California State Board of Pharmacy
1625 N. Market Blvd, Suite N 219, Sacramento, CA 95834
Phone (916) 574-7900
Fax (916) 574-8618
www.pharmacy.ca.gov

STATE AND CONSUMERS AFFAIRS AGENCY
DEPARTMENT OF CONSUMER AFFAIRS
ARNOLD SCHWARZENEGGER, GOVERNOR

Communication and Public Education Committee Report

Ken Schell, PharmD, Chair
Hank Hough, Board Member
Andrea Zinder, Board Member
Susan Ravnan, Board Member

Report of the
Communication and Public Education Committee Meeting of January 8, 2008

The Communication and Public Education Committee met January 8, 2008. Minutes from this meeting are provided in **Attachment A** at the back of this packet.

Report and Action of Items Discussed at the Communication and Public Education Committee Meeting of January 8, 2007.

1. Consumer Fact Sheet Series

For Information:

Four years ago, the board approved a proposal by the committee to integrate pharmacy students into public outreach activities. The intent was to offer students the opportunity to work with the board on meaningful projects promoting consumer education, while the board would benefit from the production of these materials. The project was initiated at UCSF, at its specific request.

The UCSF Center for Consumer Self Care worked directly with its students to develop the fact sheets, which were then reviewed by faculty members and then by the board. The board and the center distribute these fact sheets at community health fairs and has them available online.

Nine fact sheets were developed under this program with UCSF:

- Generic Drugs – High Quality, Low Cost
- Lower Your Drug Costs
- Is Your Medicine in the News?
- Did You Know? Good Oral Health Means Good Overall Health
- Have You Ever Missed a Dose of Medication?

- What's the Deal with Double Dosing? Too Much Acetaminophen, That's What!
- Don't Flush Your Medicine Down the Toilet!
- Thinking of Herbals?
- Diabetes – Engage Your Health Care Team

These nine fact sheets have been translated into Spanish, Vietnamese and Chinese. Copies of some of the English versions are in **Attachment 1**.

However, since September 2006, no additional fact sheets have been produced, although 11 additional fact sheets are in varying stages of completion. Since April 2007, the board has been unable to correct addresses on the existing fact sheets and otherwise finalize the new ones for publication.

During the early fall of 2007, UCSF explained that it could no longer perform these duties without a stipend to offset its expenses. Specifically, that while the Center for Consumer Self Care was interested in continuing to work on developing fact sheets, they could no longer do so without a subsidy. UCSF suggested that a contract be developed to produce 16 fact sheets over the next year for a fee of $25,000.

At the October 2007 Board Meeting, the board accepted the committee's recommendations to invigorate this program by offering other schools of pharmacy the opportunity to have their students develop one-page fact sheets on various topics, and then have the developed fact sheets reviewed by experts. Representatives of other California pharmacy schools were very interested in this project for their students when contacted by committee members or staff.

The board directed that staff proceed with the committee's recommendations for development of a template for future fact sheets, and work with the schools of pharmacy to initiate this intern project. The template will include the general format for the fact sheet, and require an annotated copy with footnotes citing the origin of information. The board will then confirm, edit and otherwise review this information, and then finally format each into a standardized fact sheet.

The board also very much liked the committee's recommendation to host an annual competition to acknowledge the interns who have produced the published fact sheets and select the very best fact sheets for a specific award.

During the committee meeting, the committee refined the letter to school deans to encourage student involvement and suggested changes to the template. The committee also suggested that the board highlight priorities for the fact sheets.

The priority topics for the fact sheets were determined at the July 2007 Board Meeting as:

- Counterfeit medicine
- Immunizations
- Direct to consumer drug marketing

- Buying drugs off the Internet (revision to existing brochure)
- cold medication for young children under the age of two
- pediatrics and over-the-counter products

There is also a lengthy list of potential topics for the fact sheets that has been developed over time. This list is included in **Attachment 1**.

A new format for the fact sheets will be designed as well.

2. Update Report on *The Script*

The next issue of *The Script* is at the Officer of State Printing for publication. The focus of this issue will be on new laws, questions and answers about pharmacy practice asked of the board, and new regulation requirements.

The next newsletter is planned for July. The committee suggested that medication errors and prevention steps be the core of some articles, as information from ISMP on recurrent errors has been a feature in the last few newsletters.

The committee would also like input from the board on topics for inclusion in the newsletter.

3. Development of New Brochures

FOR INFORMATION:

a: Revisions to Board Overview Brochure, Complaint Brochure and Drug Discount Brochure:

Board staff revised the text and graphic layout of the following board brochures:

- Healthy Californians Through Quality Pharmacists Care
- Do You Have a Complaint?
- Drug Discount Program for Medicare Recipients

Each has a similar appearance with respect to the board's logo and state seal.

During the committee meeting, the committee changed the title of the second brochure to "Do You Have a Concern or Complaint About a Pharmacy or Pharmacist? We Want to Hear From You."

A copy of these completed brochures are in **Attachment 2**.

b. Text for Buying Drugs From Foreign Countries or on the Internet Brochure

Staff has initiated working on updating and revising this brochure. The goal is to have this draft completed by the next committee meeting.

c. Informational Materials for Pharmacist Applicants

There is a wealth of information on the board's Web site regarding instructions for the pharmacist exam, but some applicants do not read this information or perhaps do not retain it or reference it throughout the application process.

Staff will developed specialized fact sheets for specific applicants (foreign graduates, pharmacists licensed in other states) to make it easier for them to submit applications. Additionally, staff is developing a check list applicants can use to monitor/track their applications and progress through the process.

We will have drafts of this material before the next committee meeting.

