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ENGELBERG CENTER for Health Care Reform at BROOKINGS

Discussion Guide

Technologies and Nonprescription Medications:
Addressing Undertreated Diseases and Conditions through Technology Enabled Self-Care

Background

Undertreatment of common diseases and conditions contributes to critical gaps in the public health of the United States. While the factors contributing to medical undertreatment are complex, a lack of regular access to medical and pharmacologic care and a failure to administer recommended therapy are among those most commonly cited.[1] Poor medical adherence also contributes to this problem, as research suggests 20% to 30% of prescription medications are never filled and 50% of medications for chronic disease are not taken as prescribed.[2] Improving access to appropriate pharmaceutical care while ensuring the safe and effective use of drugs can contribute to mitigating the problem of undertreatment, and will require substantial commitment and effort by all health care stakeholders, including providers, patients, researchers, regulators, and the regulated industry.

Nonprescription Safe Use Regulatory Expansion (NSURE) Initiative

Recognizing the impact of undertreatment on public health, the U.S. Food and Drug Administration (FDA) is exploring how a regulatory expansion of the nonprescription drug class might increase access to medications for undertreated diseases and conditions. FDA is investigating how health care professionals and innovative technologies can serve as a condition to the safe use of drugs in a nonprescription setting. This nonprescription paradigm is referred to as the Nonprescription Safe Use Regulatory Expansion (NSURE) initiative.

In March, 2012, FDA held a public meeting, "Using Innovative Technologies and Other Conditions of Safe Use to Expand Which Drug Products Can Be Considered Nonprescription," which requested input from stakeholders on this potential nonprescription paradigm.[3] During this public hearing, FDA received information and public input on a variety of subjects, including issues related to consumers, healthcare professionals, and payers.

Building on this initial input, the Engelberg Center for Health Care Reform at Brookings in cooperation with the FDA convened an expert workshop, "Nonprescription Medications with Conditions of Safe Use as a Novel Solution for Undertreated Diseases or Conditions," to explore practical considerations in the development of the NSURE initiative. Objectives of this workshop included clarifying the scope and intent of the NSURE initiative, exploring opportunities which permit expanded access to nonprescription medications, and exploring the ability of health care professions to facilitate Conditions of Safe Use.

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[1] McGlynn, Elizabeth A, et. a. "The Quality of Health Care Delivered to Adults in the United States." *New England Journal of Medicine* 348 (2003): 2635-645

[2] Meera Viswanathan, Carol E. Golin, Christine D. Jones, Mahima Ashok, Susan J. Blalock, Roberta C.M. Wines, Emmanuel J.L. Coker-Schwimmer, David L. Rosen, Priyanka Sista, Kathleen N. Lohr; Interventions to Improve Adherence to Self-administered Medications for Chronic Diseases in the United States: A Systematic Review. Annals of Internal Medicine. 2012 Dec;157(11):785-795.

[3] 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 March 5, 2012, http://www.gpo.gov/fdsys/pkg/FR-2012-02-28/pdf/2012-4597.pdf.

During this expert workshop, FDA representatives emphasized that the NSURE paradigm is not intended to create a "third class" of drugs, but will work within the existing two-class system of prescription and nonprescription drug classes. FDA representatives indicated that nonprescription drug status could be granted through the existing regulatory approval processes, with each Condition of Safe Use tested as part of a comprehensive approach that ensures that the drug will be safe and effective in the nonprescription setting. The regulatory approval of each nonprescription drug would remain product-specific and driven through industry application. FDA representatives also emphasized that the main objective of the program is to reach patients who are currently undertreated or without regular access to physicians. FDA representatives clarified that the conceptual framework for NSURE is still being developed.

Nonprescription Medications

Drug products in the United States are regulated in a two-class system of prescription and nonprescription medications. Currently, there are over 300,000 marketed nonprescription drug products, spanning over 80 therapeutic classes of drugs.[4] Generally, nonprescription drugs may have the following characteristics:

- The potential for misuse and abuse of the drug is low;
- Consumers can use the drug for self-diagnosed conditions; and
- The drug can be adequately labeled.[5]

Drug products are approved for nonprescription use either by conforming to standards established in "OTC monographs," or by approval through the New Drug Application (NDA) process. The NDA process serves a vital role as a path for the introduction of novel therapies into the nonprescription drug market. The NDA process for nonprescription approval can either evaluate a new drug product for nonprescription use, or it can evaluate an existing drug product that is currently approved for prescription-only use, to be reclassified or "switched" for use in a nonprescription setting. These reclassifications have enabled a range of prescription medications to become widely available as nonprescription products (e.g. antihistamines, nasal decongestants, analgesics, acid reducers). As part of the switch process, product sponsors utilize a series of specific study designs to assess the public's ability to safely and effectively use the drug in a nonprescription setting.[6] These study designs typically include label comprehension studies, self-selection studies, and actual use studies. The evidence generated by these studies allows the FDA to determine whether consumers can safely diagnose, select, and self-use drugs.

Barriers to Self-Care with Nonprescription Medications

Increasing the availability of nonprescription medications has the potential to expand the range of treatment options available to consumers. However, limitations in consumer self-care have prevented the widespread availability of many drug products in a nonprescription setting. Addressing the barriers to self-care may provide opportunities to increase access to medications that have a significant public health benefit.

