ENGELBERG CENTER for Health Care Reform at BROOKINGS

October 2010

DISCUSSION GUIDE

Public Workshop: Ensuring Access to Effective Patient Medication Information

Background

In order to use prescription medications safely, consumers need to receive clear, actionable information. This medication information must be accurate, balanced, and delivered in a consistent and easily understood format. In 2008, an evaluation of Consumer Medication Information (CMI) showed that while 94 percent of consumers received CMI with new prescriptions, only 75 percent of information met the minimum criteria for usefulness, demonstrating that this need is not being met.[1] At present, the written prescription communications patients receive are numerous, uncoordinated, and sometimes inaccurate or conflicting. At the point of dispensing, a consumer may receive any or all of the following:

- Patient Package Inserts (PPI) – Prescription information for oral contraceptives, other estrogen-containing products, and some additional drugs, which is developed by the manufacturer, approved by the Food and Drug Administration (FDA), and dispensed with specific products.
- Consumer Medication Information (CMI) – Prescription information written by the pharmacy or an outside company, which is not FDA-reviewed and is voluntarily distributed by pharmacies to consumers.
- Medication Guides – Prescription information for certain medications "that pose a serious and significant public health concern," which is developed by the manufacturer, approved by FDA, and required to be given to consumers each time the medication is dispensed. [2]

For the purpose of this workshop, we will use the term Patient Medication Information (PMI) to refer to any written prescription drug information intended for use by patients.

Historical Context

The issue of ensuring effective PMI has a long history, marked by great interest and effort by the federal government and stakeholder groups. Appendix A provides a timeline of important events, the most relevant of which are described below.

In August 1996, Congress mandated that the Secretary of the U.S. Department of Health and Human Services (HHS) convene a committee to devise a long-term action plan for improving oral and written prescription drug information.[3] In December 1996, that committee delivered what has come to be called the Keystone action plan, which outlined specific criteria for evaluating the usefulness of PMI for patients.[4]

Over the next decade, FDA held several important meetings, commissioned studies, and considered public input on the issue of effective PMI. In June 2008, the Agency received a citizen petition from a large group

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[1] Kimberlin CL, Winterstein AG. Expert and Consumer Evaluation of Consumer Medication Information-2008. US Food and Drug Administration. November 4, 2008. Available at: http://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/RiskCommunicationAdvisoryCommittee/UCM117149.pdf. Accessed June 10, 2010.

[2] 21 CFR 208

[3] Public Law 104-180 (August 6, 1996). Agriculture, Rural Development, Food and Drug Administration, and Related Agencies Appropriations Act of 1997.

[4] Steering Committee for the Collaborative Development of a Long-Range Action Plan for the Provision of Useful Prescription Medicine Information. Action Plan for the Provision of Useful Prescription Medicine Information. December 1996. Available at: http://www.fda.gov/downloads/AboutFDA/CentersOffices/CDER/ReportsBudgets/UCM163793.pdf.

representing pharmacy practice, medical consumers, and medical communications companies, requesting that FDA adopt a "one-document solution" to replace CMI, PPI, and Medication Guides.[5]

In February 2009, the FDA Risk Communication Advisory Committee (RCAC) recommended FDA adopt a single standard document for communicating essential information about prescription drugs, which would replace CMI, PPI, and Medication Guides.[6]

In September 2009, FDA held a public workshop to discuss optimal content and format of written prescription drug information, during which they sought input on four draft patient information prototypes developed through review of the scientific literature and current labeling practices and guidance.[7] In response to the feedback provided during both the February and September 2009 meetings, FDA developed three draft patient information prototypes.

