The Safe Use Initiative and Health Literacy: Workshop Summary

ISBN
978-0-309-15931-9

90 pages
6 x 9
PAPERBACK (2010)

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THE SAFE USE INITIATIVE AND HEALTH LITERACY

WORKSHOP SUMMARY

Cori Vancheri, *Rapporteur*

Roundtable on Health Literacy

Board on Population Health and Public Health Practice

INSTITUTE OF MEDICINE
OF THE NATIONAL ACADEMIES

THE NATIONAL ACADEMIES PRESS
Washington, D.C.
www.nap.edu

THE NATIONAL ACADEMIES PRESS 500 Fifth Street, N.W. Washington, DC 20001

NOTICE: The project that is the subject of this report was approved by the Governing Board of the National Research Council, whose members are drawn from the councils of the National Academy of Sciences, the National Academy of Engineering, and the Institute of Medicine.

This project was supported by contracts between the National Academy of Sciences, the Agency for Healthcare Research and Quality, GlaxoSmithKline, Johnson & Johnson, and the Missouri Health Foundation (09-0290-HL-09).

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International Standard Book Number-13: 978-0-309-15931-9
International Standard Book Number-10: 0-309-15931-8

Additional copies of this report are available from the National Academies Press, 500 Fifth Street, N.W., Lockbox 285, Washington, DC 20055; (800) 624-6242 or (202) 334-3313 (in the Washington metropolitan area); Internet, http://www.nap.edu.

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Suggested citation: IOM (Institute of Medicine). 2010. *The Safe Use Initiative and Health Literacy: Workshop Summary.* Washington, DC: The National Academies Press.

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Willing is not enough; we must do."
—Goethe

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This report has been reviewed in draft form by individuals chosen for their diverse perspectives and technical expertise, in accordance with procedures approved by the National Research Council's Report Review Committee. The purpose of this independent review is to provide candid and critical comments that will assist the institution in making its published report as sound as possible and to ensure that the report meets institutional standards for objectivity, evidence, and responsiveness to the study charge. The review comments and draft manuscript remain confidential to protect the integrity of the process. We wish to thank the following individuals for their review of this report:

Deborah Fritz, GlaxoSmithKline
Cheryl Parks, University of Connecticut
Lee Sanders, University of Miami
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Although the reviewers listed above have provided many constructive comments and suggestions, they did not endorse the final draft of this report before its release. The review of this report was overseen by **Harold Fallon,** School of Medicine, University of Alabama. Appointed by the Institute of Medicine, he was responsible for making certain that an independent examination of this report was carried out in accordance with institutional procedures and that all review comments were carefully considered. Responsibility for the final content of this report rests entirely with the rapporteur and the institution.

Acknowledgments

Without the support of the sponsors of the Institute of Medicine Roundtable on Health Literacy, it would not have been possible to plan and conduct the workshop on health literacy and the Safe Use Initiative which this report summarizes. Sponsorship for the Roundtable comes from the Agency for Healthcare Research and Quality, GlaxoSmithKline, Johnson & Johnson, and the Missouri Foundation for Health.

The Roundtable wishes to express its appreciation to Joshua Sharfstein of the Food and Drug Administration (FDA) who provided an overview of the FDA Safe Use Initiative and encouraged exploration of the collaborations that could be formed to increase the safety of patient drug use. The Roundtable is also grateful to H. Shonna Yin and Michael Wolf for their illuminating presentations about health literacy and the safe use of over-the-counter products. Discussion was stimulated by the expert presentations of Daniel Budnitz, William Ray Bullman, Edwin Kuffner, and Joanne Schwartzberg on initiatives to advance patient-centered drug safety. Thanks also go to Sandra DeBussey, Jill Griffiths, Mimi Johnson, Gerald McEvoy, and Susan Pisano for their presentations and insights into identifying activities around which to build partnerships for patient-centered drug safety.

The Roundtable would also like to thank the members of the workshop planning committee for their efforts in developing an excellent workshop agenda. Members of the planning committee were Benard Dryer, Deborah Fritz, and Ruth Parker.

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1

Introduction

Tens of millions of people in the United States use prescription and over-the-counter (OTC) medications (FDA, 2009a). When consumers and patients use medications improperly, they risk illness, injury, and death. The Institute of Medicine (IOM) estimates that at least 1.5 million preventable adverse drug events occur within the health care system each year (IOM, 2007).

To reduce unnecessary adverse events resulting from inappropriate use of medications, the Food and Drug Administration (FDA) launched the Safe Use Initiative in November 2009 (FDA, 2009b). The goal of the Safe Use Initiative is to create and facilitate public and private collaborations within the health care community in order to reduce preventable harm by identifying specific, preventable medication risks and developing, implementing, and evaluating cross-sector interventions with partners who are committed to safe medication use.

The IOM Roundtable on Health Literacy brings together leaders from the federal government, foundations, health plans, associations, and private companies to discuss challenges facing health literacy practice and research and to identify approaches to promote health literacy in both the public and private sectors. The roundtable also serves to educate the public, press, and policy makers regarding issues related to health literacy. The roundtable sponsors workshops for members and the public to discuss approaches to resolve key challenges.

The IOM Roundtable on Health Literacy has previously met and discussed standardization of drug labels as a patient-centered approach to

improving medication safety and health literacy (IOM, 2008). Discussions incorporated all components of the medication labels, including primary and secondary container labels, consumer medication information, package inserts, and medication guides as a system of information seamlessly engineered for patient understanding and safety.

The roundtable seeks to envision ways to advance meaningful partnerships and actionable goals that encourage a systems approach to patient-centered health literate drug safety. Building on prior activity in this area, a workshop was held April 27, 2010. The role of the workshop planning committee was limited to planning the workshop. Unlike a consensus committee report, a workshop summary may not contain conclusions and recommendations. Therefore, this summary has been prepared by the workshop rapporteur as a factual summary of what occurred at the workshop. The workshop featured presentations and discussions on the FDA's Safe Use Initiative and other activities related to improving drug safety and drug labeling for both prescription and OTC medications. The workshop was moderated by George Isham. The following pages summarize the workshop presentations and discussions. Chapter 2 presents the FDA's description of the Safe Use Initiative. Chapter 3 focuses on OTC products with data on OTC health literacy challenges. In Chapter 4, existing patient-centered drug safety initiatives are reviewed. Chapter 5 covers actions taken by the pharmaceutical industry, pharmacy groups, insurers, health plans, and consumer advocates. Chapter 6 follows with a general discussion including participants' suggestions for FDA action to move the Safe Use Initiative forward.

2

FDA Safe Use Initiative

Joshua Sharfstein, M.D.
U.S. Food and Drug Administration

The Food and Drug Administration (FDA) is a public health agency committed to protecting lives wherever possible, said Joshua Sharfstein. Since its inception, people have looked to the FDA to take action when there are deaths related to medications. Now the FDA is looking to the roundtable and other stakeholders for critically important input on its Safe Use Initiative, which is in its formative stages.

Launched in November 2009, the Safe Use Initiative (FDA, 2009b) aims to minimize the risk of medications to improve their ratio of benefits to risks. If successful, many lives will be saved, injuries and suffering will be prevented, and health care costs will decrease.

The Safe Use Initiative is not a broad, amorphous concept. The idea is to tackle one drug at a time in order to make progress, working within structures and systems to achieve the goal of patient safety. Janet Woodcock and her team at the FDA Center for Drug Evaluation and Research (CDER) unveiled the approach in a concept paper, *FDA's Safe Use Initiative, Collaborating to Reduce Preventable Harm from Medications* (FDA, 2009a). The aim of the Safe Use Initiative is to identify specific preventable problems related to medication use and identify specific metrics that can measure progress; and to do it all by developing collaborations.

Partnerships will be important in the Safe Use Initiative. Clearly the clinical community is an important partner. Pharmacies have a very important role. Insurers should be engaged as they have the access to patients and know what is being prescribed. Pharmaceutical companies also have a vested interest in seeing their medicines used well. Patient groups and

consumer groups must also be engaged, as should those involved in the development and deployment of electronic medical records (EMRs).

It is the FDA's job to propel this initiative forward, highlighting the issue of safe medication use because there are lives to be saved. Medication injuries can occur in two scenarios. In the first scenario, questions are raised about the benefit/risk balance for a particular drug. In the second scenario, medication-related injuries include cases where the benefit does exceed the risk, but unnecessary injuries still occur.

In the benefit/risk balance scenario, the FDA has the authority to pull the drug from the market or to put new safety restrictions on the use of the drug. Restrictions are deemed necessary for making the benefits exceed the risks. The FDA can restrict sales to a single pharmacy, or make sure doctors obtain training, and make sure patients are informed. Restrictions have been put in place for several medications because the FDA believes those drugs cannot be safely marketed without these restrictions.

The second scenario for medication injuries where benefit does exceed the risk has been overlooked historically, but there are lives that can be saved by reducing the risks of these medicines. Examples of this category include children who ingest adult medicines or patients who experience difficulties with warfarin or insulin. This second category has been overlooked historically, but we know that there are lives that can be saved by reducing the risks with these medications. If systems can be put in place to make medication use safer in practice, then regulation is less necessary.

The FDA prefers not to have to employ burdensome restrictions on use to keep medications safe. The Safe Use Initiative is about identifying areas where there are unnecessary, preventable medication adverse events, developing a coalition, setting clear goals, and accomplishing real things so people are not injured. The agency wants to be able to measure progress. One way to do this is to monitor what happens in emergency rooms in the United States before an action is taken and how those measured events change after the action.

Since launching the Safe Use Initiative in late 2009, the FDA has been holding listening sessions to obtain input from the public and professional groups about the kinds of issues the initiative should address. The FDA also wants to know about existing efforts and ongoing activities. Having FDA become part of the process may be just the extra push that is needed to move the activities forward. For example, professional societies, pharmacies, insurers, and many others have guidelines for making decisions based on evidence. How can such existing knowledge and energy be channeled to reduce medication harms?

Karen Weiss, director of the Safe Use Initiative, is here to participate

in the conversation, Sharfstein said. Others from the FDA are here as well. There is also an open docket for comments on the Safe Use Initiative.[1]

DISCUSSION

Isham started the discussion, saying that the Safe Use Initiative is about identifying specific preventable problems related to medication use, developing cross-sectoral interventions to reduce harm, identifying specific metrics that can measure progress against actions, and doing all of this through collaborations. Sharfstein added that preventable injuries include such things as a patient being on a medicine that his or her doctor does not know about, or a doctor incorrectly prescribing a medicine, or children taking medicines they should not be taking. All of these scenarios are preventable.

Will Ross from the Washington University School of Medicine asked for greater involvement from developers of EMRs. For example, there needs to be a linkage of EMRs and appropriate dispensing and accurate recording of medications. Sharfstein responded that there is a great deal of evidence that EMRs can be used to avoid specific medical errors. Determining how the tools of EMR could help with educating physicians is difficult but important.

Cindy Brach of the Agency for Healthcare Research and Quality (AHRQ) said the IOM Roundtable on Health Literacy has engaged in a number of activities focused on communications between clinicians and patients around the problems of prescription medication labeling, areas in which health literacy plays a major role. How, she asked, does health literacy specifically fit in with the Safe Use Initiative? Sharfstein responded that it is unlikely anyone would defend the kind of confusing information patients currently receive, and the FDA is pursuing some regulatory initiatives with respect to labeling. The FDA is open to input from the roundtable. But once labels have appropriate information, what other tools are needed to make the information meaningful and useful to people? Are there electronic ways to make it useful? How can the usefulness of the information be measured? Are there targets to focus on to see if health literacy efforts can prevent adverse events? For example, if the FDA changes the information that is disseminated on warfarin and that change helps people really understand the need to come back to get their levels checked, then they avoid the bleeding risk and trips to the emergency room; that is the Safe Use Initiative.

Isham asked how the FDA will create the coalitions. How can interested people get involved and stay informed about what is happening

[1] See http://www.regulations.gov/search/Regs/home.html#documentDetail?R=0900006480a517a4.

with the initiative? Sharfstein expects that information about the different efforts is going to be available on the FDA Safe Use Initiative website.[2] However, the FDA does not envision convening the different collaborations that are needed. It does not want the Safe Use Initiative to be considered a regulatory initiative. The FDA would like to see so much interest and activity that it can tag along and ask how it can help. It is the FDA's job to highlight the need for the Safe Use Initiative, to put the initiative before the public, and to emphasize that lives can be saved through work in this area. But then the agency wants potential collaborators to come forward to identify how the FDA can help support the efforts of others in different ways. The FDA wants to know if there are particular issues it should address, what outcomes need to be tracked, and which partners should be involved.

For populations with mental illness in residential outpatient rehabilitation, their mental health care needs to be coordinated with their medical care, said Carolyn Cocotas, Quality Corporate Compliance at F.E.G.S. Health and Human Services System, a nonprofit health, education, and human services organization. It is a challenge. Clients are often on psychotropic drugs and dealing with treatments for chronic conditions such as heart disease or diabetes. She asked if the FDA has given thought to coordination around medical and behavioral health care. Sharfstein said the question raises two important issues. First, it is not sufficient to think about safe use related to specific diseases or medications alone without also thinking about different populations of patients. The issues may be different for different ethnic populations, or, as was mentioned, for those with both medical and behavioral health issues. Methods that work for one group might not be effective for another. When developing interventions, it is important to engage people who really understand the needs of different groups.

The other issue is the idea of combination medicines. Combinations medicines are a challenge for the FDA because these medicines must be regulated one at a time. This is an issue that the medical community can weigh in on because they have the necessary tools to educate physicians in this area.

The FDA wants to address both physical and mental health issues, which is challenging because the usual methods of communication may not be useful, Sharfstein noted. And the issues of drug combinations are also important. What kinds of systems should be in place for patients on multiple medicines to alert their doctors to problems, he asked. Rather than thinking about the whole challenging system, Sharfstein said he would, for example, choose to begin by identifying particular types of

[2] See http://www.fda.gov/Drugs/DrugSafety/ucm187806.htm.

drug combinations used by people who are severely mentally ill that cause trouble for them. A structure for addressing that particular problem could be identified and then, perhaps, be used to address other problems. Of major importance is determining who needs to come to the table to move such a project forward.

Ruth Parker, at the Emory University School of Medicine, said that the first IOM report on health literacy (IOM, 2004) stated there are a large number of people who can not do what is necessary to use medications safely and effectively for a variety of reasons. Another way of saying this is, it is hard to be a patient and it is easy to mess up. Now, however, it is being realized there is more to health literacy than a focus on the individual and his or her capabilities. This other focus is the demands and complexities of the system and what the system is asking consumers to do. How can the FDA help shine a light on the need for a health literate system for safe use?

Sharfstein agreed that critically important information must reach patients in a way that they can use, and that it needs to be made relevant for different groups of patients. He said this is an area in which the FDA could seek guidance through collaborations with others.

