Congress of the United States
Washington, DC 20515

September 20, 2013

Dr. Margaret Hamburg
Commissioner, Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, Maryland 20993-0002

Dear Commissioner Hamburg:

We are writing to request information on the proposed regulatory changes the FDA is considering related to the labeling of generic drugs, which could expose generic drug makers to expanded and unnecessary tort liability by changing the legal requirements for the labeling of generic drugs. We are concerned that these changes could lead to the undermining a uniform federal standard for drug labeling, and ultimately impact public safety. Specifically, we request information related to:

- FDA's Notice of Proposed Rule Making (NPRM) which would "create parity between" generic and branded drugs (See RIN: 0910-AG94)
- a 2011 Citizens Petition (Docket Number FDA2011-P-0675) which was filed with the FDA seeking such a change
- FDA's recommendation to the Solicitor General related to the recently filed a brief in the United States Supreme Court , (Mutual Pharmaceutical Co. v. Bartlett ,133 S.Ct. 2466 (2103)), which stated that the "FDA is considering a regulatory change that would allow generic manufacturers, like brand-name manufacturers, to change their labeling in appropriate circumstances."

In the past, the FDA had been clear that a generic drug manufacturer cannot revise its labeling to provide updated safety information. We are concerned that undoing this time-honored policy as contemplated in the NPRM will generate unintended consequences such as increased liability exposure, resulting in increased drug costs for consumers and the government. As you may know, briefs filed in the recently decided Supreme Court case Mutual Pharmaceutical Co. v. Bartlett cited concerns that increasing liability for drug makers will serve primarily to increase costs to the healthcare system. Specifically, the United States Chamber of Commerce noted in its brief "the cost of drugs inevitably would increase" if federal preemption of drug labeling safety laws were replaced by conflicting localized standards.

Accordingly, we ask that your provide a full and complete reporting on the status of this proposed regulatory change, as well as a description of resources expended on the proposed rule and information regarding the statutory authority to issue a rule that allows generic companies to control labeling, as well as a detailed listing of any non-government parties the FDA has met with regarding the proposal referenced in the Supreme Court brief and in the NPRM.

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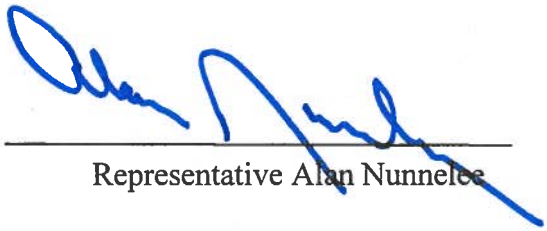
Sincerely,

Representative Kevin Yoder



Representative Alan Nunnelee

Representative David Valadao

Cc: Chairman Robert Aderholt, House Appropriations Subcommittee on Agriculture, Rural Development, Food & Drug Administration and Related Agencies