May 9, 2013

ENGELBERG CENTER for Health Care Reform at BROOKINGS

Meeting Summary

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

Background

Undertreatment, underdiagnosis, and medical nonadherence pose significant barriers to the quality of health care for patients and consumers. Lack of regular access to medical and pharmacologic care and a failure to administer recommended therapy are among the factors most commonly believed to contribute to medical undertreatment. While preventable, an approximate 30% to 50% of U.S. adults are nonadherent to long-term medications, leading to an estimated $100 billion in medical costs annually.[1] Improving access to appropriate pharmaceutical care while ensuring the safe and effective use of drugs can help to mitigate the problem of undertreatment, an effort that 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. With a new initiative, the *Nonprescription Safe Use Regulatory Expansion (NSURE),* FDA is investigating opportunities to address the public health problem of undertreatment within its existing regulatory authorities. An important aspect of this initiative is to explore how health care professionals and innovative technologies can serve as a condition to the safe use of drugs in a nonprescription setting. The focus of NSURE is to identify how, within the existing two-class system of prescription and nonprescription drug classes Conditions of Safe Use could be developed and tested as part of a comprehensive approach that ensures that a drug will be safe and effective in the nonprescription setting.

The NSURE initiative could have the potential to promote the use of essential medications, and could serve as an important mechanism to bring undertreated patients into the healthcare system. Developing the NSURE initiative will require an understanding of the health, economic, behavioral, and technological factors involved. Through a cooperative agreement with FDA, the Engelberg Center for Health Care Reform initiated a three-part series of expert workshops which will explore these factors and inform FDA's exploration of a potential regulatory expansion of nonprescription medications.

The first expert workshop, held on November 8, 2012, explored issues and practical considerations in the development of the NSURE initiative. Stakeholders discussed lessons from previous initiatives that addressed pharmaceutical access, explored patient populations of interest, and investigated strategies to utilize health care professionals as a Condition of Safe Use. A summary of the workshop discussion is available on Brookings' event webpage.

[1] Marcum ZA, et al. "Medication Nonadherence: A Diagnosable and Treatable Medical Condition." *Journal of the American Medical Association.* 2013;309(20):2105-2106. doi:10.1001/jama.2013.4638.

Meeting Objectives and Scope

On May 9, 2013, in cooperation with FDA, the Engelberg Center for Health Care Reform convened a second expert workshop, "Innovative Technologies and Nonprescription Medications: Addressing Undertreated Diseases and Conditions through Technology Enabled Self-Care," which explored the potential for innovative technologies to facilitate safe and effective use of nonprescription drugs within a nonprescription setting. Specific workshop objectives included the following:

- Exploring the use of innovative technologies as a Condition of Safe Use;
- Sharing perspectives on the role of technology to support the safe and effective use of nonprescription products; and
- Investigating the integration of innovative technologies within the existing health care delivery system.

This meeting brought together a diverse set of stakeholders from both public and private sectors, including FDA and other federal agencies, technology developers, pharmaceutical manufacturers, health care professionals, retail pharmacy representatives, and patient advocacy organizations. During this meeting, participants discussed a number of issues relating to a potential nonprescription regulatory expansion, with a particular focus on the use of innovative technologies which might help to facilitate self-care. This document highlights the major points of discussion.

Promise of Technology-Enabled Self-Care

During the workshop, participants prefaced discussion of the role of technology in facilitating self-care by highlighting the reality that medical self-care represents one of the most significant factors in the healthcare of a patient. Health care professionals cannot always provide direct supervision and consultation outside clinical settings. A substantial amount of health care is left to the patient to self-administer, and over the course of an individual's lifetime, self-care will represent a very large proportion of overall medical care, compared to care administered by a health care professional. The types of activities involved in self-care can vary widely, from routine medication regimens to complex diagnostic testing. Self-care involves several critical steps for patients to safely and effectively use medications in a nonprescription setting, including:

- *Self-diagnosis*: Safely and effectively diagnosis a disease, condition, or treatment option, including asymptomatic diseases or conditions.
- *Self-selection of treatment*: Appropriately select treatment options, including following complex or difficult decision making processes, evaluation of contraindications, or risk of potential unsafe uses.
- *Self-management*: Manage ongoing treatment compliance, including modification of treatment plans, and the ability to monitor treatment outcomes and adverse events.

