warnings because the label of generic drugs must match the label of their brand counterpart (*PLIVA, Inc. v. Mensing*). This ruling prevents generic manufacturers from updating their labels even when they know the information is out of date or incorrect. Consumers need the most recent and accurate safety and efficacy information to make health care decisions otherwise they face unnecessary and significant health risks. The proposed rule would rectify this serious and unsafe situation caused by the inability of generic manufacturers to update their own labels.

Impact of Generic Drugs on the Market

Often, the choice between generic and brand drugs is left to the discretion of the pharmacist filling the prescription. The health care provider prescribes a brand name drug, but the patient may receive the generic version – with an out-of-date label explaining the risks and contraindications of the product. The average consumer is unlikely to be aware of the regulatory differences between generic and brand name drugs. Both consumers and prescribers of generic drugs deserve to make informed health care decisions, and need the same safety and efficacy information in order to do so. Requiring both brand and generic manufacturers to update the label on prescription drugs is the best way to alert consumers to new risks or contraindications. The proposed rule would help ensure that these important protections are achieved.

The proposed rule also ensures that drug labels are updated in a time sensitive manner. The rule would require both brand name and generic manufacturers “to update labeling promptly to include a warning about a clinically significant hazard as soon as there is reasonable evidence of a causal association with a drug” - a much needed improvement for both consumers and health providers. NWHN supports the revised guidelines which would help ensure consumers receive the latest drug safety information as it becomes available.

We understand that approval of this rule may result in temporary differences between brand and generic drugs. As such, we support efforts to establish a dedicated Web page on which FDA would promptly post information regarding proposed labeling changes. But even in the absence of an FDA webpage, we believe that updating drug labels with new information is always a benefit to consumers, even if brand and generic versions are not updated at the exact same time. We also support the enhanced notification requirements supported in the proposed rule. Under the current rule, both generic and brand manufacturers have an indefinite amount of time to update their label after new safety and efficacy information is released. Under the proposed rule, brand and generic manufacturers would be required to



update their labels within 30 days after a CBE supplement has been approved. These safeguards are designed to reduce the possible confusion between drug labels for therapeutically equivalent products and we support their inclusion in the rule.

In conclusion, NWHN supports moving this proposed rule expeditiously through the regulatory approval process. Every day that this proposed rule is not approved, millions of women and families face unnecessary health risks. Parity must be established between brand and generic drug manufacturers to update drug safety labels according to enforceable FDA standards to ensure that women continue to have access to safe, affordable, and effective drugs. We urge you to move forward with the proposed rule regarding *Supplemental Applications Proposing Labeling Changes for Approved Drugs and Biological Products*.