

The Honorable Rosa L. DeLauro
Chair
House Committee on Appropriations
H-307 The Capitol
Washington, DC 20515

The Honorable Kay Granger
Ranking Member
House Committee on Appropriations
H-307 The Capitol
Washington, DC 20515

June 22, 2022

Dear Chair DeLauro and Ranking Member Granger:

PRINTING United Alliance, the most comprehensive member-based printing and graphic arts association in the U.S., is committed to advocating public policies that demonstrate the reliability, relevance and renewability of printed material.

One such policy is the long-standing FDA requirement that prescription drugs sent to health care prescribers and pharmacists are accompanied by an ink-on-paper Packaging Insert (PI) also known as “labeling content.” While PRINTING United Alliance supports the current option allowing health care providers to access an electronic version of a PI if they wish, we believe the secure, reliable nature of print is and should remain the standard, regulated format for disseminating this critical information.

Specialty print companies invest in high-end equipment and workforce training in order to produce PIs in a manner that meet qualified, audited and approved current Good Manufacturing Practices (cGMPs) - the same cGMPs as required by the FDA of drug manufacturer themselves. The resulting PI literature accompanying pharmaceuticals thus contains reliable, tamper-free patient safety information. While a website or e-version may also provide PI guidance, we live in a world of ransomware, online hacking, and the very basic “computer glitch.” Having PI always available in paper format as a first step or back up is critical.

And these printed PI’s are not “throw away” papers as some have suggested. At least, they should not be, as the FDA mandates PIs contain 16 elements of printed content, including: boxed warnings, indication and usage, dosage and administration, contraindications, and drug use and dependence, among others. Again, this patient safety information is simply too important to allow a healthcare provider’s possible lack of online access – whether due to geography, a disaster-related outage, or untrained staff – to hinder.

Accurate and always-available PIs save costs, too. While those who would prefer to “modernize” labeling content by moving it online decry costs of printing and packaging, the real costs Congress and the FDA should focus on are the ones associated with failed patient safety.

According to the CDC, adverse drug events cause 1.3 million emergency visits each year and cost \$3.5 billion in medical costs annually. Making sure health care prescribers and pharmacists are fully informed with PI content is one key way to prevent such events from occurring.

It must not go unmentioned that detractors of printed PIs have questioned the environmental impact of distributing patient safety information in this format. Quite simply, paper is a renewable resource with a high recycling rate of 68.2 percent, according to the EPA, in fact, the highest rate compared to other materials in that agency's 2018 Materials, Waste and Recycling Report. Corporate sustainability programs and responsible forest stewardship is commonplace in the industry and electronic communication is not without environmental impact.

Again, the real debate should be on the patient safety impact of PIs and their value for well-informed health care providers. PRINTING United Alliances urges Congress to reaffirm its support of printed PIs and pharmaceutical literature throughout the legislative and appropriations process. Thank you.

Sincerely,

A handwritten signature in black ink, appearing to read 'Ford Bowers', with a long, sweeping horizontal line extending to the right.

Ford Bowers
CEO