Each individual disease, condition, and drug product presents a unique set of risks and safety issues that can prevent appropriate self-care. Identifying the specific risks and safety issues for each drug can inform the development of targeted interventions that can serve as a Condition of Safe Use in a nonprescription setting. Technology (e.g., mobile and/or computerized technology) has the potential to facilitate and improve the quality of self-care, and can serve an important role in helping to ensure the safety and effectiveness of medications. Technology can also complement existing patient and provider relationships by facilitating self-care.

Participants noted that emerging trends have demonstrated an increase in the usage of the Internet and mobile technologies to aid in healthcare decision-making. Approximately 80% of Internet users currently search for health information online and 50% of smartphone users use their devices to obtain health information.[2,3] As such, smart phones, tablets, and other electronic technologies have significant potential to help improve patient health and health promoting behaviors. Technological solutions, however, must be simple, relevant, and flexible to effectively engage consumers. Technology-enabled Conditions of Safe Use must also be mindful of consumer time and motivation. Understanding how technological solutions provide incentives and/or barriers for patients will be critical for a successful implementation within a nonprescription setting.

Range of Health Technologies

Technologies have been used in many aspects of healthcare delivery and patient care, often through applications (apps) developed for computers, smart phones, tablets, and other electronic devices. When used appropriately, these technologies have shown potential to improve medical outcomes and decrease costs.[4,5] Participants described a wide variety of mobile and electronic technologies that have been developed which might further enable patient self-care within the nonprescription setting. This spectrum of technologies includes:

- *Basic Technologies*
  - *Product labeling* – Technologies have the potential to enhance patient understanding of medical product labeling though the use of interactive text, video, and audio.
  - *Health behavior apps* – Health behavior modification apps have been developed to facilitate a variety of health enhancing and correcting behavior, including medication adherence and treatment compliance.
- *Advanced Technologies*
  - *Information sharing and diagnostics* – A wide range of mobile health apps have been developed for use in smart phones, tablets, and other electronic devices, which are capable of collecting health information from patients and transmitting the data to providers and consumers to inform treatment. Mobile technologies have also been developed which utilize innovative monitoring tools (e.g., biosensors) to enhance patient knowledge and promote information sharing between patients and physicians.
  - *Virtual monitoring* – Tools have been developed which allow health care providers to monitor vital signs, detect warnings, and diagnosis patient conditions in an outpatient setting. Virtual portals have also been developed which allow patients to communicate with physicians for consultation and prescriptive services.

Potential Challenges of Technology-Enabled Self-Care

While technologies have the potential to further enable patient self-care, a number of issues must be addressed in order for them to be successfully integrated within the nonprescription setting. A list of potential challenges relating to cost, patient and provider behavior, and regulatory considerations are highlighted below.

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[2] Pew Internet Project as referenced by Henley Centre HeadlightVision and Yankelovich. "The Futures Company "2011/12 Health and Wellness MONITOR: How to Sell 'Health.'" 2011

[3] Pew Research Center. Mobile Health 2012.

[4] Litan R, "Vital Signs via Broadband: Remote Monitoring Technologies Transmit Savings," Better Health Care Together Coalition, October 24, 2008, p. 1.

[5] Wang H and J Liu, "Mobile Phone Based Health Care Technology", Recent Patents in Biomedical Engineering, Volume 2, 2009, pp. 15-21.

