PHARMACEUTICAL PRINTED LITERATURE ASSOCIATION

Patient Medication Information

There is currently no standard for Patient Medication Information (PMI). PPLA is advocating for a one-page FDA approved, manufacturer distributed PMI, optimized for maximum cognitive impact. Dr. Ruth Day's Duke University study compared PPLA's recommended format to the FDA endorsed "bubble format" which was a single page. The PPLA format was found to be far superior for patient cognition and retention. PMIs printed at the pharmacy is current pharmacy practice. However, studies have shown they are inconsistent and ineffective in communicating the critical consumer knowledge that is necessary.

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] GAO found that seniors in particular could be hit hard by a transition to electronic labeling as many seniors may not be comfortable accessing drug labeling information online. What's more, GAO found that patients impacted by power outages or during the aftermath of natural disasters could lose access to critical medication information if such information was only available online.

Package Inserts for Health care Professionals

Package Inserts (PIs) or "Labeling Content," is the primary source of reliable, scientific information for health care professionals as "learned intermediaries" to patients. In 1938, the United States *Federal Food, Drug, and Cosmetic Ac*t required PIs to be printed and accompany the drugs from the manufacturer to the pharmacy. PIs are developed during the drug approval process that the manufacturer must submit to the FDA. The Food and Drug Administration (FDA) provides manufacturers clear directions not only on the content required, but also on format, including legibility, readability, and limits on type size.

Why It Matters

Making sure that prescribing physicians are fully informed with PI content can help 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.[2] People age 65 and older, are **three times more** likely to visit ERs due to adverse drug events and **seven times more** likely to be hospitalized.[3]

Health care professionals receive critical information through PIs which helps keep patients safe. In addition, PIs saves our health care system money. According to the FDA, almost half a billion dollars is saved from avoiding adverse drug events and saving practitioners' time, balanced against minor costs for printing and designing to the new format.[4]

For those who suffer chronic conditions, requiring and managing multiple prescriptions can be complicated. With the help of PMI, patients and their caregivers can digest critical information to avoid preventable medical errors and increase compliance with prescribing instructions.

1 https://www.gao.gov/products/GAO-13-592
2 https://www.cdc.gov/medicationsafety/program_focus_activities.html
3 See footnote 2
4 http://pplaonline.org/package-inserts-pis