

November 27, 2023

Comments Regarding the Food and Drug Administration’s Notice of Proposed Rule on Medication Guides: Patient Medication Information (FDA-2019-N-5959)

Public Citizen, a consumer advocacy organization with more than 500,000 members and supporters nationwide, submits the below comments about the Food and Drug Administration’s (FDA) notice of proposed rule on Patient Medication Information (PMI), published in the Federal Register on May 31, 2023.¹

For decades, we have advocated for the distribution of FDA-approved prescription drug information to patients, with each new or refilled prescription, that is congruent with a drug’s labeling.²

Currently, the FDA requires two types of patient-directed information pertaining to limited subsets of medications. The first are Medication Guides (MGs), which are required only for prescription drugs that the agency has determined are posing a serious and significant public health concern requiring distribution of FDA-approved information. The second are patient package inserts (PPIs), which the agency only requires for oral contraceptives and estrogen-containing products.

Under the proposed rule, the FDA would amend its regulations by requiring a new type of written one-page document with standardized content — called PMI — that would be handed to patients each time they acquire a prescription drug product, biological product, or blood or blood components product for use or transfusion in an outpatient setting, with few exceptions. Each PMI would contain a product’s name, its indications and uses, important safety information (including warnings, common serious side effects, and what to tell a health care professional before taking the drug), and directions for drug use.³

The proposed rule would require applicants for all new and previously approved drug and biologics license applications (hereafter, applicants) to submit their PMI to the FDA for approval. Once approved, PMI would be updated periodically in consultation with the FDA and would replace existing medication guides and patient package inserts, where applicable.

We appreciate that the FDA is finally proposing this historic new rule to address existing knowledge gaps among patients in outpatient settings with regard to various therapeutic

¹ Food and Drug Administration. Proposed rule. Medication guides: Patient medication information. May 31, 2023. <https://www.govinfo.gov/content/pkg/FR-2023-05-31/pdf/2023-11354.pdf>. Accessed November 21, 2023.

² Public Citizen. Letter concerning FDA-approved medication guides. July 25, 2005. Accessed November 21, 2023. <https://www.citizen.org/article/letter-concerning-fda-approved-medication-guides>. Accessed November 21, 2023.

³ Food and Drug Administration. Example of patient medication information for a fictitious drug, Rheutopia. Last updated November 6, 2023. <https://www.fda.gov/drugs/fdas-labeling-resources-human-prescription-drugs/patient-medication-information>. Accessed November 21, 2023.

products. To improve PMI, we urge the agency to implement the following suggested changes in the final rule.

I. Plain-language use and consumer testing

At a 2010 FDA public hearing, experts stated that plain language should be used in patient-directed information to increase comprehension of the material. Furthermore, plain language principles were used in the development of the Rheutopia PMI example provided by the FDA.^{4,5} However, the proposed rule does not explicitly require applicants to use plain language in developing the specific contents of their PMI. Instead, it requires PMI to “be written in terms that are likely to be read and understood by most individuals.” We, therefore, urge the FDA to require the use of plain language per the Plain Writing Act of 2010.⁶ This would mean the use of plain language for all PMI, as well to the development of a related guidance that applicants can use when developing their PMI. This is a critical issue since approximately 54% of Americans between the ages of 16 and 74 read below the equivalent of a sixth-grade level.⁷ Furthermore, nearly nine out of 10 adults struggle with health literacy.⁸

Importantly, the FDA is not requiring any type of patient testing of PMI. Instead, the agency is considering the establishment of a publicly available database of consumer-tested phrases and terms that would assist applicants in the development of PMI for their products, possibly in partnership with the private sector. We urge the FDA to reconsider this position and mandate consumer testing of PMI in the final rule. The use of consumer-tested phrases cannot assure enhanced readability and comprehension of drug-specific information in PMI for all products. For example, previous studies assessing suitability and readability of FDA-approved medication guides concluded that these materials are “of little value to patients” because they are too complex and difficult to understand, particularly for patients with limited literacy.^{9,10} Although standardizing the format and headings of PMI and the development of consumer-tested terms are good steps, these measures cannot eliminate the need for testing these materials directly with patients. In fact, experts have recommended that patients should be involved in the development of patient-directed information,¹¹ and this should apply for all products. Testing PMI among patients is the best way to ensure that they are understood by their intended users, especially those with low literacy levels. This testing appears to be the best way to fully realize the FDA’s

⁴ *Ibid.*

⁵ Boudewyns V, O’Donoghue AC, Kelly B, et al. Influence of patient medication information format on comprehension and application of medication information: A randomized, controlled experiment. *Patient Educ Couns.* 2015;98(12):1592-1599.

⁶ H.R. 946/Public Law 111-274.

⁷ Schmit E. Reading the numbers: 130 million American adults have low literacy skills, but funding differs drastically by state. March 16, 2022. <https://www.apmresearchlab.org/10x-adult-literacy>. Accessed November 21, 2023.

⁸ Centers for Disease Control and Prevention. Talking points about health literacy. May 21, 2021. <https://www.cdc.gov/healthliteracy/shareinteract/TellOthers.html>. Accessed November 21, 2023.

⁹ Wolf MS, King J, Wilson EAH, et al. Usability of FDA-approved medication guides. *J Gen Intern Med.* 2012;27(12):1714-1720.