Increased Cost for Patients and Consumers
Reliance on potentially costly or inaccessible technologies to obtain nonprescription medications may result in increased costs and/or additional barriers to access for patients. Participants recommended that product sponsors be conscious of a potential cost increase for consumers to obtain and/or use such technologies. This is an issue that is particularly true for populations who remain undertreated for common diseases and conditions.

Nonprescription medical products are rarely reimbursed from insurance providers and largely paid out-of-pocket by patients. As a result, prescription medications moving to nonprescription status might result in a greater cost burden for patients and consumers. Although certain medications have been shown to produce cost savings for patients and payers when "switched" from prescription to nonprescription status, the economic effect of the NSURE initiative has not been fully explored, and would likely need to be evaluated on a case-by-case basis.[6] The implications of the NSURE initiative on reimbursement and access will be explored at a third expert workshop convened by Brookings in the fall of 2013.

Populations with Low Literacy and Technical Knowledge
Understanding and evaluating the impact of these technologies in different populations and communities will be a critical component in developing a Condition of Safe Use. Certain population segments may be reluctant or unable to use technology within a nonprescription setting, particularly in populations with low literacy or technical knowledge. Additional research should be conducted in this area to better understand which populations are willing and able to utilize these tools.

Potential for Misuse
Certain patients and consumers may attempt to inappropriately obtain access to medications that are otherwise available through prescription through misuse of Conditions of Safe Use. For example, consumers might answer untruthfully about their medical history or provide inaccurate information to receive medications. These issues would need to be evaluated on a case-by-case basis, as the clinical significance and potential for misuse will need to be weighed against the potential net-benefit resulting from increased accessibility.

Increased Costs for Health Care Professionals
An increased demand on health care professionals as part of implementing Conditions of Safe Use has the potential to increase costs. Increased compensation for the additional work and responsibility related to implementing Conditions of Safe Use needs to be considered. In addition, the potential for increased professional liability from such services should be further explored by relevant stakeholders.

Nonprescription Drugs and Medical Reconciliation
Nonprescription medications can add complexity to routine medical reconciliations during physician examinations, a challenge which stems from an underreporting of nonprescription medical information and a lack of information captured by pharmacy recording systems. These issues can result in problems with medication interaction and adherence. An expansion of the use of technologies as a condition of

[6] Cohen J, et al. Assessing the economic impact of Rx-to-OTC switches: systematic review and guidelines for future development. *Journal of Medical Economics* 2013; 16(6): 835-44

safe use with nonprescription drugs could potentially alleviate the issues with medical reconciliation and reporting of OTC drug usage to physicians.

Regulatory Approval and Proprietary Ownership
While no decision has been made regarding the regulatory pathways of products with Conditions of Safe Use, technologies have the potential to be evaluated through multiple channels, including through separate application, as a companion device, or as a diagnostic. Issues may arise concerning the proprietary ownership of technologies which are used to ensure Conditions of Safe Use. Proprietary ownership has the potential to serve as a barrier for product sponsors seeking approval using similar technologies or platforms. This may be particularly true for generic drug sponsors, who may be unable to use the technology for an equivalent product.

Short-Term Strategies to Safely and Effectively Increase Access to Nonprescription Medications

Participants discussed a number of strategies that can be implemented in the near future to resolve many of the challenges and enhance the use of technology within a nonprescription setting. Those strategies have been outlined below.

Modernize Labeling Regulations to Incorporate Existing Technologies
Broadening the definition of medical product labeling could help to facilitate adoption and integration of innovative technologies into the nonprescription setting and improve the functionality of nonprescription product labeling. Participants noted that previous examples of nonprescription medical products have incorporated technologies as a part of FDA-approved product labeling, such as the inclusion of audiocassette instructions with nonprescription smoking cessation products. However, current labeling definitions do not permit other modern technologies to serve the same function. Modifying the labeling regulations to allow additional technologies, such as the kiosks, smart labels, or smart phone apps, may permit sponsors to more easily and efficiently incorporate new technologies as part of their product application.