Sharon Barrett of the Association of Clinicians with the Underserved suggested that when talking about different population groups and different cultures, limited English proficiency is an important issue. Safety net providers are often the ones who see individuals with low literacy and limited English proficiency. They need to participate in efforts aimed at safe use. They are the ones who deal with populations who may have to use medications that could potentially harm them if they don't understand how to use them. Sharfstein suggested that members of the roundtable could provide input on who should be at the table so that no one is left behind. The FDA needs help with coalition building, since that is not its historical strength.

The U.S. Pharmacopeia Health Literacy Advisory Committee has developed recommendations for patient-centered labels for prescription drugs (USP, 2010), noted Cindy Brach. The recommendations are specific as to what a patient-centered label should look like and what it should and should not include. How, she asked, could the FDA use that standard? Currently the information on the label serves the pharmacy more than the patient. The labels are not regulated, and the FDA has said it is not in its bailiwick to regulate prescription labels as opposed to OTC labels. Sharfstein replied that the FDA has made recommendations to state pharmacy boards on labels, and if there are things that mislead patients they need to be fixed. What productive role could the FDA play? Even if the FDA role is not regulatory in this case, it should be able to bring people together

and catalyze action. Isham offered that a small group from the roundtable could meet with relevant FDA staff to explore this further.

Sue Johnson from the FDA added that the agency has regulatory authority with regard to properly labeling prescription medications. A strong coalition around this issue makes sense. Isham reminded participants that the roundtable does not make recommendations, but it can create conversations, stimulate interest, and influence people to take action.

Winston Wong, Kaiser Permanente, asked if there are timelines or milestones for building coalitions and stakeholder involvement in the Safe Use Initiative. What are some of the sentinel things to look for regarding progress? Sharfstein said he envisions a collection of discreet, focused efforts around different medication issues. Some are moving forward now. Sharfstein will determine success by counting how many of the initiatives are going on, whether they have clear goals and are making changes happen, and assessing whether the goals are being met. This is a big umbrella project, and progress will only occur one drug at a time and one set of adverse reactions at a time. Whether people are healthier at the end of the initiative will be the measure of success.

The FDA's Weiss added that because the agency's main role is regulatory oversight and enforcement, it is not in the exam room when a physician decides to prescribe a long-acting opioid when a less-potent medication would be better. And it is not at the pharmacy when the patient is looking at an acetaminophen-containing medication and is confused about whether he should take two every 4 hours or four every 2 hours. The FDA wants to work in partnership with the greater community of health-care providers, practitioners, and consumers who are in the room when the medications are being prescribed, paid for, and used. These groups need to identify the big safety issues. The FDA is asking for input at Let's Move sessions with various health care communities. It started with some professional societies, pharmacy groups, and nursing communities. More will come this fall, and the FDA will learn about things already going on that FDA can help move forward.

Specific things the FDA is working on through regulatory activities include misprescribing long-acting beta-agonists for children with asthma (Chowdhury and Pan, 2010). Safe prescribing of long-acting, sustained-release opioids is another area. There are risk evaluation and mitigation strategies (REMS) required of manufacturers to ensure that the benefits of a drug or biological product outweigh its risks being developed as an educational component for health-care providers. What else can the FDA do to compliment REMS, which only go so far? The FDA is working with the Acetaminophen Awareness Coalition to disseminate and communicate information about safe use of acetaminophen and acetaminophen-containing products. These are just some examples.

Lee M. Sanders, Associate Professor of Pediatrics at the University of Miami, runs a federally funded (Title V) program that coordinates care for more than 10,000 children with special health-care needs, all of whom have parents with low literacy or limited English proficiency. Can the FDA reduce confusion by serving as a warehouse for low literacy point-of-care tools for parents—such as an easy-to-use personal health record and easy-to-understand health information for special needs children, Sanders asked?

Sharfstein replied that under existing authority, the FDA is very interested in this. The agency has a pilot program on sending the MedWatch bulletin[3] to mobile devices for clinicians. There is an effort to make sure the information the FDA has is available for use by clinicians and others. One approach would be to make sure the National Library of Medicine has the information. For patients, the FDA would like guidance from the group as to what the FDA's role could be. There are many ways to interact with patients other than at the point of care. For example, cell phones might be a potential tool for interaction. It would be very helpful for the roundtable to identify partners and convene discussions about where and how patients get into trouble with medications.

Margaret Loveland, a pulmonologist now working for Merck & Company, stated that clinicians are often reluctant to report adverse events because they believe such events indicate they did something wrong. Also, sometimes physicians stop prescribing a drug or patients stop taking a drug, with disastrous consequences, because of publicity about adverse events. Loveland said that the FDA and health literacy advocates need to make sure clinicians and the public understand that there are many causes of preventable adverse events and that reducing such events requires the collaboration of many types of people. Sharfstein responded that it is important to make clear that one of the goals in reducing the risk is not reducing the benefit at the same time. The FDA does not want to cut out appropriate use of medications; rather it is attempting to decrease inappropriate use.

Isham said that it might be useful for the roundtable members to identify one or two issues and the kinds of individuals who could be brought together to stimulate discussion of those issues in a way that includes health literacy as one aspect. It could be that bringing individuals together for discussion might lead to those individuals deciding to form a coalition to pursue the issue further. Sharfstein responded that the FDA does wish to facilitate that kind of activity.

Arthur Culbert from Health Literacy Missouri described a coalition of states that is organizing around the issue of health literacy. The coalition

[3] See http://www.fda.gov/Safety/MedWatch/.

will include as many as 20 states and provides an excellent opportunity for partnering with the FDA at the state level. Sharfstein encouraged contact with Weiss to discuss this further.

Bernard Dreyer from the New York University School of Medicine said that he is concerned that, other than the issue of vaccines in the United States, children are viewed as basically healthy with very few problems. We know in pediatrics that medication errors are generally the result of parent confusion about how to administer over-the-counter and prescription medications. Most of these errors do not lead to mortality, even though they do result in adverse events. When you speak of the Safe Use Initiative, he said to Sharfstein, you mention saving lives, and if that is the criteria by which the FDA chooses issues of importance, then medication errors in children will not rise to the top as a key issue. Yet those children do end up in emergency rooms and require medical treatment.

Sharfstein responded that while he emphasized saving lives in his presentation, other outcomes are extremely important. In fact, there is a tremendous amount of effort being expended on children's use of OTC medicines. The FDA very much supports the efforts of the American Academy of Pediatrics (AAP) and encourages AAP to bring together individuals to address the issue of safe use of medicines in children.

3

Over-the-Counter Products

CURRENT STATUS OF OVER-THE-COUNTER LABELS

H. Shonna Yin, M.D., M.S.
New York University School of Medicine

Inconsistency and variability in medication labeling is a source of confusion for patients and consumers, said Shonna Yin. Confusion increases risk for error. This is a significant health literacy and patient safety issue. In a first attempt to systematically look at the variability in over-the-counter (OTC) products, the study described here focuses on pediatric medications because of the prevalence of OTC medications used in children and the unique challenges of dosing liquid medications. The expectation is that the findings would likely be reflective of a wider sample of medications. Others involved in this study include Bernard P. Dreyer, Ruth M. Parker, Lee M. Sanders, and Michael S. Wolf.

There are several national initiatives focused on labeling. About the same time the Food and Drug Administration (FDA) launched its Safe Use Initiative, it also released a guidance for industry focused on dosage delivery devices for over-the-counter liquid drug products (FDA, 2009c). The Consumer Healthcare Products Association (CHPA) also released a guidance document, in cooperation with the Centers for Disease Control

and Prevention's (CDC's) PROTECT Initiative.[1] Each contains recommendations, but neither discusses existing levels and types of inconsistencies. The study reported in this presentation aims to quantitatively clarify the issues.

The study sampled 200 top-selling OTC products that included oral liquid medications, analgesic, cough/cold, allergy, or gastrointestinal (GI) products with dosing directions for children under 12 years of age. More than half (59 percent) of the products were cough/cold remedies, followed by GI products (22 percent), analgesics (11 percent), and allergy medicines (8 percent).

The study found a very high rate of inconsistency and variability in labels and devices for pediatric OTC liquid medications. Problems included

- No dosage delivery device included
- Inconsistency between label and dosage delivery device
- Superfluous markings on the device
- Missing necessary markings on the device
- Markings for units of measure that do not match what is on the label
- Format of numeric text (decimals/fractions) does not match label text
- Inconsistency across products
- Nonstandard abbreviation for milliliter (not mL)
- Nonstandard abbreviation for teaspoon (not tsp)
- Units of measurement other than milliliter, teaspoon, and tablespoon
- Inconsistent use of numeric text (decimals/fractions)
- Lack of consumer guidance on appropriate use

One out of four products did not include a device for administering the medication. Almost all (99 percent) products had one or more inconsistencies between the label and dosage delivery device. For example, 81 percent had superfluous markings on the device (Table 3-1), such as ounce or milliliter measurements when the dosing called for measurements in teaspoons. Two thirds (67 percent) used a nonstandard abbreviation for milliliter. The FDA recommended standard and the U.S. Pharmacopeia (USP) standard is lowercase *m* and uppercase *L* for *mL*.

[1] The CHPA Board of Directors adopted a voluntary program that recommends manufacturers take specific steps in labeling, packaging, and promotion of over-the-counter oral pediatric cough and cold medicines (http://www.chpa-info.org/scienceregulatory/Voluntary_Codes.aspx#PediatricCoughCold).

TABLE 3-1 Inconsistencies Between Label and Dosage Delivery Device

Type of Inconsistency	Percent
Superfluous markings on device	81
Missing necessary markings on device	22
Markings for unit(s) of measurement do not match	89
Format of numeric text (decimals/fractions) does not match	53

SOURCE: Adapted from Yin, 2010.

Two-thirds (64 percent) did not use small font size for numerals (e.g., used *1/2* instead of $^1/_2$ which may increase the risk of administering 1 or 2 tsp, for example).

Regarding consumer guidance, most products had no definitions of abbreviations, and the majority had no strategy to ensure the delivery device was used with the drug product. Two-thirds had no statement to only use the device with the specific product. Almost all (97 percent) had no mechanism to secure the device to the bottle.

Based on these enormously high rates of inconsistency and variability in labels and devices for pediatric OTC liquid medications, the likelihood for confusion and mis-dosing is very high. Given the facts that one in four parents has low health literacy and that these medications are often dosed under stressful conditions (i.e., a child's ill health), the likelihood for confusion and error is compounded. Therefore, efforts by the FDA and others to standardize labels and dosing devices for pediatric OTC medications are greatly needed, Yin concluded.

HEALTH LITERACY TASKS FOR OVER-THE-COUNTER DRUG SAFETY

Michael Wolf, Ph.D., M.P.H.
Feinberg School of Medicine
Northwestern University

Health literacy is about helping patients and families understand their health and health care, translate knowledge to recommendations, and apply problem-solving skills to new situations, especially in the context of OTC medications, since the consumer is making the decision to use a product, to take it home, and determine how to use it. A particular challenge occurs when the instructions for a specific medication change, because the consumer is accustomed to using the product in a particular way and probably does not check the instructions.

As presented in *Standardizing Medication Labels* (IOM, 2008) there is a great deal of evidence of patient misunderstanding in prescription drug labeling. It was hoped that OTC labeling presented fewer challenges to consumers, but there have been limited studies to rigorously evaluate the OTC drug fact labeling. The research presented here involves investigating the prevalence and root causes of misunderstandings common to OTC products.

A perfect example of confusing labeling is written in a correspondence published in the *New England Journal of Medicine* (Parker et al., 2009). A 6-year-old girl was diagnosed with H1N1 influenza and prescribed Tamiflu oral suspension. Her mother is a master's degree health educator and her father is an internist. Instructions called for ¾ teaspoon by mouth twice a day for 5 days. The syringe that was included in the box had 30, 45, and 60 milligram hash marks. It took the highly educated parents an hour to figure out how to appropriately dose their child because of the inconsistencies between the prescription and the dosage device. The CDC and the FDA responded within a week (Budnitz et al., 2009) and the problem was resolved; a great example of partnership between academia and industry.

This example illustrates how health literacy is important for helping patients and families understand their health and health care, translate knowledge to recommended actions, apply problem-solving skills to new situations, foster ongoing health learning opportunities, and instill health promotion attitudes.

Individuals must make all kinds of decisions in the use of OTCs (Box 3-1). For example, how do people approach the pharmacy aisle dedicated to analgesics and pain relievers? How do they differentiate between the array of medicines—some are combination products, some

BOX 3-1
Health Literacy Tasks in OTC Drug Use

- Match symptom to treatment without learned intermediary (self selection)
  - determine personal appropriateness (pt hx)
- Know active ingredient
- Proper dosing (of a PRN)
  - how many pills to take at a time?
  - how long to wait before next dose?
  - when to stop (maximum daily dose)

SOURCE: Adapted from Wolf, 2010.

have single-acting ingredients. Twenty-five billion doses of acetaminophen were sold in 2008 (Woodcock, 2009). The drug surpasses viral hepatitis as the leading cause of acute liver failure in the United States. Half to two-thirds of overdoses leading to acute liver failure are unintentional (Larson et al., 2005). How do we keep patients from unintentionally overdosing on acetaminophen?

When a doctor writes a prescription, he or she is legally responsible for communicating information on how to use the medication safely. With OTCs that safeguard does not exist. The consumer needs to recognize the active ingredient, especially with acetaminophen, to avoid unintentional overdose. Many prescription and OTC medications contain acetaminophen. They also need proper dosing information such as how many pills to take at a time, how long to wait before they take the next dose, and the maximum daily dose.

Because serious health risks have been documented with use of many OTCs, particularly analgesics, Wolf said, he and colleagues are undertaking four studies: a prevalence study to determine the rate of consumer misunderstanding of nonprescription analgesic medications, a follow-up study to determine why people misunderstand current labeling to inform better product language development, icon/message development to help consumers understand which products contain acetaminophen, and finally, a clinical trial testing labeling changes and whether they improve understanding.

Study 1 began in June 2009. The goal is to recruit 500 consumers in Chicago and Atlanta, recruiting 125 patients from two academic settings and two community-based settings. Each patient's functional understanding of OTC instructions and their knowledge of active ingredients are evaluated in interviews. Of the 300 patients recruited to date, the mean age is around 50 years of age, 52 percent are non-Hispanic white, 35 percent are African American, 56 percent have a college degree or higher, and 64 percent are female. Of those 300, about 1 in 5 patients have limited literacy skills.

From preliminary findings, based on the 300 individuals recruited so far, respondents do relatively well determining pills per doses, with 81 to 96 percent getting the pills per dose correct; 61 to 86 percent got the dosing interval correct. The most significant issue was maximum daily dose: just 42 to 65 percent got that right.

