



American Pharmacists Association[®]

Improving medication use. Advancing patient care.

May 4, 2017

Senator Kirsten Gillibrand
478 Russell
Washington, DC 20510

Dear Senator Gillibrand:

On behalf of the American Pharmacists Association (APhA) and its members, we are writing to thank you for your efforts to inform and protect patients by advocating for the Cody Miller Patient Medication Information Actⁱ (hereinafter, the “Cody Miller Act”). APhA, founded in 1852 as the American Pharmaceutical Association, represents 64,000 pharmacists, pharmaceutical scientists, student pharmacists, pharmacy technicians, and others interested in improving medication use and advancing patient care. APhA members provide care in all practice settings, including community pharmacies, hospitals, long-term care facilities, community health centers, physician offices, ambulatory clinics, managed care organizations, hospice settings, and the uniformed services.

Currently, the material pharmacists are required to provide to patients depends on the medication, drug class, and state law. While FDA does not require pharmacists to disseminate written information to patients for every prescription drug, states do regulate the information, including oral counseling and written information that must be communicated to patients upon dispensing. Some states require dissemination of written information to patients with a prescription in certain situations.^{ii,iii,iv} FDA may require the pharmacist to provide a medication guide^{vi} (MedGuides), instructions for use^{vii}, or patient package inserts^{viii} (PPIs). For example, FDA may require distribution of a medication guide as part of a medication, or drug class’s Risk Evaluation and Mitigation Strategy (REMS). Consumer medication information^{ix} (CMI), is additional information that has been developed to better communicate to patient that also may, but is not required to be provided to the patient.

The Cody Miller Act would require “patient medication information” (PMI) to be provided with prescribed drugs,^x in addition to other state and federal requirements. APhA has some concerns and recommendations related to the current bill draft.

Our recommendation would be for Congress to wait for FDA’s completion of activities already underway^{xi,xii} related to improving communications to patients and patient understanding of their medications. Legislating specific requirements will solidify a system that cannot easily incorporate and adapt to the best research, science and resources. APhA is concerned that the bill currently does not meet its intended goal of improving patient awareness and understanding of their medications.

Additional Concerns:

- **Clearly define “Patient Medication Information” (PMI)** PMI could be interpreted to mean additional information required or it is a general reference to all the information patients receive about a medication. Because PMI is not clearly defined, it is difficult to estimate the impact of the bill on pharmacists and patients. Because of its broad application to all prescription medications, APhA recommends that the definition of PMI clarify that dispensers, which includes pharmacists, are not required to disseminate such information until real-world evidence demonstrates its effectiveness.
- **Remove content requirements in Section 2^{xiii} and replace with a requirement that FDA work with stakeholders perform research and pilot projects to better inform FDA regarding the type of, or format for, information to be required.** As drafted, the bill is not consistent with research and may not achieve its intended goal.^{xiv} The information outlined in the proposal may be excessive and confusing to patients, and gives FDA limited flexibility to change the content of PMI to better conform to the effective communication practices. APhA believes FDA should have the flexibility to determine what information and format should be required using evidence-based research and FDA pilot projects to test PMI effectiveness in a real-world setting.
- **Any legislation requiring development of drug-related information should not be the responsibility of pharmacists but should include stakeholder collaboration.**

Again, APhA supports FDA’s efforts to improve the prescription medication information that patients receive. We have continually advocated for the need to improve and address the challenges associated with information distributed to patients. However, APhA emphasizes that PMI is not a replacement for the counseling, education and other medication-related services that pharmacists and other health care providers can provide. APhA is eager to work collaboratively with FDA, manufacturers and other stakeholders to improve the usefulness of patient information to help patients receive the necessary evidence-based information about the benefits and risks of their prescription medications in an effective format. Thank you for the opportunity to provide comments on this important issue. If you have any questions please contact, myself, Alicia Kerry Mica, APhA’s Senior Lobbyist, at amica@aphanet.org or 202-429-7507.

Sincerely,



Alicia Kerry J. Mica,
Senior Lobbyist

cc: Stacie Maass, BSPPharm, JD, Senior Vice President, Pharmacy Practice and Government Affairs

ⁱ In commenting on the Cody Miller Patient Medication Information Act, APhA reviewed S. 2214 (114th Congress).

ⁱⁱ See Cal. Code Regs. tit. 16, § 1707.4(3), stating that “For refills, the patient must be provided with written information, either on the prescription label or with the prescription container that describes which pharmacy to contact if the patient has any questions about the prescription of medication.”

ⁱⁱⁱ See also, D.C. Mun. Regs. tit. 22, § 1919.4, stating “A pharmacist must provide written information to reinforce the pharmacist’s consultation. Such information may include leaflets, pictograms...”