Utilize Existing Technologies
Where available, product sponsors could utilize existing technologies when developing technology-enabled Conditions of Safe Use. There are a wide range of existing technologies that can potentially facilitate improved self-care. In many cases it is unnecessarily costly and time-consuming to develop new technologies, where effective existing technologies exist. These technologies are also more likely to be readily accessible and well-known to patients and consumers.

Prioritize Low-Risk Therapeutic Areas
When determining which products might be best suitable for nonprescription status, product sponsors should prioritize therapeutic categories that are well understood and have a lower risk profile that is amenable to technology based mitigation. In the near-term, targeting lower-risk medications will help to better ensure patient safety and develop best-practices for medications with greater risk and/or complexity.

Utilize Health Care Professionals
Capitalizing on new and evolving practice roles, health care professionals can be used in combination with innovative technologies to ensure the safe and effective use of nonprescription medications. In recent years, the role of many health care professionals has expanded to include new services and programs, often performed within alternative and innovative practice settings. Nurse practitioners have taken active roles in prescriptive and consultation services within many retail medical clinics and acute-

care centers (e.g., CVS MinuteClinic). Pharmacists in multiple states have initiated medication therapy management programs, collaborative practice agreements, and immunization programs.[7,8]

Recognizing these evolving roles, product developers may be able to incorporate multiple health care professionals within Conditions of Safe Use. For example, a "hybrid" model has been developed which uses pharmacy-based consultation services and technologies to enhance anaphylaxis screening and prevention, completed through standardized risk assessments through web-based and in-store technologies. This program was also capable of transferring the collected data from the pharmacies to physician offices to better inform treatment options.

Technologies will need to be integrated within the existing health care provider workflow to ensure the safe and effective use of medications. These technological interventions will ideally support the collaboration, communication, and clinical care between health care professionals and patients. Health care professionals should not be limited to "gate-keeping" roles for medications, as their expertise and training will not be fully utilized. A limited gatekeeping role would only increase providers' workload without adding value for patients.

Long-Term Strategies to Safely and Effectively Increase Access to Nonprescription Medications

Participants also discussed a number of strategies to increase access to nonprescription medications that may require long-term development and implementation considerations in the future. These strategies are outlined below.

Electronically Integrate Nonprescription Medical Information

Capturing and integrating information about nonprescription drug use within electronic health records (EHRs) might help to overcome challenges associated with reconciliation of complex medical care delivery. Electronic integration of nonprescription dispensing information into EHRs has significant potential to better inform provider knowledge and optimize coordination of medical treatment between multiple providers. EHR vendors are key stakeholders in this effort and should collaborate on future efforts to electronically integrate nonprescription medication information within a patient's medical records.

Multiple public and private initiatives are working to develop standards, enhance patient EHRs, and increase the flow of information between patients and providers. In particular, the Office of the National Coordinator for Health Information Technology incentivizes the use of patient EHR as part of meaningful-use requirements. As a result, it is likely that patients and providers will increasingly access and input information electronically through EHRs.

Technologies which are capable of surveying and populating health records with information on nonprescription drug usage could serve to increase the efficiency and accuracy of this process. In addition, uniform and standardized processes for electronic integration of health information can help to ensure consistent care for patients. Automated triggers can also be put in place to help identify high-risk patients and those who could benefit from access to needed therapy.

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[7] Cranor C, et al. "The Asheville Project: Long-Term Clinical and Economic Outcomes of a Community Pharmacy Diabetes Care Program."Journal of the American Pharmaceutical Association 43.2 (2003): 173-84

[8] Massachusetts Department of Public Health, Drug Control Program, Immunization Program, Board of Registration in Pharmacy. Joint Policy 2012-02 and FAQs on Pharmacist Administration of Vaccines. Retrieved April 18, 2012.