On May 4, 2010, FDA announced the design of an evaluation strategy in the Federal Register (FR) and solicited comments by July 6, 2010. In response to comments submitted to the docket and to feedback provided at the July 21, 2010 expert meeting described below, FDA has further refined the three draft patient information prototypes (see Appendix B). Following approval by the Office of Management and Budget, FDA will evaluate the three prototypes using an experimental consumer testing study.[8]

On July 21, 2010, the Brookings Institution hosted an expert meeting to discuss overarching principles for communicating prescription information effectively, metrics for evaluating PMI, and the most useful content and format of a single medication information paper document, as represented in FDA's three prototypes and the proposed strategy for evaluating them.[9]

On September 27-28, 2010, FDA hosted a two-day public hearing to solicit input on processes and procedures for developing a quality management system to ensure standardized development, access, and distribution of PMI.[10]

Public Workshop: Ensuring Access to Effective Patient Medication Information

Through a cooperative agreement with FDA, the Engelberg Center for Health Care Reform at Brookings is convening three workshops to discuss optimizing, implementing, and evaluating adoption of a single standard medication information document.[11] The first meeting took place on July 21, 2010, as described above. The second meeting in the series will be a large public workshop held on October 12, 2010. The goal of this workshop is to discuss strategies to ensure that PMI is easily accessible and effectively distributed to patients. The final meeting, planned for February 2011, will be a small expert workshop that summarizes the challenges expressed in the series of public meetings and considers how best to design a pilot or multiple pilots for the implementation, distribution, and evaluation of standardized PMI.

Workshop Objectives

This workshop will explore strategies for ensuring patients receive PMI. The workshop will elicit creative approaches to distributing medication information from a variety of stakeholders including patients, providers,

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[5] Citizen Petition Requesting FDA Action on a "One Document Solution" for All Pharmacy-Based Communications. June 30, 2008.
[6] US Food and Drug Administration. Minutes of the Risk Communication Advisory Committee, FDA. February 26-27, 2009. Available at: http://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/RiskCommunicationAdvisoryCommittee/UCM152593.pdf. Accessed June 10, 2010.
[7] US Food and Drug Administration. Workshop Summary. September 24-25, 2009. Available at: http://www.fda.gov/downloads/Drugs/NewsEvents/UCM190419.pdf.
8 Agency Information Collection Activities; Proposed Collection; Comment Request; Experimental Study of Patient Information Prototypes. Docket No. FDA-2010-N-0184. Federal Register Vol. 75, No. 85 (May 4, 2010). pp. 23775-23777.
[9] http://www.brookings.edu/events/2010/0721_CMI.aspx
[10] Development and Distribution of Patient Medication Information for Prescrption Drugs; Public Hearing. Docket No. FDA-2010-N-0437. Federal Register Vol. 75, No. 166 (August 27, 2010). pp. 52765-52768.
[11] Convener of Active Medical Product Surveillance Discussion (U13). Docket No. FDA-2009-N-0275. Federal Register Vol. 74, No. 120 (June 24, 2009). pp. 30097-30098.

manufacturers, publishers, payers, and distributors. Workshop objectives will be met through presentations and a robust moderated discussion between panelists and the audience.

Session I: FDA and Patient Medication Information – The Path Forward

In Session I of the workshop, FDA will provide its perspective on PMI, laying out the background and issues and challenges to be discussed in subsequent sessions. FDA's remarks will include a review of the history of PMI and the Agency's current strategy for improving it.

Session II: Patient Perspectives – Making PMI More Effective

Ultimately, PMI must be patient-centric, from the information contained in it to mechanisms by which patients receive it. Session II focuses on patient preferences for access and distribution of PMI, and what considerations should be taken into account when delivering it to special populations such as non-English speakers, patients with low health literacy, or patients with disabilities. Panelists will be asked to describe how new forms of technology could improve access to PMI and to consider ways that patient and consumer groups could be involved in evaluating the effectiveness of pilot PMI distribution strategies.

Session III: Effective PMI – The Roles of Manufacturers and PMI Vendors

Manufacturers and vendors (publishers and distributors) will continue to have a substantial role in creating PMI under FDA's new paradigm of a single-page standardized PMI document. Panelists in the third session will discuss the roles that manufacturers and vendors should play in the development and distribution of PMI for branded products as well as for generics. Panelists will also propose interim strategies for ensuring patients benefit from incremental improvements in PMI development and distribution in the near term.

