

April 4, 2014

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

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

Dear Commissioner Hamburg and Director Burwell:

The National Community Pharmacists Association (NCPA) is writing today to respectfully request that the Office of Management and Budget (OMB) and the Food and Drug Administration (FDA) suspend plans to issue the pending proposed regulation “Electronic Distribution of Prescribing Information for Human Prescription Drugs Including Biological Products”, which was received by the Office of Information and Regulatory Affairs (OIRA) at OMB on August, 3, 2013. We are requesting the rule not be issued at this time until reliable systems are in place that will allow pharmacists to access electronic professional package inserts (PI) in a timely and efficient manner.

NCPA represents the interests of America's community pharmacists, including the owners of more than 23,000 independent community pharmacies. Together they represent an \$88.7 billion health care marketplace, dispense nearly 40% of all retail prescriptions, and employ more than 300,000 individuals, including over 62,000 pharmacists.

We would like to point to the July 2013 Government Accountability Office (GAO) report entitled *Electronic Drug Labeling: No Consensus on the Advantages and Disadvantages of its Exclusive Use* as support for our request to halt issuance of this pending proposed regulation. This report concludes that relying on electronic labeling as a complete substitute for paper labeling could adversely impact public health by limiting the availability of drug labeling for some physicians, pharmacists, and patients by requiring them to access drug labeling through a medium with which they might be uncomfortable, that they might find inconvenient, or that might be unavailable.¹

In addition, one of NCPA's recommendations for any move to electronic labeling is that there should be a single data source that is reliable and unbiased for pharmacists to use. The GAO report came to the same conclusion and pointed out that websites that currently provide electronic labeling have limitations.² For example, nongovernmental websites are not standardized, and one website can include information on a particular drug not included on another website.

¹United States Government Accountability Office Report to Congressional Committees; Electronic Drug Labeling No Consensus on the Advantages and Disadvantages of Its Exclusive Use; GAO-13-592; July 2013

² ibid

NCPA's other recommendation for any move to electronic labeling is that costs not be shifted to small business community pharmacies. If paper drug labeling ceases to exist, costs will undoubtedly shift to the pharmacies to obtain and/or provide this information to patients who ask for it.

The GAO report noted that if patients want to continue receiving drug labeling in paper form and pharmacies are expected to print drug labeling for distribution, it would shift the costs of printing to the pharmacies.³ Please note that it is common practice in community pharmacies for pharmacists to utilize the manufacturer-provided paper insert, which patients often request. Small business community pharmacies are unable to bear the costs of providing this information on their own, which would include additional computer terminals, printers and other office supplies such as paper, ink and toner. The GAO report also rightly noted that disruption to pharmacy workflow that would ensue from having to access the labeling electronically reduces the time available to counsel patients and has been shown to increase the risk for errors made when dispensing a drug.⁴

In conclusion, NCPA appreciates your review and careful consideration of our comments as we respectfully request that you refrain from issuing the pending proposed regulation "Electronic Distribution of Prescribing Information for Human Prescription Drugs Including Biological Products."

Sincerely,

A handwritten signature in black ink, appearing to read "B. Douglas Hoey". The signature is fluid and cursive, with the first letters of the first and last names being capitalized and prominent.

B. Douglas Hoey, RPh, MBA
Chief Executive Officer

³ ibid

⁴ ibid