¹⁰ Wolf MS, Davis TC, Shrank WH, et al. A critical review of FDA-approved medication guides. *Patient Educ Couns.* 2006;62(3):316-322.

¹¹ *Ibid.*

stated goal of “improv[ing] accessibility of medication information for all patients, including patients with low health literacy...”

II. Translation to common non-English spoken languages

The proposed rule would require PMI to be written in English, with the only exception being that Spanish can be substituted for English for PMI distributed in the Commonwealth of Puerto Rico or in a territory where the predominant language is not English. Instead, we urge the FDA to require Spanish language PMI to be provided to patients who need them throughout the U.S., as Spanish is spoken by 42 million Americans and it is the most commonly used non-English language in this country.¹² Given that applicants will already be required to produce PMI in Spanish under the proposed rule, the additional cost of providing these PMI nationwide, where needed, would not be a major burden.

In response to the FDA’s request for comments about possible actions to make PMI accessible to individuals with limited English proficiency, we urge the agency to expand the language-substitution requirement of PMI to include other commonly spoken languages in the United States. Among American households, 4% are of limited English-speaking, which is defined as those in which there are no members aged 14 or over who speak only English or speak English “very well.”¹³ In addition to Spanish, examples of common languages spoken in these households include Chinese (Cantonese and Mandarin), Korean, Vietnamese, Arabic, and Tagalog.

The cost of translating PMI to these additional languages should be borne by applicants, not dispensing pharmacies or other organizations. Failing to provide PMI in common alternative languages would be a disservice to the millions of Americans with limited English proficiency.

III. Expanding waivers, when needed, for exceeding the one-page limit

The FDA indicates that it envisions granting waivers, in rare cases, from the one-page format requirement of PMI. This seems to be limited to products with complicated administration instructions (such as inhalers or injectables). In such cases, the PMI will direct patients to a separate instructions-for-use document approved by the agency, as applicable, where that additional information would be available.

We urge the FDA to permit waivers of the one-page format, when needed. However, it would be sensible for the agency to determine a reasonable maximum word count or page number (such as two or three pages). For many drugs, a single page is not sufficient to include all essential drug-related information that is important to patients. For example, certain medications have multiple serious risks that applicants may omit from PMI using the excuse that they are complying with the agency’s own requirement of a one-page limit. Additional information that is essential for a specific drug should be incorporated into the PMI (for example, by printing it onto the backside

¹² Dietrich S and Hernandez E. Language use in the United States: 2019. August 2022. <https://www.census.gov/content/dam/Census/library/publications/2022/acs/acs-50.pdf>. Accessed November 21, 2023.

¹³ *Ibid.*

of the page) to facilitate its provision to patients consistent with the paper-format (print out) requirements under the proposed rule.

The FDA's proposed PMI template includes sections for a drug's serious and common side effects. The template, however, does not include numerical data on the incidence of these adverse effects. It also appears to be restrictive in terms of providing enough space to list multiple potential food-drug and drug-drug interactions. Moreover, the template does not include a section for expected benefits of a given drug; the expected benefits are usually included in the approved drug labeling that is intended for use by prescribers. The final rule should address these omissions. As the FDA has stated with regard to MGs, patients should be aware of the risks of their medications (relative to their benefits) since this information could affect a patient's decision to use or continue to use the product. In addition, based on our long-time experience with Public Citizen's print newsletter *Worst Pills, Best Pills News*, an independent source of second-opinion information about prescription drugs,¹⁴ patients appreciate this additional information and find it helpful when discussing the net benefit-risk of their medications with prescribers. Drug benefit information can be provided in plain language and can be included in a manner that enhances understandability.

IV. Other changes

The final rule should stipulate that the cost of printing PMI should be borne by applicants. This is necessary because certain pharmacies, particularly those in small towns or rural areas, tend to lack the resources to print these materials.

The proposed rule notes that PMI for prescription drug products would be stored electronically in the FDA labeling repository. It is essential that the FDA ensure that this repository is consumer friendly and easy to navigate, especially for individuals with technological challenges. Consistent with our request above for translation of the PMI into non-English commonly spoken languages, this repository should provide PMI in the most common languages spoken in the United States to ensure equitable benefits of this repository for all Americans.

Lastly, the proposed rule indicates that the FDA intends to withdraw its current regulations requiring MGs and PPIs, where applicable, once these products are given FDA-approved PMI. It would be more prudent for the agency not to discontinue these alternative patient information sources (which the agency has invested decades into developing) until the success of the final PMI rule has been ensured, rather than just the complete implementation of the final rule over a five-year period.

V. Conclusion

Public Citizen supports the proposed rule on PMI. We hope that the FDA will revise the proposed rule to incorporate our requested changes to ensure that all Americans will have access to meaningful, helpful, understandable, and easy-to-access information about their prescription drugs and biological products that are used or dispensed in outpatient settings.

¹⁴ Public Citizen. *Worst Pills, Best Pills News*. <https://www.worstpills.org>. Accessed November 21, 2023.

Thank you for the opportunity to comment on this important proposed rule.

A handwritten signature in black ink that reads "Azza AbuDagga". The signature is written in a cursive, flowing style.

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