Session IV: Effective Distribution of PMI

Effective distribution of PMI may involve prescribers, pharmacists, pharmacies, pharmacy benefit managers, hospitals, and numerous others. Panelists in this session will consider how PMI can be most effectively distributed within current and potential future workflows and how best to monitor distribution compliance. Moreover, they will discuss potential alternatives to paper leaflets, such as e-mail or establishing a central repository on the internet. Finally, panelists will consider approaches to comparing the effectiveness of different distribution methods.

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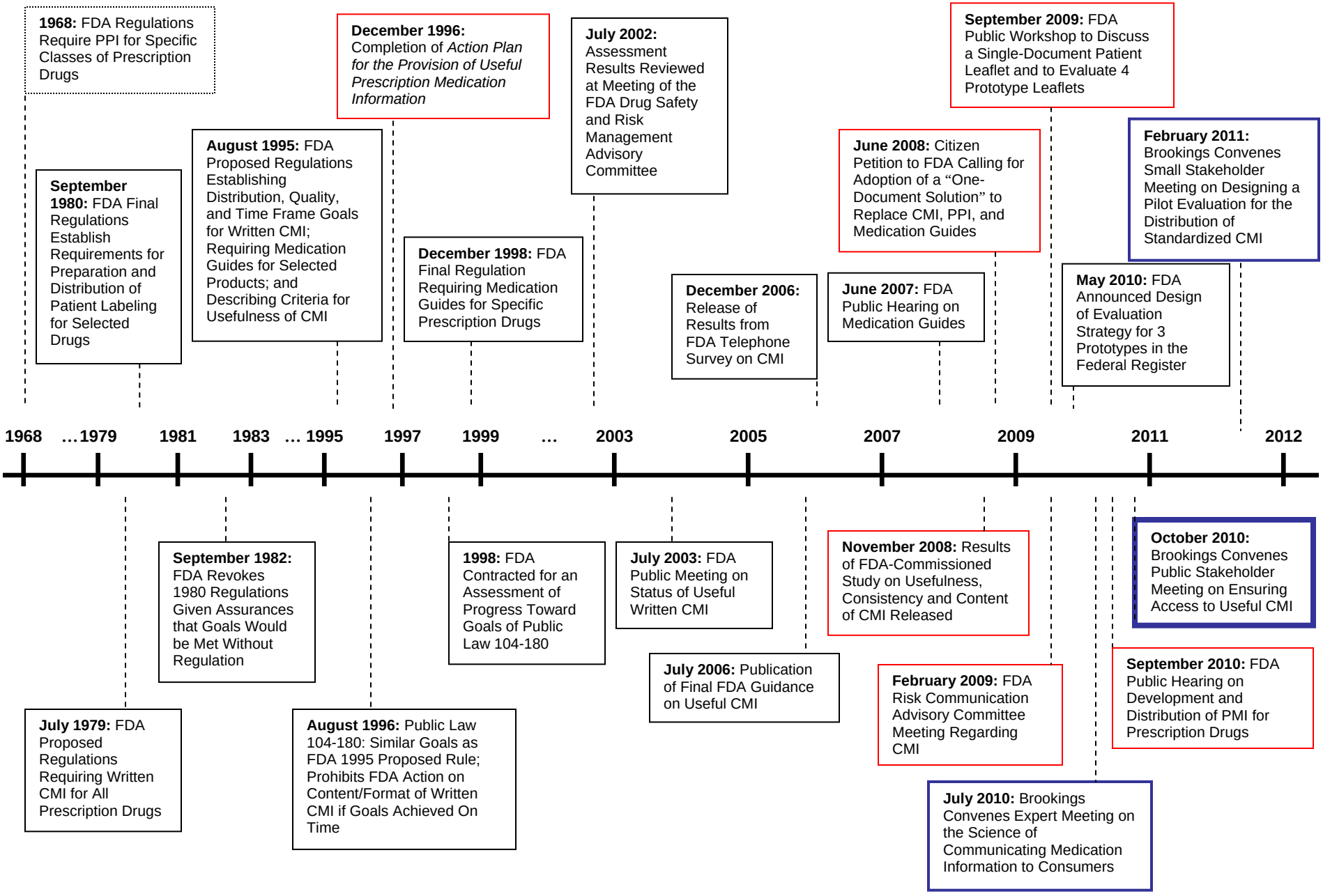
Appendix A: Consumer Medication Information: A Timeline of Key Events



