Expert Workshop: Prescribing Information for Health Care Professionals

Overview of Prescribing Information

Prescribing information (sometimes referred to as PI, package insert, prescription drug labeling, and professional labeling) is intended to provide health care professionals with information needed to appropriately prescribe prescription drugs and biologics and counsel patients on their safe and effective use. Since being standardized by the U.S. Food and Drug Administration (FDA) in 1979, PI became increasingly lengthy and complex over the following decades, impacting its usefulness to health care professionals. In an effort to address these issues, FDA solicited feedback from health care professionals and other stakeholders and proposed new rules to govern the content and format of PI in 2000. These rules were designed to make PI more informative and accessible to promote better risk communication and reduce medication errors and were finalized as the "Physician Labeling Rule" (PLR) in January 2006. PLR established new standards of compliance for manufacturers and introduced multiple content and format revisions to the previous PI, including a *Highlights* section for quick reference of key information, changes to the order and content of the Full Prescribing Information (FPI), and creation of a *Patient Counseling Information* (PCI) section for facilitating communication with patients about important uses and risks of a drug.

Six years have passed since PLR was issued. While FDA is not considering changing the regulations, it is interested in receiving feedback from key stakeholders that either develop or use PI. In addition, because regulatory requirements regarding the PCI section are not detailed, FDA has found that the content and format of this section vary considerably. This workshop, convened by the Engelberg Center for Health Care Reform at Brookings in cooperation with FDA, sought to engage stakeholders in a discussion of the utility of PI as a communication tool for health care professionals and to identify content in the PCI section that would be most useful for counseling patients.

Improving Prescribing Information

PI plays a vital role in supporting safe and effective prescribing and patient counseling. It is FDA's primary communication tool for conveying information to health care professionals about safe and effective use of a drug. PI represents a compilation of the information submitted by the manufacturer and reviewed by FDA to support approval of the drug and is provided directly from the manufacturer to health care professionals. In order for these roles to be fulfilled and to ensure the productive use of PI by prescribers in the future, experts discussed potential improvements in and emerging opportunities for enhanced performance of PI. These areas of improvement were largely broken down into the categories of content and accessibility.

Improving Overall PI Content

Given the time constraints faced by prescribers, the content of PI must be provided in an effective and familiar manner. Workshop participants identified several areas for improvement in the content of PI and areas where FDA could provide greater clarity for manufacturers drafting PI. Suggested improvements in *Highlights* include the use of bullets for conveying the most vital information and presenting of dosing recommendations for special populations under Dosage and

Administration. Further suggestions included improvements to FPI through a reduction in repetitive information, vague language, and theoretical risks, all of which complicate information and lengthen material. More specifically, participants also suggested more information on clinical trials and pregnancy and lactation issues in PI. With respect to adverse reactions, some attendees felt content could benefit from clearer descriptions of safety databases descriptions and an avoidance of non-quantitative statements. Further examination of drug interaction content was also proposed to address any inconsistencies of its content across PIs and to increase PI's utility when prescribing decisions are made for patients on multiple medications.

Overall, participants felt that consistency in content, and use of actionable and direct language, were two general improvements that could be made to PI to help health care professionals make prescribing decisions and counsel patients. Additionally, experts broadly suggested efforts to ensure consistency of information among similar products. Some workshop attendees noted that FDA could help to clarify some of the above issues through reexamining PLR guidance documents and encouraging further incorporation of useful information in PI. Finally, meeting attendees expressed general support for converting all professional labeling to the PLR format.

Addressing Content of PCI

In addition to examining PI as a whole, workshop participants were also asked to discuss potential improvements to the PCI section of PI in order to encourage its use as a primary resource when conveying information to patients. The understanding that PCI is presented with the specific challenge of being utilized during peri-prescribing colored much of the discussion; a health care professional may have more time to review with the entirety of PI during research or in-depth consultation, while PCI must be readily accessed and communicated to patients during a short amount of time and alongside competing demands on the prescriber. In short, participants made it clear that any suggested content or format revisions to PCI support the end goal of creating a tool that is geared toward the fast, accurate, and understandable communication of the most important information on safe and effective use of prescription drugs to patients.

