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Consumers for Paper Options Urges FDA to Rescind Switch to Electronic Drug Labeling

Paper Inserts Are Most Reliable Method of Delivering Guidelines, which Include Dosing & Interaction Notices, to Pharmacists

WASHINGTON, D.C. (March 17, 2015) – [Consumers for Paper Options](#) (CPO), a coalition of individuals and organizations advocating for access to paper-based services and information, today submitted comments urging the U.S. Food and Drug Administration (FDA) to maintain paper-format prescribing information for medications. Under a new proposed rule, prescription drugs would no longer include paper “professional inserts,” which contain important prescribing information – such as drug interactions and dosing guidelines – used by pharmacists.

“The U.S. is not ready for an all-electronic drug labeling mandate,” said John Runyan, executive director of Consumers for Paper Options. “According to the FDA’s own survey, many pharmacists expressed concern over e-labeling due to Internet connectivity issues or browsing restrictions at the pharmacy level. Paper format is still the most effective and reliable means of communicating potentially life-saving information about drug interactions, dosing and other safety restrictions.”

In its comments – available [here](#) – Consumers for Paper Options makes the following main points:

- The FDA has not established that the rule is necessary and has made no attempt to demonstrate the current system is qualitatively or quantitatively inadequate;
- The FDA’s Preliminary Regulatory Impact Analysis (PRIA) fails to consider the potential negative public health outcomes resulting from cyber-security risks and pharmacist workflow interruptions which all might result from this ruling;
- The FDA erroneously assumes all pharmacies have equal or adequate Internet access without contemplating emergency events, such as natural disasters, which can cause power outages and loss of Internet. Even in blue sky scenarios many pharmacists do not have reliable Internet connection or web-browsing capabilities. The Federal Communications Commission reports that 55 million Americans lack advanced internet access and more than half of the Americans in rural areas lack it. The comments also quote a 2015 national survey in which 27 percent of pharmacists indicated that their pharmacy “either does not have Internet access or that they cannot browse the Internet.”

About Consumers for Paper Options

Consumers for Paper Options is organized by the American Forest & Paper Association (AF&PA) and the Envelope Manufacturers Association (EMA) to bring together industry, non-profits and consumers in an

effort to address the transition to Internet-only resources at the exclusion of millions of citizens. Consumers for Paper Options is united in the belief that paper-based communications are critically important for millions of Americans, especially seniors and the 25 percent of households without Internet access. While regulated entities and governments at every level need to streamline services, cut costs and improve efficiencies, the goal of Consumers for Paper Options is to preserve access in a way that neither hinders the natural evolution of technology nor discriminates against those who may not, or cannot, use it. For more information, visit www.paperoptions.org.