In the second study, participants were shown a list of several brand name products that contain acetaminophen. Fifty-nine percent thought it was okay to take Alka-Seltzer, which contains multiple ingredients, and Excedrin, which has acetaminophen, aspirin, and caffeine. Nearly 60 percent thought they could take Tylenol and the generic version of Tylenol, or acetaminophen. Two-thirds thought they could take the two Tylenol

products together, since one was "post meridiem" and one was not. The majority of patients did not understand that these are the exact same active ingredients, and there could be a risk of overdose. Patients with lower literacy, older age, and African American race were more likely to misunderstand the medication.

The task was repeated with combination products and ibuprofen, with similar, slightly higher prevalence; almost 70 percent of patients thought they could take two products with the same ingredient. The evidence suggests that the majority of consumers do not know the active ingredients in OTC products nor do they understand maximum daily dose. Patients do not know what is in these common products and, because they have used them for years, they do not bother to look at the packaging because they believe they know how to take it. It is important, Wolf said, to instill in patients the understanding that there are safety concerns with OTC products just as there are with prescription products.

A new effort is under way in conjunction with McNeil Consumer Healthcare to develop and test new Drug Facts instructions and new icons for acetaminophen that could be used on both prescription and nonprescription packaging (see page 28). Clinical trials will take place at two locations (four sites) with a total of 1,200 participants.

DISCUSSION

Winston Wong of Kaiser Permanente asked whether either Yin's or Wolf's research included examination of directions written in Spanish to determine the extent to which similar problems exist. Wolf responded that Stacey Cooper Bailey of Northwestern University has been very interested in the language access issue. Conducting a study on the Spanish translation of OTC medication instructions would be very valuable but, to date, it has not been possible to find OTC medications that have instructions in Spanish. Several participants brought up the challenges of finding labeling in Spanish. Sanders called the lack of translated labeling a "glaring issue," particularly for the 1 in 10 U.S. adults with limited English proficiency. Based on a recent study conducted by Lokker and colleagues, Sanders also noted the confusion parents of young children commonly face both choosing OTC products by age and indication and dosing OTC products by age and weight.

Lois Wessell, a family nurse practitioner with the Association of Clinicians for the Underserved, asked about instruction on pediatric medications based on age versus weight. In the populations she sees, mainly Latino immigrants, the obesity issue makes dosing difficult. Her Latino patients ask if the dosing is based on age or based on weight, plus they are accustomed to weighing babies in kilograms and have trouble convert-

ing into pounds to find the correct dose. She has also seen labels listing a weight range without clarity on whether it is pounds or kilograms. Yin agreed that the issue of weight versus age-based dosing is very important for pediatric populations. As a pediatrician, she recommends dosing by weight. She noted, however, that many parents don't know their child's weight.

William Ross, expressing his surprise at the amount of misinformation reported by Yin and Wolf, asked if switching the United States to the metric system would ameliorate some of the problems. Isham replied that the roundtable could convene a discussion around that issue.

Laura Schone, University of Rochester Medical Center, described a similar study she did with colleagues in adolescents and young adults. They found that 84 percent of adolescents, based on a combination of dosing tasks, are at risk for unintended overdose of acetaminophen. The risk for those with limited health literacy rose to 94 percent. Parents need to understand dosing, she suggested, since they teach the children—or do not teach them—how to take medications. Perhaps children could be taught in school, as part of health education, how to become safe consumers of health care, with a focus on OTC medicines.

Isham asked the group what activities could be developed around the FDA Safe Use Initiative to address some of the issues that have been raised? What kind of coalition could be put together? Dale Slavin, with the FDA's Safe Use Initiative, noted that the FDA has a program called Medicines in My Home[2] that is a tool for teachers to use in health class to teach students how to read labels and understand medications.

Isham saw a clear need for tools in the home to help people manage their health care: charts, specific advice, e-mail addresses of caregivers. He shared his family's personal experience with complex medication regimens to illustrate the need—even among people with a medical background.

Cindy Brach of the Agency for Healthcare Research and Quality (AHRQ) said that agency's pharmacy health literacy center offers several tools, including the Health Literacy Universal Precautions Toolkit,[3] released in April 2010. The toolkit offers primary care providers and their practices a way to assess their services for health literacy considerations, raise awareness of the entire staff, and work on specific areas.

[2] "Medicines in My Home (MIMH) is a multimedia educational program to teach consumers from adolescence through adulthood how to choose over-the-counter medicines and use them safely. 'Rooms' of the program contain presentations, print materials, and resources that teachers, students, and adults can use online or download." See http://www.fda.gov/Drugs/ResourcesForYou/Consumers/BuyingUsingMedicineSafely/UnderstandingOver-the-CounterMedicines/ucm092139.htm.

[3] See http://www.ahrq.gov/qual/literacy/.

Margaret Loveland, of Global Medical Affairs at Merck & Co., agreed that people are often confused by combination medications, especially in the cough and cold category. Very often, she said, parents will give a medicine for cough and cold, and then give Tylenol for the fever, and they are overdosing because both medicines have acetaminophen. Some patients take Excedrin Migraine for their migraine and plain Excedrin for their arthritis. People don't realize they are taking the same medication. Problems occur for older adults who care for their grandchildren. With their aging eyesight, reading the indications on the measurement cups is very difficult, and the medicine inside the cup often obliterates the lines.

Yin noted that she intends to look at the devices from that perspective. Some have etched markings, and others have printed markings. Which are easier to read?

Before considering who to invite to the table, Ruth Parker suggested stepping back and asking for clarity on what the task is. Are we clear on the evidence of what it takes to safely use a product—be it a medication or a device? She and her colleagues, Scott Ratzan and Nicole Lurie, laid out a blueprint in *Health Affairs* (Parker et al., 2003).

Isham ended the session by asking who helps the patient when there is a minor side effect when the patient is taking the medicine? How is the side effect assessed against the active ingredient? Who do they call for help? The surgeon? The internist? A nurse? The physical therapist? Mother?

4

Initiatives to Advance Patient-Centered Drug Safety

U.S. PHARMACOPEIA HEALTH LITERACY AND PRESCRIPTION CONTAINER LABELING ADVISORY PANEL

Joanne Schwartzberg, M.D.
American Medical Association

The U.S. Pharmacopeia's (USP's) Health Literacy and Prescription Container Labeling Advisory Panel was launched after the Institute of Medicine's (IOM's) Report on Standardizing Medication Labels (IOM, 2008). Schwartzberg co-chairs the panel with Gerald McEvoy, American Society of Health-Systems Pharmacists. The panel was charged to (1) determine the optimal prescription label content and format to promote safe medication use by critically reviewing factors that promote or distract from patient understanding of prescription medication instructions, and (2) create universal prescription label standards for format and appearance, content and language. The panel included a wide range of stakeholders: academic researchers, clinicians, health literacy experts, pharmacists, and government health agency representatives.

Medication misuse results in more than a million adverse drug events each year (IOM, 2008). The label is the patient's best, and often only, source of information. It is the safety net to prevent medication errors. While written information and oral consultations may sometimes be available, the Rx container label must be able to fulfill the professional obligations of physicians and pharmacists to give the patient all the information needed to understand how to safely use the medication.

The panel made its recommendations in November 2009 (USP, 2010). These recommendations are presented in Box 4-1.

The recommendations have been adopted by the Safe Medication Use Committee. USP is preparing a General Chapter for the USP-*National Formulary*. The patient-centered prescription label standards are for the format, appearance, content, and language of prescription medication containers to promote patient understanding. These recommendations are evidence based and address optimal understanding, adherence, and safe and effective use of medications by patients, Schwartzberg said.

BOX 4-1
Recommendations of the U.S. Pharmacopeia Health Literacy and Prescription Container Labeling Advisory Panel

Recommendations

Organize the Prescription Label in a Patient-Centered Manner

Patient-directed information must be organized in a way that best reflects how most patients seek out and understand medication instructions. Prescription container labeling should feature only the most critical patient information needed for safe and effective understanding and use.

Patient-directed instructional content will be at the top of the label, and other less critical content (e.g., pharmacy name and phone number, prescriber name, fill date, refill information, expiration date, prescription number, drug quantity, product description, and evidence-based auxiliary information) should not supersede critical patient information. Such less critical information can be placed, e.g., at the bottom of the label or another less prominent location. Drug name and directions for use (e.g., specific dosage/usage/administration instructions) should be displayed with greatest prominence.

Simplify Language

To improve patient understanding and safe and effective prescription medication use, language on the label should be clear, simplified, concise, and standardized. Only common terms and sentences should be used. Use of unfamiliar words (including Latin terms; see below) and unclear medical jargon should be avoided.

Whenever available and appropriate to the patient context, standardized patient-centered translations of common prescribing directions to patients (SIG) should be used. Ambiguous directions such as “take as directed” should be avoided unless clear and unambiguous supplemental instructions and counseling are provided (e.g., directions for use that will not fit on the prescription container label). A clear statement referring the patient to such supplemental materials should be stated on the container label.

BOX 4-1 Continued

Readability formulas and software are not recommended for short excerpts of text like that on prescription labels. The principles established by Doak, Doak, and Root for maintaining simple language can facilitate the simplification process. Consumer feedback should also be sought.

Use Explicit Text to Describe Dosage/Interval Instructions

Dosage/usage/administration instructions must clearly separate dose from interval and must provide the explicit frequency of drug administration (e.g., "Take 4 tablets each day. Take 2 tablets in the morning and 2 tablets in the evening" is better than "Take two tablets by mouth twice daily"). Use numeric rather than alphabetic characters for numbers.

Include Purpose for Use

Confidentiality and FDA approval for intended use (e.g., labeled vs. off-label use) may limit inclusion of indications on drug product labels. Current evidence supports inclusion of purpose-for-use language in clear, simple terms. Therefore, the prescriber's intended purpose of use/indication should be included on the prescription medication label whenever possible and should be stated in clear, simple, patient-centered language. When such use conflicts with unit-of-use commercial packaging information, the patient should receive appropriate counseling to clarify the intended purpose of the medication vs. what is stated in commercial labeling.

Improve Readability

Critical information for patients must appear on the prescription label in an uncondensed, simple, familiar, minimum 12-point, sans serif font (e.g., Arial) that is in sentence case (i.e., punctuated like a normal sentence in English: initial capital followed by lowercase letters except for proper nouns, acronyms, etc.). Field size and font size may be increased in the best interest of patient care. Critical information should never be truncated.

The following several general rules can improve readability:

- Optimize typography
- Optimize white space (use adequate space between lines of text; use wide letter spacing; and use white space to distinguish sections on the label such as directions for use vs. pharmacy information)
- Use numeric rather than alpha representation (e.g., for dose information)
- Use horizontal text only
- If possible, minimize need to turn the container in order to read lines of text

Highlighting, bolding, and other typographical cues should preserve readability (e.g., contrast, light color for highlighting), and should emphasize patient-centric information or information that facilitates patient adherence.

continued

BOX 4-1 Continued

Provide Labeling in Patient's Preferred Language

Whenever possible, prescription container labeling should be provided in a patient's preferred language. Translations of prescription medication labels should be produced using a high-quality translation process. An example of a high-quality translation process includes the following four elements:

- Initial translation by a trained and competent translator (e.g., a translator with documented proficiency in both English and the other language and knowledge in both languages of terminology and concepts relevant to prescription medication)
- Review of the translation by another trained and competent translator and reconciliation of differences
- Review of the translation by a pharmacist or other medical professional who is a native speaker of the target language and reconciliation of differences
- Testing of comprehension with target audiences

If a high-quality translation process cannot be provided, labels should be printed in English.

Include Supplemental Information

Auxiliary information on the prescription container should be minimized and should be limited to evidence-based critical information regarding safe. The information should be presented in a standardized manner and should be necessary for patient understanding. This is necessary because of the extensive variability in the content and application of supplemental information, the lack of scientific evidence for these labels, and potential ambiguity and failure to address specific patient needs.

Auxiliary information should be critical to the medicine's safe and appropriate use and should be evidence-based, should clarify instructions for use, and should enhance understanding. Use of icons should be limited to those for which evidence demonstrates enhancement of interpretation and clarity about use. The inclusion of auxiliary information on the patient prescription medication label (e.g., warnings and critical administration alerts) should be minimized and limited to critical information that is evidence based, standardized, and complementary to the patient prescription medication label.

Standardize Directions to Patients

In recognition of the nation's move toward e-prescribing, the HL AP recommends that standards should be developed for prescribing directions to patients (SIGs). This would lead to consistency of language and use across all health care professionals and systems. An important element is the elimination of Latin abbreviations (BID, QID, PRN, etc.), which are often misunderstood and susceptible to variation in translation.

SOURCE: USP, 2010.

NATIONAL COUNCIL ON PATIENT INFORMATION AND EDUCATION

William Ray Bullman, M.A.M.
National Council on Patient Information and Education

The National Council on Patient Information and Education (NCPIE) is a patient safety coalition formed in 1982 to stimulate and improve communication of information on safe and appropriate medicine use to consumers and health care professionals. The NCPIE is a membership organization including a wide range of stakeholder groups; the FDA and AHRQ have nonvoting seats on the board of directors. It is a convener, a catalyst, and a clearinghouse of ideas and information. As a convener, the NCPIE is positioned to serve as a home for collaborations on some of the Safe Use Initiative issues.

NCPIE initiatives include the Get the Answers/I Give the Answers Campaign, which is designed to equip consumers with questions to ask in order to find out what they need to know about prescription medicines. NCPIE also sponsors October as Talk About Prescriptions month. Begun in 1986, this effort is aimed at keeping safe use of medications on the public health agenda. The organization also develops reference reports and stakeholder recommendations and conducts web outreach. The outreach websites are:

- talkaboutrx.org lists current activities
- bemedwise.org has an OTC focus
- mustforseniors.org for older adults and caregivers
- learnaboutrxsafety.org, a tool kit for families

NCPIE campaigns focus on the three Rs: risk, respect, and responsibility. First, it should be recognized that all medicines have some degree of risk as well as benefit. Second, it is important to respect the value of medicines properly taken, understanding that prescription and OTC medicines are serious and must be taken with care. Third, patients have a responsibility for learning how to take each medicine safely. Being responsible also means following the rule: when in doubt, ask. The NCPIE recommends asking questions about instructions for use, precautions, side effects, warnings, and the availability of written information.

NCPIE also encourages patients to share information about all medications taken (prescription, OTC, and dietary supplements) with doctors, pharmacists, nurses, and other health care professionals; keep a current list of all medicines taken; show the list to the health care professional at every visit; and read carefully any written information that comes with the medicine, being sure to save it for future reference.

