November 27, 2023

Dr. Robert M. Califf
Commissioner of Food and Drugs
U.S. Food and Drug Administration
10903 New Hampshire Ave.
Silver Spring, MD 20993

Dear Dr. Califf,

We are writing today as members of the printing, forestry, and labeling industry regarding the U.S. Food and Drug Administration (FDA) proposed rule, "Medication Guides: Patient Medication Information" (Docket No. FDA-2019-N-5959)[1] on patient medication information (PMI). According to the U.S. Bureau of Labor Statistics, these industries together employ over 387,000 individuals.[2][3] We are pleased that the FDA realizes the importance of PMI for patients, caregivers, and their families, and we welcome the opportunity to provide additional comments that we believe will improve the proposed rule.

Printed packaging suppliers to the pharmaceutical industry understand the importance of printed medication information, as they currently supply package inserts (PIs) to numerous pharmaceutical companies. Currently, there is no uniform standard for the information patients receive when they get their prescription medication. Many Americans are surprised that there is no federal requirement for this information to be included with prescriptions. This new proposed rule misses the mark by adopting a "text format" printed in the pharmacy on a desktop printer or sent to consumers electronically. This results in vastly inferior PMI for the consumer and puts the onus on supplying PMI to local pharmacists instead of drug manufacturers.

Additionally, we must rebuff the implications that PMI printing would negatively impact the environment. The US paper industry uses sustainable forestry practices, which, according to the US Forest Service, can increase the ability of forests to sequester atmospheric carbon while enhancing other ecosystem services. According to the American Forest & Paper Association, forests and the products made from these forests offset approximately 13% of all annual carbon dioxide emissions each year. Each year, U.S. forests grow about two times more tree volume than is harvested, with a net average annual increase in developing stock of about 25 billion cubic feet. [4][5]

Data suggests that the impact that PMI printing would make on the environment would be minimal compared to the genuine, life-saving benefits it will provide patients. A format developed through a Duke University scientific study funded by the PPLA, based on extensive cognitive research with actual patients taking real medication, is what should be mandated by the FDA. The Duke format presents PMI in a way consumers can understand and remember – especially vital when it comes to instructions for safe use and severe side effects that require immediate medical attention. Furthermore, pharmacies

[1] Medication Guides: Patient Medication Information, 88 Fed. Reg., 35694 (May 31, 2023)
[2] https://www.bls.gov/iag/tgs/iag323.htm
[3] https://www.bls.gov/ooh/farming-fishing-and-forestry/forest-and-conservation-workers.htm
[4] https://twosidesna.org/unitedstates-forests-renewable-natural/
[5] https://www.afandpa.org/priorities/marketplace-sustainability

typically print on 8.5 x 11 copy paper, as opposed to our industry 30# Book weight paper. Aside from the lightweight nature of the 30# paper, the printable surface area under the Duke format is 134% greater than that from the pharmacy, enhancing readability and utility. We also believe it is the responsibility of pharmaceutical companies to professionally print and provide PMI to pharmacies.

Studies have found that almost 90 million Americans do not understand the labeling on their medications, and non-adherence—driven in part by this misunderstanding—contributes to $300 billion in health care costs.[6][7]We believe that while the proposed rule provides some of this information, changes need to be made to achieve FDA's stated goal of improving public health by providing patients with clear, concise, accessible, and useful written prescription drug product information. To meet the specified objectives for a final rule on PMI, the regulation should: 1) require PMI to exhibit clear cognitive accessibility and ensure maximum comprehension for patients; 2) mandate manufacturers to produce and supply PMI to community pharmacies as part of the mandatory labeling under the Food Drug and Cosmetic Act; and 3) lessen the financial and time burdens on community pharmacies.

With the help of standardized printed PMI attached to prescription drugs, patients will better understand the critical information necessary to avoid preventable adverse drug events and keep patients safe and healthy. The evidence is clear—when patients have access to clear, concise, relevant, easy to understand, printed information, they have better health outcomes.

We hope the FDA will make these critical changes while considering a final rule, and we appreciate the opportunity to lend our collective voice to this important matter.

Sincerely,

PRINTING United Alliance

Visual Media Alliance

Tag and Label Manufacturers Institute (TLMI)

[6] https://www.acpjournals.org/doi/full/10.7326/0003-4819-145-12-200612190-00144
[7] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3934668/