

Issue Brief: Access to Prescription Drug Labeling

Access to Prescription Drug Labeling

The Problem

At least 10 million Americans experience significant vision loss impacting their ability to independently read prescription labeling and related information. Given that the incidence of vision loss is expected to dramatically increase, this poses a significant public health challenge.

Inadequate Response to the Problem

The Food and Drug Administration (FDA) implements laws and regulations that govern prescription drug information. However, the FDA has never issued specific regulations or guidelines to guarantee that prescription drug information intended for patients is accessible for persons who are blind or visually impaired. In general, states are the primary regulators of the content and format provided directly on a prescription bottle and/or pharmacy-provided packaging. Nearly all of the states in the union have statutory requirements pertaining to prescription labeling. However, no state law ensures that prescription labeling is accessible to persons with vision loss. Even the state of Massachusetts, which attempts to establish such requirements, merely provides: "upon the request of—a person visually impaired [sic], directions on the label affixed by the pharmacist to a container of a prescription drug shall be typed in a print size allowing no more than ten characters per inch". (Mass. Gen. Laws Ch. 94C, §21). Few states have ever considered adopting a clear accessibility requirement—the California legislature is currently considering such a proposal, AB 1399, which provides: "upon the request of a customer who is blind or visually impaired, a pharmacist shall provide a prescription drug label that is readable by an assistive technology device for the blind or visually impaired".

Some pharmacies are beginning to experiment with different ways to offer their customers alternate means of identifying prescription medications. However, while such efforts are well-intentioned, they do not amount to a national trend and are not based on any reliable standards or evidence of their effectiveness.

Nationally, few pharmacies are voluntarily providing their customers with meaningful access to the labeling and other information related to prescription medications they dispense. Moreover,

those pharmacies that have begun to try to provide their customers with vision loss with prescription information they can use are doing so in a vacuum without standards that ensure complete and consistent presentation of information.

FDA Study and Recent Actions

As part of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Congress called upon the FDA to investigate solutions addressing the problem of inaccessible prescription drug labeling. Unfortunately, the report issued to Congress in May 2005 failed to describe specific processes, regulatory changes, or other solutions ensuring access. Nevertheless, the report does affirm that "all Americans, whether visually impaired or not, should have equal access to essential prescription drug information". In essence the FDA missed an opportunity to offer meaningful answers to the challenge of inaccessible labeling and related information. Since the study's release in May 2005, some effort has been made to convene expert panels to begin to formulate questions for future research and the development/communication of stopgap solutions.

Even though the Secretary of Health and Human Services, Mike Leavitt, in announcing the introduction of FDA's new packaging insert format requirements, recognized that "clear and concise information about prescriptions will help ensure safe and optimal use of drugs", this language is limited only to package inserts and fails to consider accessibility for people with disabilities.

Action Needed Now

Congress should grant the FDA clear authority to regulate this area and develop standards to ensure that prescription labeling is accessible to individuals with vision loss. A number of existing solutions demonstrate the feasibility of providing access to prescription drug labeling and pharmacies should be prepared to provide prescription labeling in multiple modalities.

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