Finally, the NCPIE has built expertise and has pilot programs related to adherence improvement. In 2007, it released a national action plan of 10 recommendations to enhance adherence (NCPIE, 2007). The NCPIE will begin tracking progress and gaps and opportunities related to the action plan recommendations. The NCPIE has several collaborations that are ongoing:

- National Coordinating Council on Medication Error Reporting and Prevention
- National Consumers League (et al.) to develop national adherence awareness campaign
- Partnership for a Safer Maryland—current focus on poison prevention (pharmaceuticals focus)
- Maryland Acetaminophen Coalition
- Acetaminophen Awareness Coalition
- Be MedWise Tennessee & Be MedWise Arkansas—statewide outreach and educational programs using licensed NCPIE resources

Mr. Bullman said that although several projects and campaigns exist, there are still areas that need improvement:

- The current state of written consumer medicine information (consumer medicine information [CMI], med guides, risk evaluation and mitigation strategies [REMS])
- Provision of useful or actionable written information to special needs patients (e.g., blind and visually impaired)
- Balanced patient medication counseling when high-risk drugs are prescribed
- Language–appropriate medicine counseling reinforced with useful written information

CDC INITIATIVE

Daniel Budnitz, M.D., M.P.H.
Centers for Disease Control and Prevention

Dr. Budnitz offered three themes for discussing the intersection of health literacy and safe use. The first is an injury-based approach to safe use of medications. Second involves population-based harm data that the Centers for Disease Control and Prevention (CDC) collects and which may be useful for priority setting. The third theme involves a patient-centered prevention partnership called the Protect Initiative.

The injury-based approach identifies the areas with the highest num-

ber of adverse drug events, thereby identifying the highest potential for overall harm reduction. This sounds logical, but it is not how patient safety has been approached. The approach that has been followed is one of error reduction. However, addressing preventable events must be considered as well. The real focus, therefore, is the intersection of errors and harm.

The focus of today's meeting is on errors related to health literacy and how those might injure patients. The CDC policy was most influenced by the Government Accounting Office (GAO) report *Adverse Drug Events: The Magnitude of Health Risk is Uncertain Because of Limited Incidence Data* (GAO, 2000). The GAO determined that data available on emergency department (ED) visits and hospital admissions are insufficient for estimating the frequency of adverse drug events. In response, CDC created the National Electronic Injury Surveillance System-Cooperative Adverse Drug Event Surveillance Project (NEISS-CADES). This system documented at least 117,000 hospitalizations and more than 700,000 ED visits due to adverse drug events in 2004 and 2005 (Budnitz et al., 2006). More recent estimates are 130,000 hospitalizations and more than a million ED visits per year.

Adverse drug events are caused by allergic reactions, nonallergic side effects, and unintentional overdoses—about one-third each. Of the presumably more severe effects that lead to hospitalizations, more than 50 percent are due to overdoses. About 60 percent of the overdoses are due to drugs that have narrow therapeutic indexes, such as warfarin and antidiabetic agents.

More adverse events occur in older populations (Figure 4-1). In the older adult population, 1 in 150 older adults per year will visit an ED with an adverse drug event. Among this population, the severity of adverse events is greater, resulting in seven times the hospitalization rate among adults ages 67 and older than those younger. More than half of these are unintentional overdoses, which are likely preventable. Three drugs account for one-third of these ED visits among the older population: insulin, warfarin, and digoxin.

The third theme in this discussion is patient-centered prevention partnerships. The data clearly show two peaks in the incidence of ED visits for adverse drug events. The first is in children ages 0 to 5 (Figure 4-1). Unintentional overdoses accounted for 58 percent of their adverse drug events (Figure 4-2). Children at age 2 were at greatest risk for overdose (Schillie et al., 2009). About 80 percent of overdoses were due to unsupervised ingestion by children (Figure 4-3). The rest were either misuse by older children or dosing errors by parents.

CDC brought together a coalition of federal agencies, OTC manufacturers, professional organizations, and safety and health literacy experts

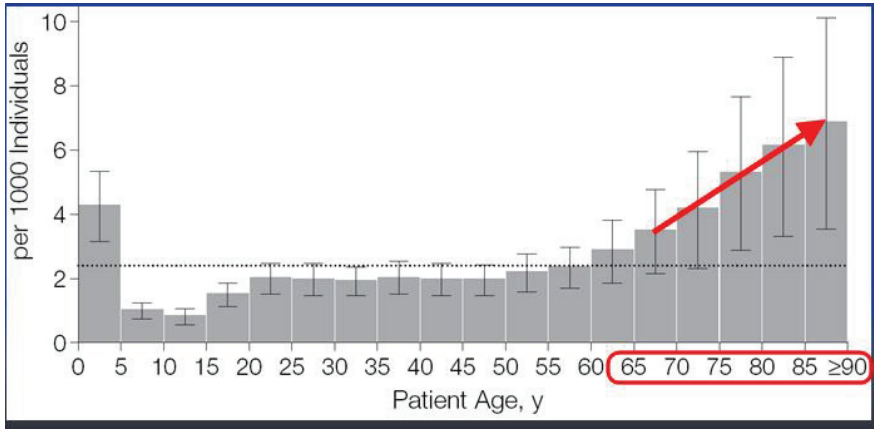

FIGURE 4-1 Advertise drug events treated in emergency departments by patient age, United States, 2004-2005.
SOURCE: Budnitz et al., 2006. National surveillance of emergency department visits for outpatient adverse drug events. JAMA 296:1858-1866. Page 1860 "Estimated Annual Incidence of Adverse Drug Events Treated in US Emergency Departments." Copyright © 2006 American Medical Association. All rights reserved.

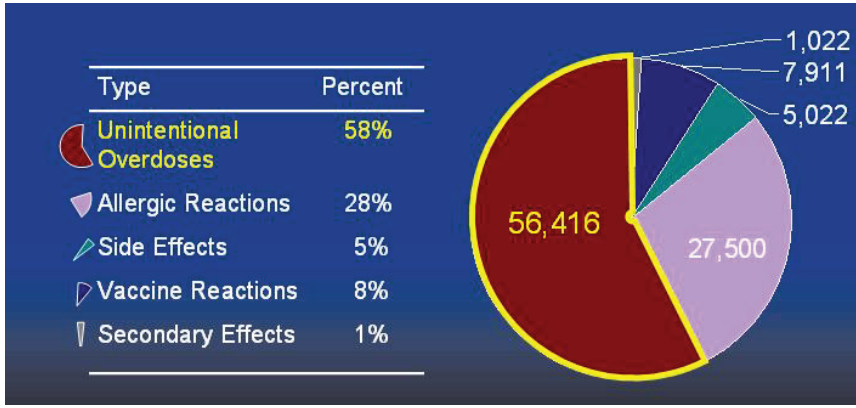

FIGURE 4-2 Unintentional overdoses cause most emergency visits in children less than 5 years old.
SOURCE: Cohen et al., 2008.

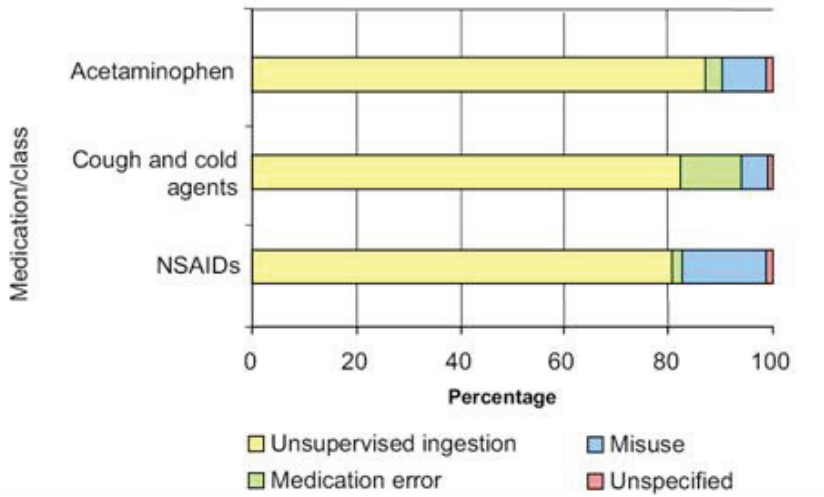

FIGURE 4-3 Underlying causes of emergency visits for child overdoses, 2004-2005.
SOURCE: Reprinted from American Journal of Preventive Medicine, 37(3), Schillie, S.F. et al., Medication Overdoses Leading to Emergency Department Visits Among Children, Pages 181-187, Copyright © 2009, with permission from Elsevier.

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to identify and discuss the most important issues and to determine feasibility of actions. They call it the PROTECT (Preventing Overdoses & Treatment Errors in Children Taskforce) Partnership. PROTECT focuses on two areas: (1) innovative safety packaging and (2) standardization of the volume metrics for liquid medications. Four workgroups were formed to facilitate packaging innovations, standardize dosing abbreviations, identify key messages for a national education campaign, and generate more data for key questions.

Budnitz suggested that identifying harms is key, as is focusing on the most common harm, such as older adults and anticoagulation agents. Dosing instructions need to be improved using health literacy concepts. To make a point about capitalizing on opportunities that arise, he pointed to the Tamiflu suspension problem that Wolf discussed (Budnitz et al., 2009; Parker et al., 2009). Researchers noted the problem with the dosing instructions and dosing dispenser. And the FDA and the CDC responded. But rather than pulling the product, because the problem occurred within the context of the H1N1 pandemic, the product information and dosing was corrected in a feasible manner. Budnitz ended his presentation

by calling for efforts to maximize benefit through adherence. Beyond preventing adverse outcomes, he said, it is important to watch also for literacy errors that prevent efficacious outcomes.

JOHNSON & JOHNSON INITIATIVES: MCNEIL CONSUMER HEALTHCARE

Edwin Kuffner, M.D.
McNeil Consumer Healthcare

McNeil is the maker of Tylenol and the leading manufacturer of over-the-counter medicines. Important gaps exist in acetaminophen awareness. On prescription medicines, acetaminophen is often abbreviated as *APAP*, which is an unfamiliar term to consumers. It is time, Kuffner said, to remove *APAP* from prescription pharmacy labels and spell out acetaminophen, plus add an acetaminophen ingredient icon to all OTC and prescription acetaminophen-containing medicines. Acetaminophen, taken in recommended doses, is both safe and effective. But gaps in patient and consumer awareness in OTC and prescription medicines contribute to medication errors, lead to overdose, and in some cases to acute liver failure. Patients may not recognize that acetaminophen is the active ingredient in their medicines, or that it is common in many OTC and prescription medicines (Figure 4-4) (Chen et al., 2002; Fosnocht et al., 2008;

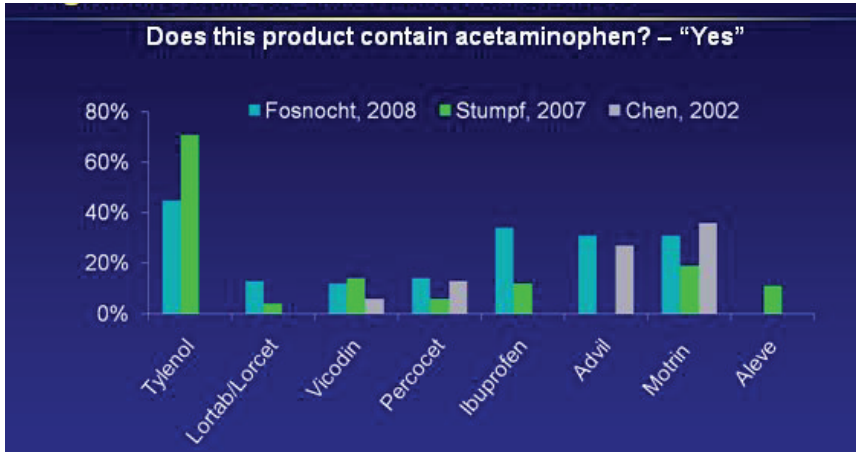

FIGURE 4-4 Variable awareness of analgesis/antipyretic ingredients in OTC and Rx products.
SOURCE: Chen et al., 2002; Fosnocht et al., 2008; Stumpf et al., 2007.

Stumpf et al., 2007). Most patients are not able to identify acetaminophen in prescription medicines labeled as *APAP* (Chen et al., 2002).

McNeil and the Consumer Healthcare Products Association (CHPA) along with expert advisors developed an acetaminophen ingredient icon to help patients and consumers recognize acetaminophen in multiple products and help minimize simultaneous use. They developed several graphical and design approaches for the icon and qualitatively tested them with patients in the health care setting and with consumers. A subset of patients had low health literacy. The icon evolved through each round of testing. Quantitative testing is planned for the third quarter of 2010. Testing indicated that *APAP* as part of the icon was confusing. An icon with text was more effective than an icon alone.

Kuffner believes that acetaminophen should be part of the FDA's Safe Use Initiative, via partnership and collaboration with relevant stakeholders, to better manage medication risks and reduce preventable harm. Use of the icon will require a multistakeholder, comprehensive, and sustained education campaign. Take *APAP* off and put the icon on all medicines—prescription and OTC—that contain acetaminophen, Kuffner said.

DISCUSSION

When roundtable member Cindy Brach asked if acetaminophen should be singled out, or if there are other drugs prone to the same kind of adverse event that require the same attention, Kuffner replied that, based on the data he has seen, acetaminophen is one of the medications that should go into the Safe Use Initiative. Brach suggested that the AHRQ Centers on Education and Research in Therapeutics should be involved in any collaboration that addresses this issue.

Isham pointed out that the panel identified the following implementation steps: facilitating packaging innovations for safety, standardizing dose abbreviations for volume metric measurements, and identifying key messages for the educational campaign and data for key questions. He then asked, as automated record systems become more common within health systems for patient use in the home, are there tools that can be provided in the home so that patients can assess multiple medications? These might offer more direct opportunities for education than a national education campaign. Can we influence health care systems to develop patient-centered systems to deal with some of this complexity?

Wolf offered that his group is working through AHRQ to use electronic health records to generate plain language automatically for the top 500 prescription medications. Single pages of information on the drug are automatically generated when any new prescription is ordered. Because they are funded through AHRQ, these are publicly available. There is a

great deal of work going on to leverage electronic health record platforms to generate patient-friendly, tailored materials on medication use. The efforts attempt to include the most common omissions, that is, OTC products that patients are taking without the physician's knowledge.

Budnitz said that he would start by focusing on common preventable harms that patients have a central role in managing. Oral anticoagulation and insulin for diabetics, for example, are drugs that cause the most acute harm and seem ripe for interventions that involve the patient and his or her literacy and how they take and use these medications.

Gerald McEvoy, American Society of Health-System Pharmacists, noted that the United States is the only country in the world that uses the term *acetaminophen*. All other countries, including the Latin American nations, use the term *paracetamol*. Could that distinction be leading to patient confusion as well? Spanish-speaking consumers know the term *paracetamol*, but may be unfamiliar with *acetaminophen*.