Integrating Technologies within Pharmacy and Retail Settings
Integrating technology into pharmacy and retail settings could promote widespread access to nonprescription products with Conditions of Safe Use. This is particularly true for larger and more expensive commercial technologies (e.g., kiosks), which would otherwise be inaccessible to patients and consumers. Such technologies should be interoperable and standardized to minimize space constraints and make efficient use of resources within retail settings. For example, kiosk technologies should be capable of satisfying the Conditions of Safe Use for multiple medications.

Retail settings will require a viable business model to provide new services for nonprescription medications. Such services should incorporate standardized billing procedures and reimbursement models. However, a reliance on expensive equipment or services may pose barriers for community pharmacies and retail settings to adopt such technologies. Moving forward, stakeholders should collaborate state Boards of Pharmacy to further explore integration within pharmacies.

Ensure the Safety and Efficacy of Technologies through New Study Designs
Nonprescription medications with Conditions of Safe Use will require consumer research studies to ensure that technologies provide meaningful improvement in the ability of patients to access and use each nonprescription drug. Product sponsors currently utilize a series of specific study designs to assess the public's ability to safely and effectively use the drug in a nonprescription setting. The evidence generated by these studies play a major role in helping to determine whether consumers can safely diagnose, select, and self-use drugs. These study designs typically include:

- *Label Comprehension Studies:* Examine consumers' ability to comprehend product labels, particularly for new nonprescription indications, directions for use, and new warnings.
- *Self-Selection Studies*: Determine consumer's ability to make correct decisions about whether or not the product is appropriate for use after reading the product label.
- *Actual Use Studies*: Assess the adherence, safety, and efficacy of a medical product when used by consumers in a nonprescription setting.

However, nonprescription medications with Conditions of Safe Use will likely require new practices and approaches based on existing consumer research methodologies. New study designs should provide a data-driven justification for the use of a technology to improve patients' ability to diagnose, select, and self-use drugs. Such study designs might also determine the incremental benefit and risk for each technological intervention, as well as the potential for the technology to serve as an additional barrier to access.

Address New Access Challenges for Patients
As previously discussed, issues surrounding increased costs, low literacy, and potential for abuse may present novel challenges for patients accessing nonprescription medications. It was noted that while the widespread implementation of technologies as a Condition of Safe Use may not directly benefit all populations, they might still provide significant net public health benefit. Specifically, in circumstances where technology based Conditions of Safe Use increase overall access to a drug, and access is not limited or decreased for any populations that are not able to use the technology, the use of technology based Conditions of Safe Use should be supported.

Specific efforts should be made to ensure that the use of technology based Conditions of Safe Use do not cause a decrease in access to nonprescription medications among certain populations. To ensure that all populations have access, sponsors could provide non-technological options for consumers to

access the medications (e.g., through paper questionnaires). Such low-tech options will provide both a "back-up" alternative in case the technology fails, and can prevent lack of access to technology from acting as a barrier to treatment. Furthermore, traditional means of accessing prescription medications through a health care provider should be preserved so that those unable to access nonprescription medications through Conditions of Safe Use are able to obtain treatment. The presence of "dual-status" medications, which are available in both prescription and nonprescription forms, ensures that options are not eliminated for patients.

Explore Cost and Reimbursement Strategies

Economic implications should be further explored to understand how nonprescription medications with Conditions of Safe Use might be financed to avoid "cost-shifting" or other unintended consequences for patients and consumers. Topics relating to reimbursement and other economic considerations will be the focus of the third NSURE expert workshop hosted by the Engelberg Center for Health Care Reform.

Summary and Next Steps

This expert workshop helped to demonstrate how technologies might serve as Conditions of Safe Use to support the safe and effective use of nonprescription medications. Technology-enabled Conditions of Safe Use can be used to play an active role in the self-care of patients and consumers. FDA and stakeholders should continue to explore how the many health, economic, behavioral, and technological factors of the NSURE initiative might fit within the existing and evolving healthcare system.