^{iv} See also, Fla. Stat. Ann. § 465.0255(2), (4) stating “A community pharmacist must provide information about the expiration date, if requested by the patient, and appropriate instructions about proper use and storage of medicinal drugs. The pharmacist will not be liable if a patient does not follow the notice or follow the instructions for storage.”

^v See also, Minn. R. 6800.0910(2), stating “For a prescription that is being delivered or mailed, counseling must still be provided. Written information may be provided to the patient to accomplish the counseling requirements. If written information is provided, it must include information regarding the medication and the availability of the pharmacist to answer questions through the provision of a toll-free telephone phone number.”

^{vi} 75 Fed. Red. 52765 (2010), stating in the “Supplementary Information”: A *Medication Guide* is also patient labeling that is part of the FDA-approved prescription drug labeling. Medication Guides are required for certain drugs “that pose a serious and significant public health concern” (see 21 CFR part 208). Medication Guides are developed by the manufacturer, approved by FDA, and are required to be given to patients each time the medication is dispensed.

^{vii} Food and Drug Administration, (May 2015), Learn About Your Medications, Food and Drug Administration, available at: <https://www.fda.gov/ForPatients/sucm412663.htm>, last accessed February 21, 2017, stating, “*Instructions for use* - Patient labeling that is developed by the manufacturer, approved by the FDA, and dispensed with specific products that have complicated dosing instructions to help the patient use the product properly.”

^{viii} 75 Fed. Red. 52765 (2010), stating in the “Supplementary Information”: A *Patient Package Insert* (PPI) is patient labeling that is part of the FDA-approved prescription drug labeling. PPIs are developed by the manufacturer, approved by FDA, and are required to be dispensed with specific products or classes of products (i.e., oral contraceptives and estrogen-containing products). Other PPIs are submitted to FDA voluntarily by the manufacturer and approved by FDA, but their distribution is not mandated.

^{ix} 75 Fed. Red. 52765 (2010), stating in the “Supplementary Information”: *Consumer Medication Information* (CMI) is written information about prescription drugs developed by organizations or individuals other than a drug manufacturer that is intended for distribution to consumers at the time of drug dispensing. The information is not FDA reviewed or approved and is voluntarily distributed by pharmacies to consumers.

^x 21 U.S.C. §353(b)(1) codifies 503(b)(1) of Chapter V of the Federal Food Drug and Cosmetic Act. A 503(b)(1) product is “a drug intended for use by a man” which for certain reasons is not safe for use except under the supervision of a practitioners licensed by law to administer such drug; or is limited by an approved application under 21 U.S.C. § 355 (new drugs).

^{xi} See Food and Drug Administration, CDER 2016 Priorities, available at: <https://www.fda.gov/downloads/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDER/UCM477299.pdf> which includes “Continue the Drug Label Improvement Initiative” and “Develop legal framework for Patient Medication Information (PMI) project”.

^{xii} See, Food and Drug Administration, Drug Safety Priorities 2016: Initiatives and Innovation, available at: <https://www.fda.gov/Drugs/DrugSafety/ucm522941.htm>, describing Risk Communications Research, including a number of ongoing research that will be used to improve CDER communications.

^{xiii} “(b) CONTENT.—The regulations promulgated under subsection (a) shall require that the patient medication information with respect to a drug—

“(1) be scientifically accurate, include relevant patient safety information, and be based on the professional labeling approved by the Secretary; and

“(2) include standard, nontechnical, understandable, plain language that is not promotional in tone or content, and contain at least—

“(A) the established name of the drug or the proper name of the biological product, as applicable;

“(B) drug uses;

“(C) general directions for proper use;

“(D) contraindications, the most frequently occurring adverse reactions, and adverse reactions that are important for other reasons (such as because they are serious), especially with respect to certain groups such as children, pregnant women, and the elderly;

“(E) measures patients may be able to take, if any, to reduce the side effects and risks of the drug;

“(F) when a patient should contact his or her health care professional;

“(G) instructions not to share medications, and, if any exist, key storage requirements, and recommendations relating to proper disposal of any unused portion of the drug;

“(H) known clinically important interactions with other drugs and substances; and

“(I) a statement of whether sufficient data are available concerning the use of the drug in specified subpopulations, such as women, pregnant women, lactating women, women and men of reproductive age, pediatric, geriatric, racial and ethnic minority groups, and other subpopulations.

^{xiv} See Kish-Doto, J., Scales, M., Eguino-Medina, P., Fitzgeralds, T., Tzeng, J.P., McCormack, L.A., O’Donoghue, A., Oguntimein, O. & West, S.L. (2014). Preferences for Patient Medication Information: What Do Patients Want? *Journal of Health Communication*, 19:77-88.