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February 28, 2014

Hon. Joe Pitts
Chairman, Subcommittee on Health
Committee on Energy and Commerce
2125 Rayburn House Office Building
Washington, DC 20515
(202) 225-2927
(202) 225-1919 (facsimile)

Re: ***Examining Concerns Regarding FDA's Proposed Changes to Generic Drug Labeling: Hearing Before The Subcommittee On Health*** **(March 3, 2014)**

Chairman Pitts:

In connection with the above-noted hearing, please find attached to this letter a copy of the written remarks that I am submitting jointly with my law partner, Jay P. Lefkowitz, P.C. I look forward to appearing before the Subcommittee on Monday afternoon.

Respectfully submitted,

Michael D. Shumsky, Esq.

Prepared Remarks of
Michael D. Shumsky and Jay P. Lefkowitz, P.C.

Chairman Pitts, Ranking Member Pallone, and Members of the Subcommittee:

Thank you for inviting us to testify in connection with this hearing.

Over the past thirty years, the Hatch-Waxman Act has generated literally trillions of dollars in cost savings. That success stems from a simple, but brilliant, insight: Because two drugs with *the same* chemical and biological properties will have *the same* safety profile, FDA can safely approve generic copies of an already approved drug without requiring new clinical trials. And precisely *because* two drug products with *the same* chemical and biological properties will have *the same* safety profile, the statute naturally requires that generic drug labeling be "*the same as* the labeling *approved* for the" product's brand-name equivalent (or "RLD"). 21 U.S.C. § 355(j)(2)(A)(v) (emphasis added); *see also id*. § 355(j)(4)(G). In a word, *sameness* is the statute's core principle and the driving force of its success.

FDA now wants to permit generic drug warnings that are "*inconsistent* with the labeling for the RLD." FDA, *Proposed Rule: Supplemental Applications Proposing Labeling Changes for Approved Drugs and Biological Products*, 78 Fed. Reg. 67985, 67986 (Nov. 13, 2013) (emphasis added). The Agency has no

power to do so. In our system of separated powers, the Executive Branch and Judiciary are bound by the laws Congress passes. Indeed, as the Supreme Court explained the same year Congress passed Hatch-Waxman, "If the intent of Congress is clear, that is the end of the matter; for the court, as well as the agency, must give effect to the unambiguously expressed intent of Congress." *Chevron USA, Inc. v. Natural Res. Def. Council, Inc.*, 467 U.S. 837, 842-43 (1984).

By this standard, FDA's proposal is indefensible. It pays no heed to Hatch-Waxman's plain text, which explicitly requires generic labeling to be "the same as the labeling" FDA previously "approved for the" generic drug's brand-name equivalent, and indeed bars FDA from approving a generic drug if its labeling is *not* "the same as" the approved labeling for the brand-name drug. 21 U.S.C. §§ 355(j)(2)(A)(v) & 355(j)(4)(G).

The proposal also ignores FDA's own record on this issue. Indeed, FDA has recognized during every Administration in recent memory that generic labeling must be the same as the FDA-approved branded labeling. It did so during the first Bush Administration, *Final Rule: Abbreviated New Drug Regulations*, 57 Fed. Reg. 17950 (April 28, 1992); during the Clinton Administration, *Proposed Rule:*

Requirements on Content and Format of Labeling for Human Prescription Drugs and Biologics; Requirements for Prescription Drug Product Labels, 65 Fed. Reg. 81082 (Dec. 22, 2000); during the second Bush Administration, *Final Rule: Requirements on Content and Format of Labeling for Human Prescription Drug and Biological Products*, 71 Fed. Reg. 3922 (Jan. 24, 2006); and even earlier in this Administration, Br. for the United States as *Amicus Curiae, PLIVA, Inc. v. Mensing*, 131 S.Ct. 2567 (filed Mar. 2, 2011).

FDA's rulemaking proposal defies what Representative Waxman himself has said about this issue. In his words, "*it is clear that a generic and a brand-name label must be the same and that a generic firm cannot unilaterally change its label.* To permit individual generic drug labels to differ significantly from their brand-name counterparts—particularly with respect to safety information—would thwart the 'sameness' goal reflected in the Hatch-Waxman Amendments." Br. of Rep. Henry A. Waxman as *Amicus Curiae*, *PLIVA, Inc. v. Mensing*, 131 S. Ct. 2576, at 14 (filed Mar. 2, 2011) (emphasis added).

And FDA's proposal conflicts with the Supreme Court's recognition that the statute itself—not merely the FDA regulations—bars generics from presenting

different warnings. As the Court explained in *Bartlett*, Hatch-Waxman embodies "*Congress' decision* to regulate the manufacture and sale of generic drugs in a way that reduces their cost to patients but leaves generic drug manufacturers incapable of modifying either the drugs' compositions or their warnings." *Mutual Pharm. Co. v. Bartlett*, 133 S. Ct 2466, 2480 (2013) (emphasis added).

We firmly believe that Hatch-Waxman's sameness requirement is supported by sound public policy and that FDA's rulemaking proposal threatens to harm to the public health, though those issues are beyond the scope of our testimony today. We also understand that the Supreme Court's recent decisions in this area are controversial. But as the Court recognized in both *Mensing* and *Bartlett*, it is up to this body—not FDA—to change the law if it believes change is warranted.

Respectfully submitted,

Michael D. Shumsky, Esq.
Jay P. Lefkowitz, P.C.