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The Honorable Margaret A. Hamburg, M.D.
Commissioner
U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, Maryland 20993

Dear Commissioner Hamburg,

I am writing about a proposed Food and Drug Administration (FDA) regulation entitled the Electronic Distribution of Content of Labeling for Human Prescription Drug and Biological Products, which would negatively affect a small business in my district. I respectfully request that the regulatory agenda more accurately reflect a realistic timeline for the implementation of this rule.

It is my understanding that the FDA held a public hearing on April 27th, 2007, to receive public input on the implementation of electronic inserts for prescription drugs and biological products, and comments were submitted by the Pharmaceutical Printed Literature Association (PPLA) in strong opposition to this proposal. However, since that time, the FDA has included this proposal in their regulatory agenda, and the latest entry in the February 13, 2012 Federal Register lists the Notice of Proposed Rulemaking (NPRM) date as December of 2011, a date which has long since passed.

Pharmaceutical insert manufacturers, like Gooding Company, Inc., in Lockport, New York, are suffering due to the uncertainty caused by the delayed rulemaking. Gooding Company, which manufactures printed prescribing information, has proposed a local expansion. However, the ambiguity caused by the FDA's regulatory agenda entry precludes them from securing investments and loans for improvement, which prevents the creation of local jobs. Small businesses are the economic engines that create good-paying jobs and fuel our economic growth.

In addition, I would also like to express my concern regarding the impact that such a rule would have on the distribution of the vital information included in these paper inserts. As a representative of a rural district, I am conscious of the technological challenges facing our underserved communities. At a time when rural communities are struggling to bring computer technology and internet infrastructure into their homes and businesses, including health care providers, paper inserts continue to play an important function in the safe distribution of prescription medication. The production costs of these inserts are infinitesimal in comparison to the drugs they accompany, and there is no assurance that healthcare practitioners have uniform access to the technology required to access electronic distributions.

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Once again, I respectfully request that this entry in the FDA's regulatory agenda reflect a realistic timeline. Currently, the harm that it produces seriously outweighs its purpose, especially since the outdated NPRM is proof that the FDA is far from implementing such a rule. I hope you will give these concerns your full and fair consideration and respectfully await your decision. If you have any questions or concerns, please feel free to contact me.

Sincerely,

Kathleen C. Hochul

Kathy C. Hochul
Member of Congress

KCH/aps