Because very few drug benefit plans cover nonprescription products, those products are not routinely tracked via pharmacy claims data, including Part D Medicare, noted Lee Rucker from the AARP Public Policy Institute. This leads to difficulties tracking drug-related problems caused by interactions between prescription and nonprescription drugs. Health literacy comes into play because it falls to the consumer to be proactive in sharing information at every point along the dispensing and prescribing process regarding all prescription, OTC, and dietary supplements that he or she is taking. Many organizations—AARP, the FDA, the NCPIE, and others—have easily accessible medication records that consumers can fill out. But the onus is on the consumer to do it.

Angela Long, vice president of Healthcare Quality and Compendial Affairs at USP, noted that the United States Pharmacopeia-National Formulary (USP-NF) General Chapter will be posted on its website for public comment.[1] She encouraged input. She offered the USP Health Literacy and Prescription Container Labeling Advisory Panel's further assistance, suggesting that perhaps the panel could work on OTC labeling and delivery devices, a challenge brought up earlier in the session.

An additional concern raised by Wendy Mettger of Mettger Communications, relates to adult learners who don't understand terms such as *acetaminophen, ibuprofen,* or even *active ingredient*. She asked if those terms have been tested with consumers. Parker agreed that *active ingredient* is a difficult term for patients. She has an upcoming study showing that consumers think that acetaminophen and antihistamine are the same thing. Research has not focused on this area. She hopes to call attention to the problem of knowing what a product is. If there is agreement that

[1] See http://www.usp.org/.

to safely use a medication, the patient needs to know what it is before he or she takes it, then knowing what a product is comes to the forefront every time safe use of a medication is addressed. Bernard Dreyer added that a lot is known about what patients with low literacy need so they can understand a label. They need pronunciation guides and simple definitions. The problem is that the real estate on all labels is very minimal. But it is the only thing that is really going to help low literacy patients understand what is on the label.

Dreyer then asked what impact USP's General Chapters have. Are they law of the land? Does the FDA play a role? Long responded that the USP sets voluntary standards, and now the USP will work with the National Association of Boards of Pharmacy to adopt the standard. The USP will also talk with the FDA about what role it might play to get the standards taken up.

One participant asked whether patients are involved in product and standard development. Bullman used the example of the NCPIE-developed program called "Maximizing Your Role as a Teen Influencer: What You Can Do To Help Teens Prevent Prescription Drug Abuse." The content was derived from data from the Substance Abuse and Mental Health Services Administration (SAMHSA), the National Institute on Drug Abuse (NIDA) and other published research. NCPIE brought together 15 organizations that were all working on the same issue but had not worked together before.[2] Representatives of school health, school psychologists, parent-teacher associations, Partnership for a Drug-Free America, and American Academy of Pediatrics, for example, came together. Messaging was focus tested in two states. Now that it is launched, three states are doing an assessment of up to 500 people who have been exposed to the workshop, asking questions before, after, then at 3-month intervals. It is a fairly extensive program.

Isham ended the morning session by saying a great deal of progress can be made in the area of medication safety. For example, his health system has an ambulatory health record for its 850,000 patients and an inpatient record. The systems do not talk to each other. The doses for Coumadin, for example, do not transfer across the systems. Now a group is working on that issue. A second issue is that there is an opportunity to develop sophisticated tools to help people manage their own medications.

[2] See http://www.talkaboutrx.org/maximizing_role.jsp.

5

Identifying Activities Around Which to Build Partnerships for Patient-Centered Drug Safety

PHARMACEUTICAL COMPANY

Sandra DeBussey
GlaxoSmithKline

Health literacy and better patient understanding about their medications have an important safety aspect but also relate to overall patient outcomes. "Health literacy can be difficult to assess, however, as it is not only a measure of an individuals' understanding of health information at various points in time but also a measure of how well various health care systems have been organized" (IOM, 2009).

The research shows that *simple* is not always *clear* (Table 5-1). People with low literacy have more trouble than those with higher health literacy

TABLE 5-1 Understanding Label Information

Common Rx Bottle Warning Labels	Percent Voicing Understanding	
	Lowest Level Readers	Basic Level Readers
Take with food	61	89
Medication should be taken with plenty of water	14	52
Refrigerate, shake well, discard after (date)	0	13

SOURCE: Adapted from Wolf et al., 2006.

TABLE 5-2 Voicing Understanding vs. Taking Correct Action

When Asked to Demonstrate the Instruction "Take Two Tablets by Mouth Twice Daily"

Reading Level	Voiced Understanding	Demonstrated Correctly
Low	71%	35%
Marginal	84%	63%
Adequate	89%	80%

SOURCE: Adapted from Davis et al., 2006.

understanding label information. But even people with good reading skills have poor comprehension when labels include information that is not relevant or does not go together. If too much information is on the label, or if it is too cryptic, people will not be able to perform the actions necessary to take their medications correctly.

There is a difference between people saying they can understand a statement and being able to take the correct action. The gap widens as literacy decreases (Table 5-2). It is important to foster more discussion so that the words we use are actionable by the patients.

Visuals add to people's comprehension and to their willingness to look at information (Delp and Jones, 1996). But if visuals are not good or if they are not well tested, they may not make a difference.

GlaxoSmithKline has made a concerted effort to foster internal awareness of health literacy principles and facilitated application of those principles to patient- and consumer-directed materials. The company developed standardized health literacy training that is available across the organization including the marketing departments, patient recruitment and product labeling teams, and research and development staff. Medications are complicated and needs vary, but giving staff good tools—review checklists, a style guide, internal and external expert review support—makes implementation easier. The company is seeing a difference.

Depending on the medication, patient information is available in several forms: med guide, patient package insert (PPI), patient information leaflet (PIL) and consumer medicine information (CMI) (Table 5-3).

GlaxoSmithKline has conducted consumer testing to improve consumer medication information, taking such standard information and putting it into a more patient friendly format in a type of drug fact box found on over-the-counter (OTC) labels. As expected, consumers found it easier to correctly find and restate information from simplified formats: adequate print size and print quality, spacing between lines, information presented in tables with gridlines, bolding of important words and phrases, and easy-to-understand language with actionable information. There were also surprises. Participants had clear opinions on what kinds

TABLE 5-3 Types of Patient Information Leaflets

Type of Patient Information	Mandatory?	Who Is Involved?
MedGuide Certain Rx meds with serious and significant public health concerns as decided by the FDA—currently 180+	Yes	Written by drug company FDA approved
Patient Package Insert (PPI) Oral contraceptives and medicines with estrogen	Yes	Written by drug company FDA approved
Patient Information Leaflet (PIL)	No	Written by drug company FDA approved
Consumer Medication Information (CMI) Rx medicines filled for the 1st time	No Provided voluntarily by Pharmacies	Written by private vendors

of information they wanted and how it should be presented. They wanted to know, first, what action they needed to take. For example, go to the hospital if …, followed by the list of side effects, rather than providing a long list of effects and the action afterwards. DeBussey said that GlaxoSmithKline plans to publish this in the *Drug Information Journal* later in 2010.

PHARMACY

Gerald McEvoy, Pharm.D.
American Society of Health-System Pharmacists

The American Society of Health-System Pharmacists (ASHP) is a national professional and scientific society of 35,000 members practicing in hospitals and organized health systems. Quality and safety is an advocacy priority for the ASHP. Pharmacists play a key role in managing medication risk and reducing preventable harm. The Food and Drug Administration's (FDA's) Safe Use Initiative acknowledges the role of ASHP and its members in terms of medication orders screening, benefit/risk communication to patients and caregivers, medication histories and

medication reconciliation,[1] therapy monitoring, medication therapy management, and collaborative practice models. Another key area for pharmacist involvement is in using technology to improve medication use processes and building the safety nets to catch problems.

Three collaborative opportunities involving pharmacy are specific to health literacy: prescription container labeling, patient counseling, and consumer medication information (CMI). The prescription container label is the most widely used means for communicating medication use information, yet there is confusion among patients about dosing instructions, auxiliary information, and intended use. McEvoy is co-chair of U.S. Pharmacopiea's (USP's) Health Literacy and Prescription Container Advisory Panel, the work of which Schwartzberg summarized earlier (see pages 20-22). The USP is developing standards for content and format of the limited piece of real estate that is the label (USP, 2010).

The second opportunity in health literacy is in patient counseling. Time constraints are a reality among healthcare providers, at the pharmacy where the prescription is filled, in the physician's office where it is prescribed, and in the hospital where the nurses do not have enough time to discuss a medication plan with the patients.

The third health literacy opportunity is in the CMI, the most widely used supplemental means for communicating medication use information. ASHP is a commercial provider of a database of CMI. In its current state, CMI is focused on risk information, with very little benefit information provided. Lack of health literacy is a barrier to understanding the CMI in the context of safe medication use. CMI has also been criticized because current standards for its production focus on content and format rather than on the effects the CMI has on patient understanding and actions. The standards were established in 1996 (Steering Committee, 1996) and clarified by an FDA-issued guidance in 2006 (FDA, 2006). That document recommended testing in patients and consumers, but testing never occurred.

The FDA has determined that CMI documents do not meet the agency's criteria for containing useful and relevant information for patients. The Safe Use Initiative identifies CMI as a key opportunity for collaboration. Many stakeholders favor replacement of several existing documents (CMI, med guides, and PPIs) with a single document. Two FDA-commissioned studies in 2001 and in 2008 examined this issue. The 2001 study

[1] Reconciliation is the process of comparing a patient's medication orders to all of the medications that the patient has been taking in order to avoid medication errors such as omissions, duplications, dosing errors, or drug interactions. This is a requirement of the Joint Commission within hospitals (http://www.jointcommission.org/sentinelevents/sentineleventalert/sea_35.htm).

showed about half of all CMI met the definition of usefulness; the 2008 study showed a higher percentage, 64 percent to 75 percent, met the definition of usefulness. McEvoy noted, however, that the criteria used exceeded criteria set out in the Keystone Guidelines (Steering Committee, 1996), which are incredibly flexible in what can or should be included.

In the 2006 FDA guidance, clarifications were made. The guidance states, for example, that information about the effectiveness of treatment should be limited to physical reactions that a patient can detect. Yet roughly half of the criteria set forth for one of the drugs, Lisinopril, dealt with laboratory tests that had nothing to do with physical reactions. A detailed analysis by the ASHP looked at nitroglycerin patient information. There is a very serious adverse effect of the drug interaction between Viagra and nitrates, but none of the CMI that was tested 5 years after the contraindication included any information on the drug interaction dangers. Even today, 12 years after the contraindication appeared in the Viagra labeling, only one piece of FDA-approved CMI actually includes this life-threatening contraindication.

Dr. McEvoy concluded by saying that the ASHP has several recommendations regarding CMI. They are:

- Involve stakeholders to improve the quality, consistency, and simplicity of CMI.
- Pursue a single, comprehensible document.
- Create evidence-based models and standards for CMI and develop detailed guidance.
- Validate CMI models in actual-use studies in relevant patient populations.
- Clearly establish what is most important to communicate with consumers, how, and at what points of care.
- Work with state boards of pharmacy to ensure down-stream compliance with FDA-established standards for content, format, and distribution at point of dispensing.
- Engage existing infrastructure for content development and deployment; investigate private-public partnerships.
- Explore certification process for publishers of CMI.
- Implement only change that has sound, supportive evidence and economic- and workflow-impact considerations.

INSURER

Jill Griffiths
Aetna

Research with Aetna members ages 18-64 clearly indicates that members with lower literacy are desperately in need of education and information (Table 5-4). They are much less likely than those with moderate health literacy or higher health literacy to strongly agree that they actively seek information to improve their health and well-being, that they are aware of all the tests and screenings that are recommended for their age group and gender, and that they have a good understanding of how to use their health insurance plan. The layers in health care—medical, pharmaceutical, behavioral health, and health insurance systems—are all trying to individually communicate to people about what they should be doing. And it is not being done very well.

This research also reveals that low health literacy and moderate health literacy are problems, not only with health, but also with how people experience their health insurance plan, in this case, Aetna.[2] Only 28 percent of members with low literacy strongly agree that it is easy to find out what is covered and what is not by their health plan (Table 5-5). That means the other 72 percent are not maximizing their health insurance coverage or their pharmaceutical coverage. So not only is labeling a problem, but patients do not even know whether they can obtain a drug at the pharmacy.

Aetna asked members what it can do to improve their experience and more than one in four of the lower health literacy members asked for better or more communication and explanations. They asked for more explanation of coverage, simpler language, and updated information. If people understand the health plan better, if things are clearer, their satisfaction will go up, and their relationship will be better.

Most of Aetna's patient safety and medication adherence programs—alerts to pharmacists about drug interactions or drug-to-disease interactions and messaging to physicians about gaps in care—are not visible to members. Because members do not understand their benefits, Aetna is moving to go directly to members and physicians with simpler information. Staff pharmacists at Aetna provide the opportunity to engage in more data sharing of medications, lab tests, and information regarding patient visits to a doctor, so that care is coordinated among the patient, physicians, and caregivers.

[2] To define low health literacy, medium health literacy, and higher health literacy, Aetna pulled data from a variety of research sources to set these definitions, however no additional information was provided by the speaker.

TABLE 5-4 Lower Health Literacy Members Are in Need of Education and Information

General Health and Insurance Attitudinals (percentage who strongly agree among 18-64-year-old commercial members; n = 207)		Lower Health Lit (n = 95) (A)	Mod Health Lit (n = 47) (B)	Higher Health Lit (n = 66) (C)
I am sure I'm always taking my prescription medicines correctly	89%	83%	94%	96%[A]
I am comfortable filling out medical forms by myself	77%	59%	83%[A]	97%[AB]
I know how much I'm going to pay out of pocket when I visit a doctor*	66%	41%	80%[A]	91%[A]
I have a good understanding of how to use my health insurance plan*	63%	36%	76%[A]	95%[AB]
I am aware of all the tests and screenings that are recommended for my age group and gender*	60%	42%	73%[A]	78%[A]
I actively seek information to improve my health and well-being	55%	44%	63%	66%[A]

NOTE: *Questions included in the DSS health literacy algorithm. Statistically significant differences denoted by ABC (95% confidence level).

TABLE 5-5 Discrepancy in Scores Between Highly Literate and Lower Literate Members Continues to Exist on Elements Related to the Actual Insurance Experience

Insurance Attitudinals (percentage who strongly agree among 18-64-year-old commercial members; n = 207)		Lower Health Lit (n = 95) (A)	Moderate Health Lit (n = 47) (B)	Higher Health Lit (n = 66) (C)
I know how to contact Aetna if I have a question or concern about my plan*	79%	69%	83%	91%[A]
I am comfortable contacting Aetna if I have a question or concern	74%	66%	75%	86%[A]
It is easy to find out if a doctor or hospital is in my health plan's network	68%	55%	71%	84%[A]
It is easy to reach a live person at Aetna	57%	48%	65%	66%
I am confident that it will be easy to get Aetna to answer or address my questions and concerns	55%	40%	58%	73%[A]
Aetna provides access to the information I need to make informed decisions about my health care*	55%	42%	52%	77%[AB]
It is easy to find out what's covered and what's not by my health plan	46%	28%	48%[A]	71%[AB]

NOTES: *Questions included in the DSS health literacy algorithm. Statistically significant differences denoted by ABC (95% confidence level).
SOURCE: Griffiths, 2010.