Each individual disease, condition, and drug product presents a unique set of risks and safety issues that can prevent appropriate self-care. Self-care in a nonprescription setting involves several critical steps for patients and consumers, including self-diagnosis of a condition, self-selection of treatment, and self-management of therapy. Failure at any step of this process may lead to unsafe and ineffective use of a drug, and can prevent the approval of a drug product for use in a nonprescription setting. Typical barriers to self-diagnosis include lack of information on a disease, condition, or treatment option, including patients with asymptomatic diseases or conditions. Barriers to self-selection for treatment generally include an inability to appropriately

[4] U.S. Food and Drug administration (October 2012). Drug Applications for Over-the-Counter (OTC) Drugs (page). Retrieved April 17, 2013 from, http://www.fda.gov/drugs/developmentapprovalprocess/howdrugsaredevelopedandapproved/approvalapplications/over-the-counterdrugs/default.htm

[5] U.S. Food and Drug Administration (January 2012). About FDA (page): Regulation of Nonprescription Products. Retrieved April 17, 2013, from, http://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDER/ucm093452.htm

[6] U.S. Food and Drug administration (September, 2006). Executive Summary: Nonprescription Drug Advisory Committee Meeting. Retrieved April 17, 2013 from, http://www.fda.gov/ohrms/dockets/ac/06/briefing/2006-4230B1-01-Executive%20Summary.pdf

select treatment options, including complex or difficult decision making processes, evaluation of contraindications, or risk of potential unsafe uses. Barriers in self-management can include issues in ongoing compliance to a treatment plan, including modification of treatment plans, or the ability to monitor treatment outcomes and adverse events. Innovative applications of technology may help patients and consumers overcome these barriers.

Identifying the specific risks and safety issues for each drug can inform the development of targeted interventions and technologies that can serve as a Condition of Safe Use in a nonprescription setting. By addressing the barriers at critical points of self-diagnosis, self-selection, and self-management, the innovative application of technologies may facilitate the safe and effective use of a wide variety of products in a nonprescription setting.

Innovative Applications of Technology

Technologies have been utilized in many healthcare delivery settings to enhance patient care, and have demonstrated the potential to improve outcomes and decrease costs. New display technologies (e.g., point of care displays) can deliver dynamic and specific information to consumers and patients more effectively. Applications developed for the Internet, smart phones, or other electronic devices can assist patients in making complex health care decisions. Portable and wireless diagnostic technologies can collect valuable health information and transmit the data to providers and consumers to inform and optimize treatment. These technologies can be employed to address a wide range of barriers to self-care. An expansion of the FDA regulatory framework to permit and encourage innovative uses of technology to address barriers in self-care might allow more drugs to be made available in a nonprescription setting, and thereby increase access to beneficial medications for undertreated diseases and conditions.

Workshop Objectives and Discussion Questions

This workshop will explore the use of innovative technologies as a condition of safe use and practical strategies that might support the safe and effective use of medications in a nonprescription setting. Three key areas have been identified which relate to the use of technologies as a Condition of Safe Use within the NSURE initiative. Questions relating to those areas have been posed to help guide discussion.

Session I: Innovative Technologies as a Condition of Safe Use

This session will investigate how innovative technologies can address critical barriers in self-care. This will include a discussion on existing technologies that might enable consumers to safely and effectively use nonprescription medications within the NSURE paradigm. Key discussion questions may include:

- Which technologies might help to address the barriers that exist for self-diagnosis, self-selection, and self-management with current prescription medications?
- How can innovative technologies allow a consumer to make a correct decision about whether a product is appropriate for their personal use?
- How can technologies serve as a safety tool to allow for new Rx-to-OTC switch pathways?

Session II: Perspectives on the Role of Technologies as a Condition of Safe Use

This session will explore stakeholder perspectives on the use of technologies as Conditions of Safe Use in a nonprescription setting. Key discussion questions may include:

- What interests and concerns exist regarding the use of technologies as a tool to facilitate self-care?
- What are the characteristics of medications that have the potential to be switched from prescription to non-prescription with a technology based condition of safe use?
- How might the effectiveness of technology based Conditions of Safe Use be evaluated?
- What can be done to encourage the development of technologies that can be applied as Conditions of Safe Use?
- What are the interests and concerns of consumers regarding the use of technologies as a tool to assist in self-care?

Session III: Integrating Technologies as a Condition of Safe Use into Nonprescription Health Care Delivery Systems

This session will examine opportunities and challenges in the integration of technologies with Conditions of Safe Use into the health care system. Key discussion questions may include:

- How might technologies with Conditions of Safe Use interact with health professionals (e.g. pharmacists, physicians, nurses)? In what capacity?
    - How will these technology-driven Conditions of Safe Use be integrated into provider practice and workflow?
    - How can these technologies assist or simplify care provider roles while still ensuring quality care?
- How might these technologies be integrated into community settings (i.e., pharmacies, acute care centers, community medical clinics)
    - Are there approaches to standardize the technologies to support the implementation of Conditions of Safe Use across various nonprescription products/classes?
- How might technology-based Conditions of Safe Use be integrated into electronic health records (EHRs) or electronic medical records (EMRs) and personal health records (PHRs)?
- How can such technologies help monitor the use of nonprescription drugs?
    - Could these technologies be leveraged for postmarketing surveillance activities to better understand drug performance?