PHARMACEUTICAL PRINTED LITERATURE ASSOCIATION

About PPLA

The Pharmaceutical Printed Literature Association is a coalition of printers, equipment manufacturers, raw material suppliers, and distributors of regulated pharmaceutical information, including Package Inserts (PI), Medication Guides and Patient Package Inserts, as well as other label packaging like folding cartons and pressure sensitive labels. Our members include 25 companies, employing over 10,000 individuals with manufacturing operations in 15 states. Given our expertise in the field of prescription labeling, PPLA has long advocated for the continued and broad utilization of pharmaceutical information, including patient medication information (PMI) and PI for professional use.

PPLA is committed to three guiding principles:

- Promote and improve patient safety through the use of accessible, relevant, and understandable printed medical information that accompanies drug products.
- Advocate for printed literature as research has proven that people prefer and better comprehend technical information when it is printed.
- Increase the body of knowledge and provide education regarding the importance of printed literature.

About PI

Paper format PI is the primary source of reliable, scientific information for health care professionals throughout the country, including clinicians and pharmacists. The Food, Drug, and Cosmetic Act requires that PI be printed and accompany all drugs from the manufacturer to the pharmacy or clinician's office. PIs are developed during the drug approval process at the Food and Drug Administration (FDA), which provides manufacturers with clear guidelines for what must be included. They contain valuable information and can help prevent potentially fatal drug interactions or adverse drug events.

State of Play

Despite Congress' intent to maintain the paper PI, there may be attempts to strip this important language out of funding legislation for Fiscal Year 2021. They seek this change for one reason – cost savings. Meanwhile, the intended audience for PIs, health care providers and pharmacists in particular, overwhelmingly prefer that PIs be provided in paper format. Access to paper format PI must be preserved for several key reasons –

- Electronic information is not always available due to lack of internet connectivity.
- Search engines often link first to marketing information rather than the official package inserts.
- Numerous studies have shown that information is more effectively retained via printed material than electronic. According to a 2013 study by the Government Accountability Office (GAO), relying on electronic labeling as a complete substitute for paper labeling could adversely impact public health.[1] In their study, the GAO notes that an absence of printed labels is particularly problematic for prescribers and patients in rural practice settings, deployed military practice settings, and in all areas in the event of a severe weather or man-made disaster.[2]
- Another study by NERA Economic Consulting found that pharmacists prefer paper labels over the electronic version.[3] And, as the GAO highlighted, when pharmacists have to print their own labels, they have less time available to counsel patients.[4]

1 U.S. Government Accountability Office. "Electronic Drug Labeling: No Consensus on the Advantages and Disadvantages of Its Exclusive Use." U.S. Government Accountability Office (U.S. GAO), 8 July 2013, www.gao.gov/products/GAO-13-592.
2 *ibid*
3 NERA Economic Consulting. "Pharmacy Practice: A Report On Pharmacists' Use of Printed Package Inserts." NERA Economic Consulting. 20 January 2015, https://www.nera.com/content/dam/nera/publications/2015/Survey%20of%20Pharmacists%20Attitudes%20Towards%20E_labeling%20Final.pdf
4 See GAO Study

PI Myth Vs. Fact

Several false and exaggerated claims have been made about paper format PI. **Here we set the record straight.**

Myth #1 **Electronic labeling in lieu of paper improves patient safety.**

Fact: There is no data that backs this claim. In fact, health care professionals receive critical information through paper format PIs, which helps keep patients safe. What's more, ensuring that prescribing physicians are fully informed with paper format PI content can prevent potentially fatal drug interactions. According to the Centers for Disease Control and Prevention adverse drug events send more than 1 million people to hospital emergency rooms each year.[5] What's more, it is estimated that adverse drug events associated with ER visits and hospital admissions cost the health care system $671.6 billion in 2017.[6]

Myth #2 **A transition to an electronic only PI labeling system will save money.**

Fact: A FDA cost benefit analysis monetizes the time lost by pharmacists using the proposed system at between $31.9 million and $39.8 million annually, but this estimate underestimates these costs because it fails to include time lost from using the automated phone line for prescribing information.[7]

Myth #3 **Health care providers want or prefer electronic labeling and are sometimes "confused" by paper format PI.**

Fact: Time and time again, health care professionals have made it clear their preference for paper format PI clear. Approximately 93% of health care providers opposed a previously proposed transition to electronic labeling.[8] What's more, 80% of pharmacists stated that they had referred to a paper format PI within the last month to review critical prescription information on behalf of patients.[9] There are no studies to support claims that health care providers are "confused" by paper format PI and even if they were, the manufacturers and FDA would be at fault given their role in developing the content itself.

Myth #4 **Only 6% of pharmacists reported using exclusively paper resources to retrieve prescribing information.**

Fact: According to a 2014 NERA study, 88% of pharmacists indicated that they had utilized the printed package insert, with 73% having used the printed package insert at least monthly.[10] No pharmacist in the NERA study relied exclusively on the printed package insert for prescribing information, nor did they rely exclusively on electronic reference sources.Having access to both options is important to pharmacists, particularly community pharmacists.[12]

Myth #5 **Electronic labeling, which patients prefer, ensures patients have the most up-to-date information.**

Fact: It is unlikely that PI would need a major revision. In the unlikely event that it does, updated materials can be printed and delivered to manufacturers within 24 hours if needed. The development of content for PI is a process driven by pharmaceutical manufacturers and the FDA. And, according to submitted comments to the FDA, public sentiment on this matter is clear. Consumers to the tune of 96% overwhelmingly opposed efforts to eliminate paper format PI.[13]

Myth #6 **FDA has the authority to eliminate paper format PI.**

Fact: FDA does not have the authority to eliminate paper format PI and has said as much.[14] The requirement that paper format PI be provided to pharmacists by manufacturers was codified into law by an act of Congress.

5 Centers for Disease Control and Prevention (CDC). "Adverse Drug Event Monitoring." CDC, 17 August 2017, https://www.cdc.gov/medicationsafety/program_focus_activities.html
6 See NERA Study
7 U.S. Food & Drug Administration (FDA)."Proposed Regulatory Impact Analysis: Electronic Distribution of Prescribing Information for Human Prescriptions Drugs, including Biological Products." FDA, December 2014, https://www.fda.gov/media/90685/download
8 Department of Health and Human Services (HHS), Food and Drug Administration (FDA). "Comments on Federal Register/Vol. 79, No. 243:Electronic Distributaion of PRescribing Information for Human Presciption Drugs, Including Biological Products." FDA, HHS, 19 December 2014. https://www.regulations.gov/docketBrowser?rpp=25&po=0&dct=PS&D=FDA-2007-N-0363&refD=FDA-2007-N-0363-0040
9 *ibid*
10 See NERA Study
11 *ibid*
12 See HHS, FDA Comments
13 *ibid*
14 See GAO Study