Appendix B: Single Document Prototypes

Drug Approved by FDA: 2005
Last Revised: May 2009

Rheutopia [Roo-TOH-pee-ah] (also known as arixalate)

Uses

- Rheumatoid arthritis in adults. Rheutopia reduces painful and swollen joints, slows joint damage, and improves mobility and the ability to do physical activities.
- Polyarticular juvenile rheumatoid arthritis in children at least 4 years old who did not have good results from other medicines. Rheutopia reduces pain, improves mobility, and decreases the number of painful joints.
- Ankylosing spondylitis. Rheutopia reduces back pain, swelling, and improves mobility.
- Plaque psoriasis in adults who may benefit from taking medicine or receiving phototherapy (using ultraviolet light). Rheutopia improves or clears up areas of skin with psoriasis.

Important Warning: Serious Infections

- Rheutopia affects the immune system. It can lower your ability to fight infections. Do not use Rheutopia if you have an active infection.
- People taking Rheutopia have gotten serious infections including tuberculosis (TB) and infections caused by viruses, fungi, or bacteria. Some people have died from these infections.

Tell Your Doctor

Before using Rheutopia, tell your doctor if you:

- have an infection, are being treated for an infection, or think you have an infection (such as a cold, flu or skin infection).
- have TB or have been near someone who has TB. You may be tested and treated for TB.
- have any nervous system or heart problems.
- have lived in or traveled to other countries. There is more risk for getting TB or other infections in certain countries.
- have been recently been vaccinated or are scheduled to receive a vaccination (including a flu shot). You should not get a vaccination while taking Rheutopia.
- are taking the medicine Kineret (anakinra). The risk of serious infections increases when used with Rheutopia.

Call Your Doctor

Stop using Rheutopia and tell your doctor right away if you develop:

- Fever, cough, flu-like symptoms, skin infection (red, warm, painful skin or open sores). These can be symptoms of a serious infection.
- Numbness, tingling, weakness, vision problems, or dizziness. Symptoms of nervous system diseases, like multiple sclerosis, may develop or get worse.
- Chills, swollen lymph nodes, night sweats, fever, or weight loss. You may have a higher chance of getting lymph node cancer.
- Bruising, bleeding, and pale skin. Your body may not make enough blood cells to fight infection or to help stop bleeding.
- Shortness of breath, swelling of ankles or feet, or sudden weight gain. These are symptoms of heart failure that may develop or get worse.
- Chest discomfort or pain, shortness of breath, joint pain or a rash on your cheeks or arms. These may be symptoms of an immune reaction with lupus-like syndrome.

Common Side Effects

- Redness, rash, swelling, itching or bruising where the shot was given.
- Headache
- Runny nose

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

Directions for Use

- Rheutopia is an injection (shot). Do not use Rheutopia until your doctor has shown you how to give a shot.
- Store Rheutopia in the refrigerator. Do not shake or freeze.
- If you forget to take a dose, take it as soon as you remember. Take your next dose at your regularly scheduled time.
- Your doctor will tell you how often to use Rheutopia. Do not use Rheutopia more often than prescribed.