Aetna has been involved in three clinical studies in recent years. The Aetna Foundation funded studies at University of Pennsylvania and Brigham and Women's Hospital on warfarin use and myocardial infarction to understand the effect of removing financial barriers on medication adherence. An asthma outcomes study demonstrated that plain language intervention decreased use of rescue medication and increased use of controller medications. A study on migraine was conducted to evaluate whether technology, plain language, and a case worker can provide measurable improvement in discharge instruction compliance, quality of life, and decreased emergency room use.

In 2004, Aetna launched a public health education program on health benefits literacy and financial literacy to show people how to maximize their benefits.[3] The company started a working group in 2005 that has begun an awareness campaign for employees, established criteria and requirements for communication with constituents, and that continues to provide stakeholders with training and tools to address health literacy. Aetna is working to simplify communication efforts at every patient touch point in the system to improve their experience.

Griffiths concluded her presentation by saying that opportunities to partner include patient safety collaborations to help patients understand, safely use, and adhere to medication protocols; personal health records as vehicles for educational outreach; formulary simplification and education; and data sharing among the care team to improve patient understanding and confidence.

HEALTH PLANS

Susan Pisano
America's Health Insurance Plans

The community of health plans is eager to collaborate to promote safe use of medications; it is the right thing to do, said Pisano. America's Health Insurance Plans (AHIP), representing nearly 1,300 member companies, has several established vehicles for partnerships among member companies, including the AHIP Health Literacy Task Force (chaired by Jill Griffiths, Vice President, Thought Leadership Clinical and Provider Relations, Aetna), the Addressing Disparities in Health Work Group, and the National Health Plan Collaborative. Several AHIP Health Literacy Task Force members are at this workshop. The task force's focus is recruiting more member companies to become involved, providing them with tools

[3] See www.PlanforYourHealth.com.

to get started and advance progress, and sharing information so that no one has to reinvent the wheel (AHIP, 2010).

AHIP member programs to address compliance and safety around medication use are often framed as quality/adherence rather than health literacy, though they have elements of health literacy within them. There are programs to avoid hospital admissions, prevent avoidable readmissions, and prevent avoidable emergency room use. They often involve intensive one-on-one interactions between a case manager and a patient and a pharmacist. Does the patient know how to take the medications? Is the patient taking the medications properly? The results of these programs suggest that the one-on-one interaction is important and is having an impact.

AHIP is not involved with labeling issues, but it has relationships with mail order pharmacies that would be helpful. There are opportunities for AHIP to participate in general education campaigns, for example, through personal health records. Most AHIP members offer personal health records to their members. AHIP has a tradition of providing general information, such as what screening tests are important at what age and gender, but the decision making happens between the patient and the provider. AHIP could play a similar role in campaigns regarding safe use of OTC drugs; safe use of frequently used drugs such as aspirin, acetaminophen, and antibiotics; as well as how to read the prescription label or what questions to ask your pharmacist.

Finally, AHIP's work on health literacy is integrated with its work in health disparities and cultural competency. Since these programs are in place to address specific populations, they offer additional opportunities for partnerships to address the safe use of medications.

NATIONAL CONSUMERS LEAGUE

Mimi Johnson
National Consumers League

The National Consumers League (NCL) is the nation's oldest consumer advocacy organization, founded in 1899 to protect and promote social and economic justice for consumers and workers in the United States and abroad. Health issues, including food safety and drug safety, have been a big part of the NCL's mission. The NCL sees great value in public-private partnerships to leverage resources and work together toward a common goal. The NCL has entered partnerships to survey consumers regarding gaps in understanding about certain health issues. A project on acetaminophen safe use, geared toward teenagers, is in place now. The NCL is gearing up for a project examining health literacy around

vaccines. Do people understand what a vaccine is, its risks and benefits? Do they understand what immunity is? What are the risks of complications from the vaccine versus contracting the actual disease?

The NCL is working with AHRQ on a national multimedia campaign to improve public health by raising consumer awareness of the importance of good medication adherence.[4] The campaign involves a broad cross-section of public and private stakeholders. Nearly three out of four Americans report that they do not always take their medications as directed (NCPA, 2006). Average adherence rates are around 50 to 60 percent. It is a big problem. Among the top barriers to adherence is that patients are not often convinced of the need, or they do not understand what the drug is doing for them; they do not understand the active ingredient.

It is an exciting opportunity to make adherence a concept that the everyday consumer knows about. The NCL will test messages and concepts that resonate with consumers. Different cultural, socioeconomic, and linguistic groups will receive targeted outreach. Stronger partnerships on these issues with everyone at the table means there will be a unified message. Drug companies are excited about coordinating unbranded dissemination to health care practitioners.

In the NCL's experience, health care practitioners need to be prepared for the launch of a national campaign to educate consumers. If consumers are engaged and ready to ask questions, the health care practitioners need to be prepared for the dialogue. A wide range of stakeholders are involved in the NCL's adherence campaign. Three workgroups are focusing on chronic condition outreach, health care practitioner outreach, and evaluations. Stakeholders will have tool kits for their constituents so that all will use the common messages and themes. The project must be consensus driven to succeed. Everyone needs to be at the table from the beginning to find what can be agreed upon and advanced. It requires an up-front conversation between patient and physician about treatment options, considering the patient's lifestyle and what he or she can do to adhere.

The NCL values and has a history of welcoming all parties to the table, Johnson said. Such partnerships bring varied perspectives and experience to the problem at hand, extend a campaign's reach beyond that of one group, and provide an opportunity for complimentary efforts.

[4] See http://www.nclnet.org/health/106-prescription-drugs/234-ncls-medication-adherence-campaign.

DISCUSSION

William Ross, a nephrologist, began by describing practical issues he hears from his patients. They ask him why taking medications has to be so complicated. Who can take medications three or four times a day? It is not realistic. Why not simplify the process, make one pill for everything? Patients do not understand drug interactions or therapeutic concentrations of drugs. His patients also bring their medications to him, dump them on the counter, maybe five different medications—a blue pill, red pill, green pill—and expect him to know what they are. He thinks icons could help with medication identification, as well as using electronic medical records.

Johnson described what the NCL learned from focus groups with newly diagnosed patients and those who have been living with a chronic condition. Some people set up systems to help them take medications properly; others had jobs or lifestyles that did not allow them to adhere to the prescription. But they all valued their relationship with their doctor above all.

Debussey agreed that health care organizations have taken on narrow pieces of the puzzle, but they have not connected across all the organizations to see how to solve some of the complicated issues. The electronic medical records and personal health records offer an opportunity to make some information more easily available to patients. For example, there could be tools to print out an icon of the different medications to show a patient and explain why they are taking the drug. The tools could also explain to patients why they have to take a drug three times a day and another only once a day.

Robert Logan, National Library of Medicine (NLM), noted that NLM has a website called Pillbox that shows photographs of medications and explains what they are.[5] It is in beta testing and should be more comprehensive in the coming years. A separate NLM website called Daily Med[6] provides similar drug information.

Griffiths pointed out the disturbing number of medications at different dosages that look the same. McEvoy responded that most states now require that the prescription container label carry the identifying marks that are on the dose form. Unfortunately, that information is hard to find among all the other information on the label. And it is only useful if the patient keeps the container.

Wong asked the panel to comment on patient-centered meaningful use and the electronic health record (EHR). Aetna is doing a lot of work

[5] See http://pillbox.nlm.nih.gov/index.html.

[6] See http://dailymed.nlm.nih.gov/dailymed/about.cfm.

on meaningful use, but it still focuses on health care professional users. There is a tremendous opportunity, Griffith said, to determine where to connect patients and physicians and health plans. McEvoy responded that ASHP is participating in the meaningful use debate as it relates to computerized physician order entry systems. ASHP is focusing on such things as drug interaction alerts and maximum dose alerts. The NCL is part of the consumer partnership for e-health and has been weighing in on Capitol Hill with meaningful-use definitions throughout the process, Johnson said. There are exciting opportunities to talk about that which is beyond health information technology: how to collect and use data in a way that will lead to better health outcomes for patients, especially underserved populations.

According to Brach, when the Centers for Medicare & Medicaid Services (CMS) issued their meaningful-use initial regulations at the end of December (CMS, 2009), it specifically said it wanted to include aspects of patient education, cultural competence, and literacy. But that has not yet happened. AHRQ's Brach said she hopes to see some guidance on those issues soon. AHRQ is soliciting proposals to address how to improve patient education in electronic health records from the perspective of the physician users. For meaningful use, they want to see patient education options, including printable handouts for patients, or on-screen tools. The desire is to learn more about how to use technology tools to help people with limited literacy catch up, rather than letting this technology leave them further behind.

Johnson & Johnson's Scott Ratzan pointed out that with health literacy integrated into health care reform, there are opportunities to increase efforts in this area, perhaps through funding for research. He sees opportunities in public-private partnerships to speed diffusion of safe use and health literacy and strategic health communications. Programs can not be vertical, he said. We need horizontal programs to strengthen systems with pharmacists, prescribers, and individuals. We also need to look beyond best practices to next practices. One thing to explore is the use of new communication technologies such as mobile phones. Ratzan worked with Text4Baby,[7] a mobile health project with the White House, Healthy Mothers/Healthy Babies, and 60 or so partners all focused on getting health literate messages to women during pregnancy. All the groups came together because the White House convened the meeting and said it was important. There is great work out there, and the key is to find it and diffuse it for others to be successful, Ratzan said.

Cocotas said coordination between the physical and mental health sectors is challenging within the health care sector. Interesting medical

[7] See http://www.text4baby.org/.

and legal challenges arise around accountability. Although tools finally exist to coordinate care, she sees people stepping back from taking on the responsibility. Case managers are flooded with new information. Who is responsible, who communicates with the consumer about what they need to do, who will communicate what messages to consumers? Griffith added that in the health information exchanges there is not enough clarity about who is to do what. AHIP, insurers, pharmaceutical companies, pharmacies, and the government are all interested in methods to communicate with patients. Is there something different that has to happen to have all the stakeholders communicate more effectively?

Brach pointed to a study by Schillinger and colleagues (2006). In a sample of patients taking warfarin, there was 50 percent discordance between what the patients thought they were supposed to be taking and what the doctors thought they had told the patients to take. More than 30 percent admitted to missing a dose; they were not adhering to the medication regime. Yet physicians and pharmacists frequently say they do not have time to go over the information on how to take the medicine during their short visits. Can reimbursement be restructured to get better results and avoid more costly mistakes, such as emergency room (ER) visits?

AHIP's Pisano said several models are being tested with different kinds of payments. It is important to ask if these concepts include a component of health literacy. People need to make sure the patient has demonstrated understanding. There is a lot of experimentation going on that assumes physicians will spend more time with the patient given the correct payment incentive.

Using electronic health records, doctors can be given standardized, simple language about a drug to talk with the patient, Wolf said. He explained that Debra Roter at Johns Hopkins University is working on a plain language dictionary of complex medical terms. It is not an optimal tool for patients, but it gives providers the language to take a very complex term and explain it. It helps them know what they need to tell a patient about warfarin during prescribing, for example. Wolf has shown with time motion studies that it adds only one second to a doctor's visit. Using the EHR platform, doctors can be more efficient. There has been provider resistance because providers think they will have to do more in their 20 minutes, but by leveraging these tools, providers can be more effective.

The next few years will be about health reform, said Griffiths, but also about finding ways to look at reimbursement models with hospitals, health plans, and providers, looking for quality improvement and cost control. She questioned, however, whether the problem is a reimbursement issue. Is it that the health plan is not paying enough, or are there

other encumbrances on the doctors' time? Health plans are working on standardized accreditation processes and procedures to see how to make some of the work easier so that doctors can spend more of their time on patient care.

Bullman said that about 2 years ago NCPIE ran focus groups with consumers who were taking medications for acute self-limiting problems and patients taking medicines for which there is a required a medication guide. Of the second group, none were familiar with the medication guide, but once they worked through the guide and talked through what they had learned from the med guides, they consistently felt it was the kind of information they should talk about with their doctors. They wanted to receive it at the time the medicine was being prescribed, as part of a discussion about treatment options. They wanted to get it again at the pharmacy to be clear on risks from the medication. The bottom line is, consumers who are exposed to high-risk medications want to know about the medication as soon as possible during the opportunity for dialogue.

6

How Can the Lessons of Health Literacy Be Used to Build Patient-Centered Outcomes for Safe Use?

Isham framed the final discussion. How can the lessons of health literacy be used to build patient-centered outcomes for safe use? The Food and Drug Administration (FDA) is looking for specific areas of preventable medication risk through its Safe Use Initiative. One way to approach this is as the Center for Disease Control and Prevention's (CDC's) Budnitz suggested, by focusing on three drugs—warfarin, insulin, and aspirin. Every group that spoke at the workshop has looked at the issue of preventable medication risk. Different stakeholders approach the issue differently. For example, government agencies may promote education, while the FDA uses regulation as a tool, and health plans talk about case management and their tools.

Isham suggested a collaborative be formed to develop an opportunity map regarding warfarin, for example. Where are the opportunities to add value and help individuals—under a variety of socioeconomic situations, educational levels, health literacy levels—understand safe use of warfarin? That would be the analytic phase, before educational campaigns are launched or regulations set. Start from a common understanding across stakeholders. Then ask each stakeholder what it can bring to the table to close gaps and add value.

First there needs to be consensus on best practices for some of the medications discussed. For example, after hip surgery, warfarin is prescribed for some patients for weeks, others for days. If there is no literature on the subject, doctors could be encouraged to do real-time trials to figure out how to avoid needless exposure to a drug or underuse. Then,

once the medication is prescribed, how well do people consistently adhere to the instructions? There are drug-labeling issues. What can pharmaceutical companies do in labeling and information? An opportunity map can be created for each participant.

Since this is a health literacy meeting, what contribution can health literacy make in partnership with others? Who should be at the table?

Ruth Parker expressed concern about going one drug at a time, versus a more cross-cutting approach. The data exist about the top three drugs, but it might not get the process far enough. She advocated looking at all levels, all the points—labeling, dispensing containers, communication, follow-up—but from a patient-centered view. What is going to make the consumer most likely able to do what he or she needs to do safely and effectively?

Wolf said perhaps singling out the three drugs with the highest rates of adverse drug reactions could be a first step for dealing with specific things in the health care system—things such as pulling someone off a medication or not prescribing it when it is not called for—quality control issues that are not in the patient's hands, but rather the hands of the systems or providers. It is important to remember that it is unlikely the patient is taking only one medication.

