ENGELBERG CENTER for Health Care Reform at BROOKINGS

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Discussion Guide

Expert Workshop: Nonprescription Medications with Conditions of Safe Use as a Novel Solution for Undertreated Diseases or Conditions

Background

Undertreatment of common diseases and conditions has a significant public health impact in the United States. For example, recent findings from the Centers for Disease Control and Prevention (CDC) indicate that of the approximately 66.9 million adults with hypertension, an estimated 53.5 percent do not have their condition under control. Of those who were aware of their diagnosis, almost 16 percent were not receiving pharmacologic therapy.[1] Similarly, patients with chronic obstructive pulmonary disease (COPD) may have inadequate access to recommended COPD medications and maintenance therapy.[2] Varying levels of undertreatment have also been reported with other common conditions such as diabetes.[3,4] Factors that potentially contribute to the undertreatment of common disease and conditions are interrelated and could include a lack of awareness of the condition, behavioral and cultural barriers, insurance coverage, medication costs, and inadequate access to primary care.

In addition to the examples highlighted above, patient barriers to obtaining prescription medications could be another factor contributing to undertreatment. In the United States, medical products are regulated in a two-tiered system where they are broadly categorized into prescription or nonprescription classes. The U.S. Food and Drug Administration (FDA) routinely reviews new drug approval applications and applications for prescription products to be reclassified to nonprescription status.[5] When evaluating applications, FDA considers multiple streams of evidence into the decision-making process including medical product safety, relative level of benefit-risk, and intended methods of use.[6] Generally, common characteristics of a drug classified as nonprescription typically include a low potential for misuse and abuse, benefits outweighing the risks, the ability for consumers to self-diagnose, adequate labeling, and that a health practitioner is not needed to ensure the safe and effective use of the product.[7] The role of the health practitioner has generally been to ensure the safe and effective use of the product by providing access to it through a prescription.

Appropriately reducing barriers to medications by making them available without a prescription may be one mechanism to mitigate the problem of undertreated conditions. Examples of medical products where the

[1] Centers for Disease Control and Prevention. (September 2012) Vital Signs: Awareness and Treatment of Uncontrolled Hypertension Among Adults — United States, 2003–2010. *MMWR.* Retrieved November 2, 2012, from http://www.cdc.gov/mmwr/ preview/mmwrhtml/mm6135a3.htm?s_cid=mm6135a3_w.

[2] Gordon, D. (2012). Is COPD Undertreated?. *The Journal of Respiratory Diseases*. Retrieved November 2, 2012, from http://jrd.consultantlive.com/display/article/1145425/2060201.

[3] Hill, SC, Miller, GE, Sing, M. (March 2012). Adults with diagnosed and untreated diabetes: who are they? How can we reach them?. Retrieved November 2, 2012, from http://www.ncbi.nlm.nih.gov/pubmed/22080705.

[4] Viswanathan, M, Golin, C, Jones, C, et al. (September 2012). Interventions to Improve Adherence to Self-administered Medications for Chronic Diseases in the United States: A Systematic Review. *Annals of Internal Medicine.* Retrieved November 2, 2012, from http://annals.org/article.aspx?articleid=1357338.

[5] Jacobs, L. (May 1998). Prescription to Over-the-Counter Drug Reclassification. *American Family Physician.* Retrieved November 2, 2012, from http://www.aafp.org/afp/1998/0501/p2209.html.

[6] U.S. General Accounting Office. (2012). Value of a Pharmacist-Controlled Class Has Yet to Be Demonstrated. GAO/PEMD-95-12. Retrieved November 2, 2012, from http://www.gao.gov/archive/1995/pe95012.pdf

[7] U.S. Food and Drug Administration. (January 2012). About FDA (page): Regulation of Nonprescription Products. Retrieved November 2, 2012, from, http://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDER/ucm093452.htm.

switch from prescription to nonprescription status increased the accessibility and affordability of the product include nicotine replacement therapy products[8] and heartburn medications.[9]

The Nonprescription Safe Use Regulatory Expansion (NSURE) Initiative

Recognizing the potential for nonprescription drugs to expand access to drug therapy for undertreated diseases or conditions, FDA convened a public hearing, "Using Innovative Technologies and Other Conditions of Safe Use to Expand Which Drug Products Can Be Considered Nonprescription," in March, 2012.[10] FDA requested comments on a proposed new paradigm where the use of new technologies or other conditions of safe use might expand which drug products could be considered nonprescription. This potential new paradigm is referred to as the Nonprescription Safe Use Regulatory Expansion (NSURE) initiative.

During the public hearing, FDA requested information and public input on a variety of issues, including the types of technology and conditions of safe use and pharmacy, consumer, and health care provider issues. For additional information, please refer to the Federal Registry notice. Major areas of discussion included the following:

- Access to care
- Medication non-adherence and impact on health
- Concern due to lack of practitioner oversight
- General effect on health care and health care costs
- Medical conditions or diseases potentially impacted by NSURE
- Diagnostic aids and technologies
- Prospective conditions of safe use

Input from the public hearing made clear that stakeholders had numerous perspectives on the rationale for and purpose of the NSURE initiative. Perspectives differed on NSURE conditions of safe use, the role of health care professionals and reimbursement organizations, and the regulatory authority required for implementation. For additional information on the public hearing, please refer to the submitted comments.[11]

Given limitations in the tools available for risk mitigation of nonprescription products, the NSURE initiative is focused on developing innovative approaches for nonprescription drugs in order for patients to appropriately self-select drug products. The objective is to make drugs more widely accessible through conditions of safe use. FDA is currently developing the conceptual framework for NSURE and is seeking to obtain expert feedback and input.

Workshop Objectives

The Engelberg Center for Health Care Reform at Brookings, supported by a cooperative agreement with FDA, will convene a series of workshops to seek expert stakeholder feedback on the NSURE initiative and to explore potential practical strategies for conditions of safe use. The objective of this first workshop will be to clarify the goals of the NSURE initiative and to explore potential strategies to utilize health care professionals as a condition of safe use within the NSURE paradigm. Other topics to be explored in subsequent workshops include the use of innovative technologies to support the safe and effective use of nonprescription products and financial issues and concerns.

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[8] Shiffman, et al.,(1997). Public health benefit of over-the-counter nicotine medications. *Tobacco Control* 6: 306.

[9] Mansfield and Callahan, Nielsen Company, prepared for Consumer Healthcare Products Association. (December 2008). Benefits of over-the-counter heartburn medication to consumers and the healthcare system..

[10] U.S. Government Printing Office. Using Innovative Technologies and Other Conditions of Safe Use To Expand Which Drug Products Can Be Considered Nonprescription; Public Hearing. Federal Register/Vol. 77, No. 39/Tuesday, February 28, 2012/Notices 12059. Retrieved November 2, 2012, http://www.gpo.gov/fdsys/pkg/FR-2012-02-28/pdf/2012-4597.pdf.

[11] Ibid.