Toward that end, experts suggested that specific changes to PCI could help ensure utility and clarity. Some, for example, pointed out that information should be logically organized into bullets written in lay language directed toward patients to reduce "translation" time for the prescriber and the inclusion of clear phonetic pronunciations. Many stressed that this should not come at the cost of eliminating more in-depth, scientific, or quantitative language, but that a simpler writing style aimed at how prescribers talk to patients could easily be bolstered with cross references to more detailed information elsewhere in FPI. As for what types of information would be most beneficial to patients and prescribers in PCI, participants discussed major safety concerns, adverse reactions, and proper dosage and administration as the areas where PCI could prove helpful. Finally, some at the workshop felt that PCI could be improved to ensure that the information contained within it is reflective of FPI and that said information is product-specific where appropriate instead of general information for a product's class.

Improving PI Accessibility

Although many of the improvements to PI content will help to further establish it as a useful primary source of information on the safe and effective use of drugs, such changes will have little utility if stakeholders continue to turn to other sources for reference. Indeed, many attendees indicated that, when surveyed, their colleagues currently favor other sources of information for reference while PIs remain largely underutilized. In order to address this challenge and potentially foster easy

access to PI on a routine basis, technological advances were discussed as a way to increase uptake of PI and improve its integration into the normal work flow of prescribers. Increasing the number of hyperlink references, for example, could allow for easier electronic cross-referencing to other parts of FPI or external resources, increased internal navigability, and improved function and usage of PI. In short, improved coding and electronic formatting could help to create electronic PI (ePI) ready for immediate uptake into the electronic systems described below.

As standardized, more user-friendly electronic ePI is commonplace, participants in the workshop felt that dissemination of ePI could be achieved through multiple routes. The National Library of Medicine (NLM), for example, provides free and accessible information for health care professionals through its DailyMed website, which is updated daily by FDA to include PI for all drugs. Though services such as DailyMed might be underutilized, attendees felt that inclusion of improved ePIs could have the potential to increase accessibility and use of NLM's tools, especially if linked directly to electronic health records (EHRs) or third-party prescription information platforms.

Many participants noted that EHR vendors are uniquely positioned to integrate ePI into their platforms. Workshop participants believed that not only would this allow for easier direct access to PI, but also customized user experiences that could allow for things like user-defined alerts (e.g., for dosing, drug interactions, etc.) and notification of newly updated information. Furthermore, some felt that EHR vendors can provide additional improvements to ePI navigability, allowing for links to dosing information, boxed warnings, risk evaluation and mitigation strategies, and other forms of useful information. Vendors may also work toward developing a system that would link PI for drugs that are commonly used together for certain conditions and therapeutic areas. This linkage would allow for easier cross-referencing of drug interactions and contraindications. It was pointed out that inclusion of ePI would require EHR vendors to ensure that their platforms have the capability for constant updating of ePI and surfacing of linked information. Discussions surrounding EHR uptake of ePI is especially timely given that EHR vendors could take advantage of upcoming meaningful use requirements established as part of the Health Technology for Economic and Clinical Health Act in 2009.[1] As these requirements encourage the extension of EHRs into more care settings, this may allow for straightforward and cost-effective incorporation of ePI.

Finally, format and accessibility improvements could allow for third-party information developers to utilize ePI in developing their own proprietary platforms that support prescribing practices and prescription adherence. In this way, developers could ensure that the information being adapted was the most up-to-date and accurate. Workshop participants suggested that third-party platform incorporation of ePI would most notably be useful in mobile applications commonly used by their colleagues in the clinical setting.

Next Steps
Taken together, improvements to the content of and access to PI and PCI could serve to make information about prescription drugs easier to find, understand, and apply to patients. Whether it is introducing new coding or electronic formatting, incorporating new or more detailed clinical information, or identifying novel delivery methods for placing PI in the hands of health care professionals, many unique opportunities exist for stakeholders in the health care community to work together to create PI that is beneficial for prescribers and their patients.

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[1] The 2014 edition of meaningful use requirements, or "meaningful use 2", was issued as a proposed rule on March 7, 2012, and closed for public comment on May 7: http://www.gpo.gov/fdsys/pkg/FR-2012-03-07/pdf/2012-4430.pdf.

Possible next steps for manufacturers could include coordination between brand and generic manufacturers to improve consistency across similar products, working to ensure that information is written to reduce translation time by providers, and improvements in electronic coding of content to increase internal navigability. EHR vendors and third-party mobile application developers could collaborate with NLM to provide links to NLM's free tools to improve accessibility of ePI, increase incorporation of ePI into platforms, and utilize imbedded hyperlink referenced to ensure improved navigability by users. To support overall improvements in content and accessibility of PI, FDA may consider ways to further clarify the PLR guidance documents and identify ways to encourage consistency.