PHARMACEUTICAL PRINTED LITERATURE ASSOCIATION

July 2, 2020

The Honorable Richard Shelby
Chairman
Senate Committee on Appropriations
Room S-128, The Capitol
Washington, DC 20515

The Honorable Patrick Leahy
Vice Chairman
Senate Committee on Appropriations
Room S-128, The Capitol
Washington, DC 20515

Dear Chairman Shelby and Vice Chairman Leahy:

We write to you today as members of the Pharmaceutical Printed Literature Association, 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. We have long advocated for the continued and broad utilization of pharmaceutical information, including patient medication information (PMI) and PI for professional use. We request that you take action to ensure that PI continues to be made available via paper format.

Paper format PI is the primary source of reliable, scientific information for healthcare professionals throughout the country, including clinicians and pharmacists. The US *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.

It is essential that access to paper format PI is preserved for many reasons: 1) electronic information is not always available due to lack of internet connectivity; 2) search engines often link first to marketing information rather than the official package inserts; and 3) 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)[1], relying on electronic labeling as a complete substitute for paper labeling could adversely impact public health. In their study, the GAO notes that an absence of printed labels is particularly problematic for prescribers and patients in rural practice settings, deployed

[1] https://www.gao.gov/products/GAO-13-592

military practice settings, and in all areas in the event of a severe weather or man-made disaster. Another study by NERA Economic Consulting, found that pharmacists prefer paper labels over the electronic version. And, as the GAO highlighted, when pharmacists have to print their own labels, they have less time available to counsel patients.

Given this, we, and many physician, pharmacy, and patient advocacy groups, have been concerned that each year since 2009, FDA has considered a proposed rule that would require electronic PI for human drug and biological prescription products in lieu of paper. Thankfully, we have been able to work with Congressional leaders to block FDA from continuing to push this proposed rule forward through the annual appropriations process. The Senate and House Appropriations Committees have worked in a bipartisan manner and included the following language in the Agriculture, Rural Development, Food and Drug Administration, and Related Agencies Appropriations legislation for Fiscal Year 2020 and we ask that the Committee continue to support the inclusion of this language in funding legislation for the upcoming fiscal year.

> *Provided, none of the funds made available by this Act may be used to promulgate, propose, or implement any rule, or take any other action with respect to, allowing or requiring information intended for a prescribing health care professional, in the case of a drug or biological product subject to section 503(b)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 353(b)(1)), to be distributed to such professional electronically (in lieu of paper form) unless and until a federal law is enacted to allow or require such distribution.*

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. We strongly urge you oppose these advances and continue to advocate for patient safety.

We stand ready to work with you to ensure that professionals have access to paper format PI. Please do not hesitate to reach out to PPLA if you have any questions or need more information.

Sincerely,

3C Packaging
American Paper Corp.
Apex Graphics Inc.
Avery Dennison
Baumer HHS
CCL Label
Clifford Paper Inc.
Clintrak LLC
Connemara Converting LLC
Control Group USA
Delfort USA

Essentra
Flottman Company Inc.
G&K-Vijuk International
Gould Paper Corporation
Haapanen Brothers
Hylton Paper
MGS Machine
Mini Graphics, Inc.
NOSCO, Inc.
PC Industries
Pharmaceutic Litho & Label Company
Platinum Press
Precision Roll Division
Twin Rivers Paper
Veritiv
Westrock MPS