



# PHARMACEUTICAL PRINTED LITERATURE ASSOCIATION

## Overview

The Pharmaceutical Printed Literature Association (PPLA) is the leader in advancing patient safety through the use of printed medical information.

Currently, the content and wording of Package Inserts (PIs) is reviewed and approved by the Food and Drug Administration (FDA) and must include full prescribing information, covering dosage and administration, warnings and precautions about side effects, adverse reactions and drug interactions.

However, since 2009, the FDA has considered a proposed rule that would require electronic package inserts for human drug and biological prescription product, in lieu of paper.

PPLA believes that printed PIs are critical to the health and safety of American patients who benefit from taking prescription medications and the public agrees.

## Public Opinion is Clear: *Keep Printed Information*

96%

**OPPOSE**

the proposed rule

4%

**SUPPORT**

the proposed rule

\*Gathered from the FDA

**JOBS** Up to **30,000** jobs at risk including printers, suppliers, distributors, and others involved in the support of the production of paper labels.

**UNFAIR COSTS-SHIFTING** Pharmacy costs will increase up to **\$89 million per year** while drug manufacturers will save up to **\$171 million annually**.

## The Risks of E-Labeling

PPLA supports availability of medication information in electronic form as a complement to FDA-approved, manufacturer supplied information distributed on paper. Here's why:

-  Electronic information is not always available to patients and health care providers.
-  Search engines often link patients, providers, and caregivers to marketing information rather than the official package inserts that contain critical medication information.
-  It is contrary to law in place since 1938.
-  Numerous studies have shown that information is more efficiently retained via printed media than electronic.

## Patient Safety

Patients want information that is understandable and helps them learn what is going on with their bodies as they consume medication.

It is estimated that adverse drug events associated with ER visits and hospital admissions cost the health care system \$671.6 billion in 2017.<sup>1</sup>

1. NERA Economic Consulting. *An Estimation of Cost Savings Associated with Patient Medication Information*. May 2017