Budnitz weighed in on the debate over targeting high-risk medications, or situations that data show cause lots of harm, versus a more systematic change. The challenge is finding winnable battles, places where it is possible to demonstrate effect. There is the concern about building interventions in silos.

The PROTECT Initiative, which focused on medication overdoses in children, is an example of what can be done. It began with over-the-counter (OTC) medications because that was the opportunity to get stakeholders together to implement some change. The hope is those changes will be transferred to prescription medications in the future, and to how volume measures go on all liquid medications. In other words, there are some lessons that can be applied to other medications. There is a way to think about the big picture, but start somewhere with a concrete effort. If we try to start fixing everything at once, there are a lot of ways to go wrong.

Where can this group carry out some concrete, high-impact interventions that can be a model for a system-wide effort later? The FDA's Weiss liked the idea of doing both: go vertical and horizontal. She noted that Sharfstein said pick low-hanging fruit, test the idea and see how it works, then show tangible results and apply elsewhere. And do not forget the people who will be newly insured under health care reform, who haven't been plugged into the health care system. How will they be reached?

Yin pointed out that everyone is talking about a systematic approach

versus doing one medicine at a time. Looking ahead, using the acetaminophen example, active ingredients can be explained and icons used, but what about other active ingredients? What other icons can a label hold? Would it increase confusion? A systematic approach is important, Yin said.

McEvoy asked about focusing on the black box warnings. Hundreds of drugs have black box warnings, which indicate the FDA considers they carry some of the highest risks of any drugs. This could be the place to start. Dissect black box warnings, which are incredibly complex, and see what impact they are having on risk and benefit decision making.

Communication is not sufficiently valued, Schwartzberg said. There is good legal precedent that the patient has a right to understand. It is bigger than the newest technology, the electronic health record: we are not able to find a way to really communicate well to patients so they can understand. Communication needs to be valued as much as diagnosis and treatment.

Isham encouraged the FDA to look at specific initiatives, include broader initiatives that are more systems initiatives, and categorize the list of activities both ways. Dreyer agreed, adding that the FDA has a central role to play that has not been expressed clearly yet. With labeling, for example, there should be two or three main messages patients get from the box. Right now, the FDA requires too much additional information on the label. Some of those requirements need to be removed. The FDA needs to be a central player, not looking on. Weiss replied that the FDA's regulatory role is central to its mission, as authorized by Congress. The FDA does not see itself in the driver's seat, but in a joining-in role, seeing how it can help with other's initiatives, lending support as needed. The FDA has regulatory authority over medications, for example, requiring REMS[1] for certain classes of medications. Then there are other entities, the health plans and professional societies that the FDA does not have authority over but would like to voluntarily bring together to work on these issues.

McEvoy used consumer medical information (CMI) as an example of how regulation can cause problems. A set of guidelines was developed in 1996, then reinforced with an FDA guidance document in 2006. Because CMI was set up around the measurement of defined goals, the

[1] Under the Food and Drug Administration Amendments Act of 2007 (FDAAA) (Public Law 110-85), FDA has the authority to require persons submitting certain drug approval applications to submit a proposed REMS as part of the application. FDA may require a REMS when necessary to ensure that the benefits of a drug outweigh its risks. FDAAA also authorizes FDA to require holders of certain drug applications approved without a REMS to submit a proposed REMS if the agency becomes aware of new safety information and makes a determination that a REMS is necessary to ensure the benefits of the drug outweigh its risks.

ultimate consequence was stifled innovation. Publishers were prevented from coming up with effective ways of communicating with patients because the focus was on meeting criteria for content and format rather than educating patients in a manner than they understood. The nitroglycerin example is relevant. A drug interaction exists that can result in death and yet 12 years later, very little has changed in the labeling and the CMI. That is because of the way the agency has enforced its regulations. The FDA does not have the freedom to identify all 25 drugs that a given precaution might apply to and instantaneously apply it to those drugs. Each case must be negotiated with the sponsor of that drug to modify their label except in unusual circumstances. The FDA is inhibited from working more effectively and more systematically in bringing about those sorts of changes.

The FDA is asking for input to do something that is not within its traditional legislative role, Budnitz noted. He went on to say that this might be an opportunity for the roundtable to pick the number one priority and maybe number two, and get them done. Maybe systematic change is number one for the Roundtable on Health Literacy. If that can be clearly defined and backed up with data on actual harm, that would be quite useful, and the FDA and other federal agencies could act on it. Isham encouraged the group to continue with this line of thinking and take this opportunity to offer its ideas to the FDA.

Schwartzberg said the issue is communication to patients and what the patient understands. Working with the Drug Facts and redoing their structure based on the criteria that the USP has just developed is aimed at making things clear and easy. Take what is already being worked on and bring it to the next level so that information will be easier for patients to understand. Johnson noted the benefit of consumer advocates working with the FDA and suggested the agency continue to open its doors to input from consumers and consumer advocates.

McEvoy suggested a need for presenting more balanced benefit/risk information. Under ARRA (American Recovery and Reinvestment Act), money is going into funding comparative effectiveness research. But there is a disconnection between the research and what the FDA can say about a drug. To make informed choices about health care and about medication use, patients have to consider risk in the context of benefit. The focus has been almost entirely on risk, especially what comes out of the FDA, in both professional and consumer labeling.

Bullman asked that work move toward a useful, actionable written adjunctive information sheet to be provided at the point of prescribing a medication, culminating in the development of something that takes into account high risk. This would apply to med guide messages and safe use and benefit as well; messages that could be made available across

the spectrum of medicine users, not just in English or poorly translated Spanish.

Yin pointed to the very concerning 99 percent inconsistency between dosing information on the label and the dosing device. What would it take to get rid of this high level of inconsistency and variability? The voluntary guidance by the FDA was a great first step (FDA, 2006). But there needs to be continued monitoring of the situation to look for progress and improvement. Barrett would go further, asking that the FDA require accountability. If a company creates a drug, it should provide specific dosage devices that are equated to the directions on the bottle, going beyond monitoring for a simple win-win.

Isham suggested that warfarin/Coumadin be used as a probe to figure out how health literacy can contribute to developing a multistakeholder solution to improving use of that drug. Debussey would like to see basic work on how patients understand and interpret risk, benefit, and key words such as *active ingredient*. It is important to not focus just on terms as has been done with content and format, but actually develop the language that makes sense to patients, not just for written materials, but across the board for how we speak about a drug, write about it, and what patients hear on the radio.

Would it help to organize activities by disease rather than drug, Griffiths asked. We know the primary issues around safety, medication adherence, and health literacy. But do we know what patients need in order to understand what those issues are? Looking by disease rather than drug, can we ask, what are the touch points that the health plans, the pharmacies, and the pharmaceutical companies can get involved in? What can be done so that when a patient and pharmacist interact, the patient gets exactly the information needed to walk out of the pharmacy and take the drug with confidence and accuracy? Isham agreed. In the real world, no drug is taken in isolation, and they are often taken in the context of a chronic disease.

Pisano turned the question to the FDA: What are the two or three big problems that lend themselves to solutions? She also said she would take a broader approach than that of focusing on one area or problem for discussion. She would focus on all the touch points that contribute to a patient's understanding of a disease and how to take a medication properly. Media coverage of research from the medical community can be problematic as well. The media are left to translate research results and sometimes it detracts rather than helps.

McNeil's Kuffner advocated for acetaminophen being part of the Safe Use Initiative. It is a medication that is OTC and prescription, so it allows issues to be addressed on both sides. It is one of the most commonly used medications and most commonly prescribed by health care providers. To

learn how to tackle this issue, acetaminophen would be a good test. Acetaminophen is the low-hanging fruit: thousands of patients went into U.S. pharmacies today and picked up prescriptions that were labeled APAP and had no idea that the medicine actually contains acetaminophen.

The medication administration section of OTC drugs is very unclear for reasons discussed earlier, Dreyer said. We give better instructions for building a bicycle than for taking medicines that can kill you. First, the Drug Facts need to be better. Second, patients need to know what the active ingredient is. Third, FDA rules are very rigid on limited English proficiency. Those rules need to be loosened to put other languages on OTC drugs.

Amy Wilson-Stronks with the Joint Commission spoke as a consumer. If somebody she cares about is taking a drug, she doesn't want them to die or be maimed or hurt. The most important piece is whatever the FDA can do to promote effective education to both providers so they know what to tell their patients about risks involved with the drugs and off-label use of drugs, as well as providing education directly to the patient. Even people who are physicians are not free from risk of adverse events such as toxicities and drug interactions.

Ratzan reminded the group about the National Action Plan on Health Literacy that is about to be released.[2] The draft plan was developed over years of surgeon general's workshops around the country. There was one specific statement dealing with OTC safe use. If there is a way to get that funded and linked with this FDA Safe Use Initiative, that's an opportunity, Ratzan said.

Ratzan then focused on aspirin use, one of the three top drugs on Budnitz's list. As a public health issue, 10,000 deaths a year could be averted by appropriate low-dose aspirin use. Ratzan challenged others to pick up a low-dose aspirin bottle and determine what the appropriate dosage is and what aspirin use is for. Fixing low-dose aspirin would be another piece to move on. Isham agreed that one of the biggest opportunities the United States has for intervention is appropriate aspirin use.

Barrett reminded the group that patients are not all the same; there are different levels of understanding. It is important to take into consideration the hard-to-reach populations and those who have low literacy.

Most patients don't know that patient information leaflets (PIL) exists. It is not written in a patient friendly or health literate way, even with the new PIL format. Loveland suggests that patients must realize the PIL is there, and it must look more attractive and appealing to them.

[2] The National Action Plan to Improve Health Literacy was released May 27, 2010. It was presented to the public at an IOM Roundtable on Health Literacy workshop on that date. A summary of that workshop is in preparation and will be released in 2010.

Budnitz and Parker's recommendations for an evaluation of a sentinel drug that enables a systematic review made sense to Ross. The important thing, he said, is to develop a way for physicians to interact with patients, identify medications, and use electronic medical records to track adherence. This may mean charging a task force to develop that approach.

NLM's Logan asked what else, in addition to better information, influences medication understanding and adherence. The literature suggests caregivers play a big role. A couple of years ago a *JAMA* study showed a great medication adherence problem in a particular community. The researchers asked all the patients to designate a caregiver. That caregiver could be a health care provider or a friend. The result was that adherence and understanding went up geometrically. From a communication theory perspective this study makes a great deal of sense because the process of communication is often as influential as the content of communication. In a simple step, they shifted a vertical process to a horizontal process. More research is needed about what motivates people beyond good information, Logan said.

Martha Gragg with the Missouri Foundation for Health is a nurse and a hospital CEO. Because medications are being taken by patients themselves or given by a parent or caretaker, she said, it is crucial that labeling be readable and understandable by all who handle that medication. The devices must match. She stated her opinion that the problem seemed simple to solve.

Parker offered a wording preference. The FDA, in charge of drug safety for the public, should consider changing the title of this initiative to Patient-Centered Safe Use, thereby making the patient-centered focus a priority in all efforts.

Brach said a culture change is in order. The FDA's orientation is to pharmaceutical companies as its clients, those who pay the agency to approve their drugs. Doing some internal education on health literacy throughout the FDA could be the single most powerful way of starting to address this issue. There are a lot of people at the FDA who do not have a consumer or patient focus.

The FDA's Weiss was offered a chance to close. She welcomed the input from consumer groups and other stakeholders. She thanked participants for giving the FDA the opportunity to receive feedback on this very important aspect of medication safety.

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Appendix A

Acronyms

AAP	American Academy of Pediatrics
AARP	a nonprofit, nonpartisan membership organization for people 50 and older aimed at promoting well-being
ADE	adverse drug event
AHIP	America's Health Insurance Plans
AHRQ	Agency for Healthcare Research and Quality
APAP	acetaminophen
ARRA	American Recovery and Reinvestment Act
ASHP	American Society of Health-System Pharmacists
BID	medication label direction to use twice a day
CADES	Cooperative Adverse Drug Event Surveillance Project
CDC	Centers for Disease Control and Prevention
CDER	Center for Drug Evaluation and Research, a center of the Food and Drug Administration
CEO	chief executive officer
CHPA	Consumer Healthcare Products Association
CMI	consumer medicine information
CMS	Centers for Medicare & Medicaid Services
ED	emergency department
EHR	electronic health record
EMR	electronic medical record

ER	emergency room
FDA	Food and Drug Administration
GAO	General Accounting Office
GI	gastrointestinal
IOM	Institute of Medicine
NCL	National Consumers League
NCPA	National Community Pharmacists Association
NCPIE	National Council on Patient Information and Education
NEISS	National Electronic Injury Surveillance System
NIDA	National Institute on Drug Abuse
NLM	National Library of Medicine
OTC	over-the-counter
PIL	patient information leaflet
PM	post meridiem or after noon
PPI	patient package insert
PRN	medication label direction to use as needed
PROTECT	Preventing Overdoses & Treatment Errors in Children Taskforce
QID	medication label direction to use four times a day
REMS	Risk evaluation and mitigation strategies
SAMHSA	Substance Abuse and Mental Health Services Administration
SIG	prescription medication label prescribing directions
USP	U.S. Pharmacopeia
USP-NF	U.S. Pharmacopeia-National Formulary

Appendix B

Workshop Agenda

ROUNDTABLE ON HEALTH LITERACY
THE SAFE USE INITIATIVE AND HEALTH LITERACY: A WORKSHOP

Tuesday, April 27, 2010
8:30 a.m.-3:30 p.m.
Ballroom C & D
Four Points by Sheraton
1201 K Street, NW
Washington, DC

AGENDA

8:30-8:45 am — Welcome and Overview
George J. Isham, M.D., M.S.
Chair, Roundtable on Health Literacy
Chief Health Officer and Plan Medical Director
HealthPartners

8:45-9:15 am — FDA Safe Use Initiative
- What is the Initiative trying to achieve?
- What actions do they want to see taken?
- Who would they like to see involved in those actions?
- How can the Health Literacy Roundtable and others be helpful?

Joshua Sharfstein, M.D.
Principal Deputy Commissioner
U.S. Food and Drug Administration

9:15-9:45 am — Discussion and Clarification

9:45-10:15 am **Panel: Over-the-Counter Products**

9:45-10:00 Current Status of OTC Labels
H. Shonna Yin, M.D., M.S.
Assistant Professor of Pediatrics
Department of Pediatrics
NYU School of Medicine

10:00-10:15 Health Literacy Tasks for OTC Drug Safety
Michael Wolf, Ph.D., M.P.H.
Associate Professor, Medicine and Learning Sciences
Associate Division Chief-Research
Division of General Internal Medicine
Feinberg School of Medicine
Northwestern University

10:15-10:45 Discussion—using these data, what kind of activities could be developed and who could be involved?

