

Congress of the United States

Washington, DC 20515

February 7, 2014

The Honorable Sylvia Mathews Burwell
Director, Office of Management and Budget
725 17th Street, NW
Washington, DC 20503

Dear Director Burwell:

We understand that a proposed rule, RIN: 0910-AG18, Electronic Distribution of Prescribing Information for Human Prescription Drugs Including Biological Products, is under review by the Office of Management and Budget. Electronic labeling has been of significant interest to Congress. We write to request timely release of this proposed rule.

As the pharmaceutical market has evolved, electronic data interchange has become more common for commercial and regulatory interactions. For example, the Food and Drug Administration (FDA) has required manufacturers to submit drug labeling information in an electronic format since 2005.

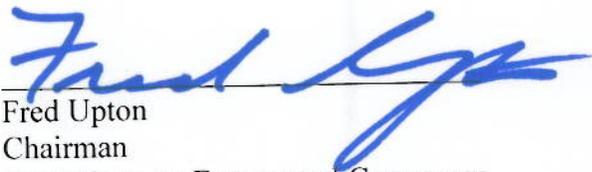
Additionally, electronic labeling has been cited by the FDA as allowing for the efficient distribution of updated information to health care providers about a prescription drug. Consequently, the agency has repeatedly included electronic labeling in its semi-annual regulatory agenda. However, FDA's specific plans regarding electronic labeling have yet to be made public.

Release of the proposed rule will allow for a thoughtful examination of this issue, and provide stakeholders an opportunity to comment and provide input on FDA's proposed implementation of electronic labeling.

We therefore encourage you to prioritize release of this proposed rule, and we appreciate your work on this important topic.

Sincerely,

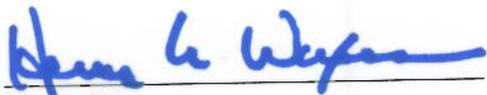
Letter to the Honorable Sylvia Mathews Burwell
Page 2



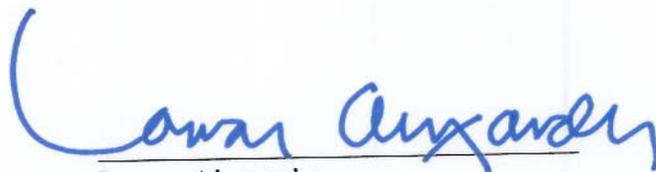
Fred Upton
Chairman
Committee on Energy and Commerce



Tom Harkin
Chairman
Committee on Health, Education,
Labor, and Pensions



Henry Waxman
Ranking Member
Committee on Energy and Commerce



Lamar Alexander
Ranking Member
Committee on Health, Education,
Labor, and Pensions