Draft Prototype 2A_Warnings

Appendix B: Single Document Prototypes

Drug Approved by FDA: 2005
Last Revised: May 2009

Rheutopia [Roo-TOH-pee-ah] (also known as arixalate)	
Uses	• Rheumatoid arthritis in adults. Rheutopia reduces painful and swollen joints, slows joint damage, and improves mobility and the ability to do physical activities. • Polyarticular juvenile rheumatoid arthritis in children at least 4 years old who did not have good results from other medicines. Rheutopia reduces pain, improves mobility, and decreases the number of painful joints. • Ankylosing spondylitis. Rheutopia reduces back pain, swelling, and improves mobility. • Plaque psoriasis in adults who may benefit from taking medicine or receiving phototherapy (using ultraviolet light). Rheutopia improves or clears up areas of skin with psoriasis.
Important Warning: Serious Infections	• Rheutopia affects the immune system. It can lower your ability to fight infections. Do not use Rheutopia if you have an active infection. • People taking Rheutopia have gotten serious infections including tuberculosis (TB) and infections caused by viruses, fungi, or bacteria. Some people have died from these infections.
Tell Your Doctor	**Before using Rheutopia,** tell your doctor if you: • have an infection, are being treated for an infection, or think you have an infection (such as a cold, flu or skin infection). • have TB or have been near someone who has TB. • have any nervous system or heart problems. • have lived in or traveled to other countries. • have recently been vaccinated or are scheduled to receive a vaccination (including a flu shot). • are taking the medicine Kineret (anakinra).
Call Your Doctor	**Stop using Rheutopia** and tell your doctor right away if you develop: • Fever, cough, flu-like symptoms, a skin infection (red, warm, painful skin or open sores). • Numbness, tingling, weakness, vision problems, or dizziness. • Chills, swollen lymph nodes, night sweats, fever, or weight loss. • Bruising, bleeding, and pale skin. • Shortness of breath, swelling of ankles or feet, or sudden weight gain. • Chest discomfort or pain, shortness of breath, joint pain or a rash on your cheeks or arms.
Common Side Effects	• Redness, rash, swelling, itching or bruising where the shot was given. • Headache • Runny nose Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.
Directions for Use	• Rheutopia is an injection (shot). Do not use Rheutopia until your doctor has shown you how to give a shot. • Store Rheutopia in the refrigerator. Do not shake or freeze. • If you forget to take a dose, take it as soon as you remember. Take your next dose at your regularly scheduled time. • Your doctor will tell you how often to use Rheutopia. Do not use Rheutopia more often than prescribed.

Draft Prototype 1A_Warnings

Appendix B: Single Document Prototypes

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Last Revised: May 2009

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- Ankylosing spondylitis. Rheutopia reduces back pain, swelling, and improves mobility.
- Plaque psoriasis in adults who may benefit from taking medicine or receiving phototherapy (using ultraviolet light). Rheutopia improves or clears up areas of skin with psoriasis.

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Tell your doctor before using if you

- have an infection, are being treated for an infection, or think you have an infection (such as a cold, flu or skin infection).
- have TB or have been near someone who has TB.
- have any nervous system or heart problems.
- have lived in or traveled to other countries.
- have recently been vaccinated or are scheduled to receive a vaccination (including a flu shot).
- are taking the medicine Kineret (anakinra).

Stop use and call your doctor right away if you develop

- Fever, cough, flu-like symptoms, a skin infection (red, warm, painful skin or open sores).
- Numbness, tingling, weakness, vision problems, or dizziness.
- Chills, swollen lymph nodes, night sweats, fever, or weight loss.
- Bruising, bleeding, and pale skin.
- Shortness of breath, swelling of ankles or feet, or sudden weight gain.
- Chest discomfort or pain, shortness of breath, joint pain or a rash on your cheeks or arms.

Common side effects

- redness, rash, swelling, itching, or bruising where the shot was given.
- headache
- runny nose

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

Directions for use

- Rheutopia is an injection (shot). Do not use Rheutopia until your doctor has shown you how to give a shot.
- Store Rheutopia in the refrigerator. Do not shake or freeze.
- If you forget to take a dose, take it as soon as you remember. Take your next dose at your regularly scheduled time.
- Your doctor will tell you how often to use Rheutopia. Do not use Rheutopia more often than prescribed.

Draft Prototype 3A_Warnings