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**STATEMENT OF JOANNE DOROSHOW, EXECUTIVE DIRECTOR
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FDA Public Meeting on “Supplemental Applications
Proposing Labeling Changes for Approved
Drugs and Biological Products”

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Thank you for the opportunity to address this very important topic. The Center for Justice & Democracy at New York Law School, of which I am Executive Director, is a national consumer rights organization that is dedicated to educating the public about the importance of the civil justice system. On March 11, 2014, we joined several other public interest organizations in comments strongly supporting the FDA’s proposed rule. Today, we reiterate our support, without modification.

The proposed rule addresses significant regulatory gaps in the FDA’s current generic drug labeling regulations. These gaps allow a generic drug manufacturer to maintain a label even if it knows that label to be inaccurate and out-of-date. In addition to raising serious safety concerns, the current regulations have had severe legal consequences for patients harmed as a result of unsafe generic drug labels. If a consumer takes the brand-name version of drug and is harmed, she can hold that manufacturer accountable in court and get needed compensation. But if her insurance company insists she take the generic version, as is typical, she has no recourse at all. She is severely penalized for taking a generic drug even though she has no control whatsoever over which drug she is given.

This unfair, two-track system has been in place only since 2011, when in *PLIVA v. Mensing*, the Supreme Court immunized the generic drug industry for marketing drugs with labels they know to be inaccurate. The Court reasoned that immunity was justified because under current regulations, generic companies are prevented from independently changing drug labels. In this decision, the Court ignored – but did not contradict – its earlier findings in *Wyeth v. Levine* about the importance of lawsuits, specifically that lawsuits are critical for both supplementing the FDA’s efforts to ensure drug safety and compensating those who are injured.

There are many ways lawsuits can – and have – led to safety improvements. In some cases, litigation has caused unsafe and dangerous drugs to be pulled from the market. Lawsuits also can have a tremendously beneficial role, spurring medical research and alerting the public to larger health risks and problems. In addition, unlike the regulatory scheme which provides no direct benefit to victims, civil cases hold companies directly accountable to those whom they have hurt, and provide their victims with compensation to help rebuild their lives.

Incredibly, rather than restoring rights to patients injured by generic drugs, GPHA and PHARMA have proposed an alternative that would allow both brand and generic companies to escape responsibility to independently fix labels they find are inaccurate or out-of-date once the first generic drug has entered the market. As a consequence, they would also escape liability even if they knew that their products’ labels lacked up-to-date safety warnings – as long as the FDA had not ordered an update. This is a terrible idea.

Under the FDA’s regulatory scheme, primary responsibility for drug safety rests with manufacturers, not the FDA. The Supreme Court noted in *Wyeth* that the adequacy of a drug’s label is the “ultimate responsibility” of the manufacturer “at all times.” This is critical because the FDA has always lacked the resources and ability to act quickly. As the Court explained in *Wyeth* (citing various FDA, congressional and outside reports), “The FDA has limited resources to monitor the 11,000 drugs on the market and manufacturers have superior access to information about their drugs, especially in the postmarketing phase as new risks emerge.” In other words, shifting responsibility for safe labels from manufactures to the FDA, which would

be required to act before any label could be changed, is completely untenable and will create a serious risk to public safety.

The generic drug industry says it opposes this rule change for two main policy reasons: increased costs and confusion. First, the cost argument is absurd. This industry has had legal immunity only since 2011. State tort lawsuits coexisted with FDA generic drug regulation for decades before that.¹ During all that time, the price of generic drugs remained low while the industry's market share grew to extraordinary levels.² Further, this rule creates no new obligation for a generic manufacturer to conduct clinical trials or anything similar.

Moreover, the rule presents less chance for labeling confusion than existing regulations. Under current regulations, a brand name drug can already initiate an immediate labeling safety change pending FDA review. As a result there already are instances where the brand and the generic have different labels for varying lengths of time. But there is currently no requirement for generic labels to be updated within a certain timeframe. The proposed rule improves upon that regime by requiring that all labels be updated within 30 days after the FDA approves a CBE change. This approach will improve the safety of generic drug labels.

The GPHA/PHARMA proposal would not only undermine the FDA's longstanding regulatory scheme, but also would further take away the rights of injured patients rather than restoring them. The FDA's proposed rule change would significantly improve patient safety and restore patients rights. We strongly support the FDA's proposed rule and oppose the GPHA and PHARMA alternative.

Thank you. I am happy to answer any questions.

¹ The current generic drug regulatory scheme was first established by the 1984 Hatch-Waxman Amendments to the Federal Food, Drug, and Cosmetic Act. 21 U.S.C. Food and Drugs, Chapter 9 § 301 et seq. Even before that, "[T]he legislative history of the [1938] FDCA suggests that Congress chose not to create a federal cause of action for damages precisely because it believed that state tort law would allow injured consumers to obtain compensation." *Mutual Pharmaceutical v Bartlett*, 133 S. Ct. 2466, ---- (2013) (Sotomayor, dissenting).

² As the agency notes, generic drugs account for over 80 percent of drugs prescribed today and "[a]mong drugs for which a generic version is available, approximately 94 percent are dispensed as a generic."