10:45-11:00 am Break

11:00-11:40 am **Panel: Initiatives to Advance Patient-Centered Drug Safety**

11:00-11:10 U.S. Pharmacopeia Health Literacy and Prescription Container Labeling Advisory Panel
Joanne Schwartzberg, M.D.
Director, Aging and Community Health
American Medical Association

11:10-11:20 National Council on Patient Information and Education
Wm. Ray Bullman, M.A.M.
Executive Vice President

11:20-11:30 CDC Initiative
Dan Budnitz, M.D., M.P.H.
Director, Medication Safety Program
Division of Healthcare Quality Promotion
Centers for Disease Control and Prevention

	11:30-11:40	Johnson & Johnson Initiatives: McNeil Consumer Healthcare ***Edwin Kuffner, M.D.*** Vice President, Medical Affairs and Clinical Research McNeil Consumer Healthcare
11:40 am-12:15 pm	Discussion	
12:15-1:15 pm	**Lunch**	
1:15-2:05 pm	**Panel: Identifying Activities Around Which to Build Partnerships for Patient-Centered Drug Safety**	
	1:15-1:25	Pharmaceutical Company ***Sandy Debussey*** GlaxoSmithKline
	1:25-1:35	Pharmacy Gerald McEvoy Assistant Vice President for Drug Information American Society of Health-Systems Pharmacists
	1:35-1:45	Insurer ***Jill Griffiths*** Vice President of Thought Leadership Clinical and Provider Relations Aetna
	1:45-1:55	Health Plans ***Susan Pisano*** Director of Communications America's Health Insurance Plans
	1:55-2:05	National Consumer League ***Mimi Johnson*** Director, Health Policy
2:05-2:45 pm	Discussion	

2:45-3:30 pm	**Panel: How can the lessons of health literacy be used to build patient-centered outcomes for safe use?** ***All of the day's speakers will participate in this panel. There will be specific questions developed which will be used to stimulate discussion.*** Moderator: George Isham
3:30 pm	Adjourn

Appendix C

Workshop Speaker Biosketches

Daniel Budnitz, M.D., M.P.H., is the director of the Medication Safety Program with the Division of Healthcare Quality Promotion at the Centers for Disease Control and Prevention (CDC) and has worked developing public health data standards and public health responses to disease outbreaks, terrorism, and natural disasters.

Dr. Budnitz received a Bachelors of Arts degree in Government from Harvard University, and an M.D. and M.P.H. in Epidemiology from Emory University. After completing residency training in internal medicine at the Hospital of the University of Pennsylvania, Dr. Budnitz served as an Epidemic Intelligence Service (EIS Officer) with CDC's Injury Center. He is currently a commander in the United States Public Health Service; and, as clinical assistant professor of Internal Medicine at Emory University, he is a practicing, Board-certified internist.

Wm. Ray Bullman, M.A.M., is the executive vice president of the National Council on Patient Information and Education (NCPIE). He joined the staff in 1985, assuming staff leadership in 1995. Under his guidance, NCPIE produced two authoritative resources on prescription medication adherence: *Prescription Medicine Adherence: A Review of the Baseline of Knowledge* (1996) and *Enhancing Prescription Medicine Adherence: A National Action Plan* (2007). In 1996, the Council collaborated with the American Medical Association (AMA) on development of AMA's Guidelines for Physicians for Counseling Patients about Prescription Medications in the

Ambulatory Setting. He also coordinated the development of NCPIE's "Talk About Prescriptions" Month (annually in October), in 1986.

In 2000, Mr. Bullman, representing NCPIE, collaborated with the FDA's Center for Drug Evaluation and Research on the organization and implementation of the Cyber-Smart Safety Coalition. In 2005, Mr. Bullman established a partnership agreement with CDER/FDA to enable NCPIE to assist with the development and promotion of FDA's Medicines in My Home OTC consumer education campaign.

Currently, Mr. Bullman is coordinating NCPIE collaboration with the Substance Abuse and Mental Health Services Administration (SAMHSA) on the development, implementation, and assessment of a national educational workshop,"Maximizing Your Role as a Teen Influencer: What You Can Do to Help Prevent Teen Prescription Drug Abuse," and the development of an online tool kit for addressing prescription drug abuse prevention and treatment on America's college campuses.

Prior to joining NCPIE, Mr. Bullman served for five years Community Program Development Specialist with the National High Blood Pressure Education Program, under a contract to Kappa Systems, Inc., from the Heart, Lung, and Blood Institute of the National Institutes of Health. He also served for 6 years as Administrator for the Rockville Community Clinic in Rockville, Maryland.

Mr. Bullman received a bachelor's degree from the University of Maryland in College Park, and a master's in Association Management (MAM) from George Washington University in Washington, DC.

Sandra Debussey is senior manager of Planning and Operations at GlaxoSmithKline. She has over 25 years of pharmaceutical industry experience spanning clinical development, clinical trials management, health information technology (HIT), disease and care management interventions, patient education, and communications. Ms. Debussey received her B.S. in zoology from Michigan State University.

Jill Griffiths is vice president of Market and Clinical Communications for Aetna, Inc., based in Hartford, Connecticut. She is responsible for all business communications for Aetna's president and business leaders —including public relations and employee communications, developing thought leadership campaigns to highlight Aetna's clinical leadership, provider relations programs and activities, and direct to consumer programs. Ms. Griffiths co-leads Aetna's health literacy initiatives with the company's chief medical officer, is co-chair of the health literacy task force for America's Health Insurance Plans, and participates on the oral health literacy advisory group for the American Dental Association.

Previously, she was vice president of Business Communications,

where she was responsible for public relations and employee communication for Aetna's businesses. She has been assistant vice president and director of Health Public Relations for Aetna, where she handled media relations for the health business of Aetna, and directed the regional public relations managers.

Ms. Griffiths holds a B.A. in English Literature with a minor concentration in Business Administration from Ursinus College and has completed continuing education courses in advertising and public relations at Villanova University.

Mimi Johnson, M.Phil., is the director of health policy for the National Consumers League. She came to the National Consumers League in August 2008. She is a member of the Health Policy team, where she works on issues ranging from medication safety and adherence to the role of consumers in health reform. Ms. Johnson also represents the League at health-related meetings with U.S. government agencies, consumer, labor, and health organizations, and coalitions.

Ms. Johnson came to the League from the O'Neill Institute for National and Global Health Law, a cross-campus collaborative housed at Georgetown University's Law Center. She began her career in policy as an intern in Senator Feingold's Washington office. Ms. Johnson has since worked for Washington-based health and environmental non-profit organizations and with the Press and Cultural Affairs staff at the Royal Norwegian Embassy in Washington, DC.

Ms. Johnson earned a bachelor's degree from George Washington University and a master's degree in health policy from Oslo University College in Norway, where she studied pediatric preventive care in the United States and Norway.

Edwin Kuffner, M.D., is the vice president of Medical Affairs and Clinical Research at McNeil Consumer Healthcare. Dr. Kuffner received his undergraduate degree in German Language and Literature from the State University of New York (SUNY) at Binghamton and attended medical school at SUNY Health Sciences Center in Brooklyn. He completed his emergency medicine residency at New York University and Bellevue Hospital Center in NYC and is board certified in emergency medicine. He also completed a medical toxicology fellowship at the University of Colorado and the Rocky Mountain Poison and Drug Center (RMPDC) in Denver and is board certified in medical toxicology.

Gerald K. McEvoy, Pharm.D., is assistant vice president of Drug Information at the American Society of Health-System Pharmacists (ASHP). In addition, Dr. McEvoy has served as editor-in-chief of AHFS Drug

Information (AHFS DI), ASHP's federally recognized drug compendium, for over 28 years. In his capacities as AVP of Drug Information and editor-in-chief of AHFS DI and AHFS DI Consumer Medication information (AHFS DI CMI), Dr. McEvoy is responsible for a variety of publishing and database management projects within ASHP focusing on dissemination of drug information in both electronic and print formats to various audiences, including health professionals and patients. Through partnership with various health information vendors and other parties, including the National Library of Medicine, Consumer Reports, and Medscape/WebMD, ASHP's professional and patient drug information is available as both referential and integrated data in a wide variety of services and settings. Dr. McEvoy has spoken widely on evidence-based development of drug prescribing information as well as on patient safety, emergency preparedness, and media-neutral publishing and electronic data interchange through SGML and XML data structuring and document tagging.

Dr. McEvoy currently serves on the BMJ Group North American Advisory Board, National Council on Patient Information and Education Board, USP Safe Medication Use Expert Committee, and USP Providers Advisory Forum for Medicare Part D Model Guidelines. Dr. McEvoy also served on an Institute of Medicine Panel on Changing Prescription Medication Use Container Instructions to Improve Health Literacy and Medication Safety and subsequently was appointed co-chair of USP's Health Literacy and Prescription Container Labeling Advisory Panel, which he continues to co-chair. In addition, Dr. McEvoy is a recognized authority on consumer medication information, testifying before and advising the U.S. Food and Drug Administration (FDA) on medication safety communication issues involving consumers, advising the Consumer Reports on medication use issues, and speaking internationally on the provision of safe medication use information to consumers.

Before joining ASHP, Dr. McEvoy obtained both his baccalaureate and doctorate degrees in Pharmacy from Duquesne University in Pittsburgh, Pennsylvania, and completed a hospital residency at Mercy Hospital in Pittsburgh. He recently was awarded the Duquesne University Pharmacy Alumni Achievement Award.

Susan Pisano, M.A., is the vice president of Communications for America's Health Insurance Plans (AHIP). She acts as a spokesperson for AHIP and is responsible for outreach to member companies, the news media, and other major audiences. She is the primary staffer for AHIP's Health Literacy Task Force.

Ms. Pisano has worked at AHIP since 1987. Before coming to AHIP she was the public relations director at Pacific Medical Center in Seattle, Washington, a local institution affiliated with an HMO since 1985. Ms.

Pisano began her career at Pennsylvania Hospital in Philadelphia, and received her bachelor of art degree at Chestnut Hill College in 1971 and her master of art degree in 1975 from Villanova University.

Joanne G. Schwartzberg, M.D., is director of Aging and Community Health at the American Medical Association (AMA) and currently directs AMA projects on older driver safety, medical management of the home care patient, health literacy, and safe communication. She has been working in the field of health literacy and clinician/patient clear communication since 1997. She led the AMA ad hoc committee of experts that developed the Council on Scientific Affairs Report on Health Literacy, organized the physician awareness campaigns based on the Health Literacy Introductory Kit and later developed the Health Literacy: Help Your Patients Understand self-study educational program. She has led the AMA foundation's Training of Trainers program for the last 6 years, helped develop the 3 module curriculum, and trained teams of physicians from 29 state and medical specialty societies. Since 2007, she has co-chaired the USP Advisory Panel on Health Literacy and Prescription Container Labeling.

Dr. Schwartzberg is also a clinical assistant professor of Preventive Medicine and Community Health at the University of Illinois at Chicago College of Medicine. She is a past-president of the Institute of Medicine of Chicago, the Illinois Geriatrics Society, and the American Academy of Home Care Physicians. She received her B.A. from Harvard University and her M.D. from Northwestern University, and is the 2001 recipient of the Henry P. Russe, MD "Citation for Exemplary Compassion in Healthcare" awarded by the Institute of Medicine of Chicago and the Rush-Presbyterian-St Luke's Medical Center.

Joshua M. Sharfstein, M.D., is the FDA principal deputy commissioner. He served as Acting Commissioner for Food and Drugs from March 29-May 25, 2009. From December 2005 through March 2009, Dr. Sharfstein was the Commissioner of Health for the City of Baltimore. In this position, he led efforts to expand literacy efforts in pediatric primary care, facilitate the transition to Medicare Part D for disabled adults, engage college students in public health activities, increase influenza vaccination of healthcare workers, and expand access to effective treatment for opioid addiction. Under his leadership, the Baltimore Health Department and its affiliated agencies have won multiple national awards for innovative programs, and in 2008, Dr. Sharfstein was named a Public Official of the Year by Governing Magazine.

From July 2001 to December 2005, Dr. Sharfstein served as minority professional staff of the Government Reform Committee of the U.S. House

of Representatives for Congressman Henry A. Waxman. Dr. Sharfstein is a 1991 graduate of Harvard College, a 1996 graduate of Harvard Medical School, a 1999 graduate of the combined residency program in pediatrics at Boston Children's Hospital and Boston Medical Center, and a 2001 graduate of the fellowship in general pediatrics at the Boston University School of Medicine.

Michael Wolf, Ph.D., M.P.H., is an associate professor of medicine, associate division chief of research, and director of the Center for Communication in Healthcare at the Feinberg School of Medicine at Northwestern University. Dr. Wolf is a behavioral scientist and health services researcher with primary interests in adult literacy and learning, cognitive factors, and the management of chronic disease. He was one of the first recipients of the Pfizer Health Literacy Initiative Scholar Award and has received numerous national awards for his work in the field of health literacy and medication safety.

Dr. Wolf has written 84 peer-reviewed publications, many of which address the problem of limited health literacy. He currently serves on advisory committees for the U.S. Food and Drug Administration, U.S. Pharmacopeia, the American Dental Association, and the Agency for Healthcare Research and Quality. He has repeatedly provided consultation to the Institute of Medicine, American College of Physicians Foundation, American Medical Association, American Pharmacists Association, and Centers for Disease Control on health literacy matters.

He is the principal investigator on grants from the National Institute on Aging, National Cancer Institute, Agency for Healthcare Research and Quality, Target Corporation, Foundation for Informed Decision Making, and the Missouri Foundation for Health. Dr. Wolf also led an Institute of Medicine white paper on health literacy and medication safety, and he is the principal investigator of a trial to test enhanced drug labeling and the use of visual aids to improve patient processing and understanding of medication instructions.

H. Shonna Yin, M.D., M.Sc., is an assistant professor of pediatrics at the New York University School of Medicine/Bellevue Hospital Center. Her research interest centers on the issue of parent health literacy and its implications on child health. A large focus of her work involves examining the intersection between health literacy and medication safety, including the development and evaluation of low literacy strategies to improve parent understanding of medication instructions. Some of her recent work is featured in the Joint Commission book "Addressing Patients' Health Literacy Needs." Dr. Yin serves on the CDC workgroup "Preventing Unsupervised Medication Ingestions and Overdoses in Children," co-chairing

the subcommittee focused on the standardization of pediatric medication dosing instructions.

Dr. Yin is currently funded as a Robert Wood Johnson Physician Faculty Scholar. She received the 2009 Academic Pediatric Association's Young Investigator Award as well as the 2007 Pfizer Fellowship in Health Literacy/Clear Health Communication.

Dr. Yin is a graduate of the Massachusetts Institute of Technology and the University of Rochester School of Medicine. She completed residency training in pediatrics at the NYU School of Medicine, and received her Master of Science degree in Clinical Investigation through the CDC-sponsored Medicine and Public Health Research Fellowship Program at the NYU School of Medicine.