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COMMITTEES:
SPECIAL COMMITTEE ON AGING, RANKING MEMBER
APPROPRIATIONS
SELECT COMMITTEE ON INTELLIGENCE

December 22, 2014

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

Dear Dr. Hamburg:

On December 18, 2014, the Food and Drug Administration (FDA) issued proposed rules to amend current FDA regulations to require "electronic distribution of prescribing information intended for health care professionals, which is currently distributed in paper form on or within the package from which a prescription drug or biological product is dispensed" and, subject to very narrow exemptions, provides that "prescribing information intended for health care professionals will no longer be permitted to be distributed in paper form with the package from which a prescription drug or biological product is dispensed."

I am extremely concerned that the publication of such a proposal requiring electronic labeling in lieu of paper is in direct conflict with the explicit direction of Congress in the Explanatory Statement accompanying the Fiscal Year 2015 Consolidated and Further Continuing Appropriations Act, which was signed into law on December 16, 2014. The legislation included, by reference, the following report language adopted by the Senate Appropriations Committee (S.Rpt. 113-64):

> *Prescription Drug Inserts. – The Committee is aware that FDA is considering regulatory changes that could eliminate printed professional inserts for prescription drugs. A July 2013 GAO report on the topic concluded that while there were potential public health benefits associated with electronic labeling, relying exclusively on electronic labeling could disadvantage physicians, pharmacists, other health care provider, and ultimately patients, potentially adversely affecting public health. Therefore, the Committee directs FDA to ensure that any proposed regulation regarding electronic inserts of drug labeling does not come in lieu of paper inserts.*

Moreover, as the former Chair of the Senate Homeland Security and Governmental Affairs Committee, I conducted an extensive investigation into Hurricane Katrina. We learned in the course of our investigation that there are times when electronic technologies simply are not available due to temporary power outages or during the aftermath of natural disasters. As a representative of a rural State, I am also concerned that many patients and health care providers still reside in areas with limited Internet access. According to data published by the Federal Communications Commission, approximately 14 million Americans have inadequate access or no access to adequate broadband capabilities. These were all issues that I raised with Dr. Janet Woodcock, Director of the Center for Drug Evaluation and Research at the FDA, when she testified before the Senate Special Committee on Aging on December 11, 2013.

I therefore am requesting that the FDA immediately withdraw its proposed rule for "Electronic Distribution of Prescribing Information for Human Prescription Drugs, Including Biological Products," consistent with the requirements in the new law.

Sincerely,

Susan M Collins

Susan M. Collins
United States Senator

SMC:ph