Additionally, an article published in CSHP's Journal written by the board will be converted into an information sheet. A copy of the published article is in **Attachment 2.**

4. New Notice to Consumers Poster

FOR INFORMATION:

In November, the Office of Administrative Law approved amendments to 16 CCR section 1707.2(g), creating additional requirements for a Notice to Consumers poster that present information about a patient's right to obtain lawfully prescribed medicine from a pharmacy. This required notice must be posted in a pharmacy, or alternatively, printed on the back of customer receipts. The board prints these posters so they have a consistent look from pharmacy to pharmacy.

The required text for the full Notice to Consumers is provided in **Attachment 3**. While the notice now contains a number of important provisions, it contains so many provisions that comprehension (or reader interest) may be compromised.

The board's challenge is to make the poster (or perhaps posters) interesting and attractive. Display of this information in a pharmacy is an important means for public education.

The committee reviewed three posters developed by two different artists on converting this wording into a readable, interesting and yet informative format.

The committee discussed the posters, none of which really hit the mark. All three posters are larger than the current poster, but two of the posters produced by the board's graphics person fit the information onto one poster. The department's draft poster designs simply list the text and use two large posters to do it.

Executive Officer Herold will work with graphic artists at the State Printing Plant and with the two other artists to secure an appropriate design.

After the design is finalized, the posters will be printed and mailed to all California pharmacies. The board should have this completed by July 2008. The estimated budget will be around $80,000, twice what it cost to print the last Notice to Consumers two years ago when the board moved into its current office.

5. Establishment of Public Hearing Schedule to Implement SB 472 (Corbett, Chapter 470, Statutes of 2007) Standardized, Patient-Centered Labels by 2011

FOR INFORMATION:

Last fall, Governor Schwarzenegger signed SB 472 that directs the board to develop a patient-centered, standardized prescription container label for all medicine dispensed to California patients after January 1, 2011.

The board drafted the amendments that were ultimately enacted as SB 472, which requires the board to hold public meetings statewide that are separate from normally scheduled hearings to seek information from the public.

The timeline envisioned for this process was:
2008: conduct public hearings statewide – six meetings were envisioned
2009: develop regulations and adopt the requirements by the end of the year
2010: pharmacies implement requirements to be ready for 1/1/11 implementation
2011: requirements become effective and labels on prescription medicine are compliant

The Medication Label Subcommittee has been formed as a subcommittee of the Communication and Public Education Committee to work on the labeling requirements. At the October Board Meeting, President Powers appointed the following individuals to this committee:

Ken Schell, Chair
Bill Powers
Ruth Conroy
Rob Swart
Susan Ravnan

Senator Corbett has asked that the first meeting be held in her district, specifically Fremont.

The first meeting may be on Saturday, February 23 in Fremont. We are working to secure a mailing list from the bill's sponsors and an appropriate location in Fremont, and on Senator Corbett's availability for this meeting (she wanted to attend the kick off).

The subcommittee may want to discuss this project during this board meeting.

A copy of SB 472 is provided in **Attachment 4**. Also included is material staff has gathered on patient comprehension of prescription container information which will provide a solid framework for proceeding.

Since the Communication and Public Education Committee, Ms. Herold has asked the California Pharmacists Association, California Retailers Association and the California Society of Health System Pharmacists to provide samples of diverse containers and labels in use in California pharmacies so the subcommittee and public can see the diversity of prescription containers that must be labeled. Additionally she requested copies of all auxiliary labels that are used on containers.

6. New Board Web Site

FOR INFORMATION:

The Governor's Office directed all state agencies to have a state-standardized Web site by November 1, 2007.

The board met this deadline on November 1.

We had two staff, Kim de Long and Victor Perez, who worked on this project.

Currently, staff is modifying the Web site to add a web page devoted to locating information on electronic pedigree requirements in California, and consolidate this into one place.

A copy of the board's Web page and that of the Department of Consumer Affairs are provided in **Attachment 5.**

7. Miscellaneous Consumer Issues in the Media

FOR INFORMATION:

Attachment 6 contains several articles of consumer interest reviewed by the committee.

8. Update on Public Outreach Activities

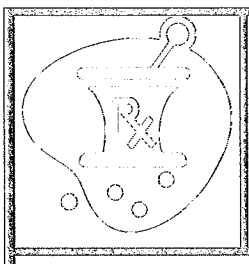
FOR INFORMATION:

From mid September through December 2007, the board provided two presentations to professional associations, four presentations at major conferences, three presentations at meetings involving public policy discussions, and staffed a booth at four public information fairs.

A detailed list of the board's public outreach activities this quarter is provided in **Attachment 7**.

Attachment 1

Consumer Fact Sheets



Ever Miss a Dose of Your Medicine?

... here are some tips

FACT: Many people miss taking one or more doses of their medicines.

FACT: Some people think they can make up for the missed doses by doubling up on their medicines.

FACT: Doubling up on your medication can cause serious, life-threatening side effects.

*It can happen like this...**

Mrs. Chase has been taking the same medicine for the last 3 months. Recently she has been very busy with work and other pressures, and she accidentally missed a dose of her medicine. She realized that she had skipped her regular dose, so she took two capsules to "make up for it." A few hours later Mrs. Chase startled her coworkers...her eyes were moving back-and-forth, her speech was slurred. She staggered and stumbled when she tried to walk, became drowsy, vomited, had involuntary muscle twitches and then became unconscious. She was rushed to the emergency room.

**Based on a case series review on a commonly used prescription medication.*

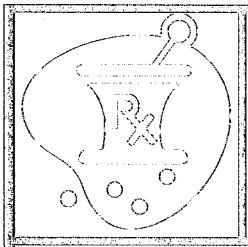
If you missed your regular dose of medicine, here's what to do:

1. Do not just double up on your medicine.
2. Read the drug information that was given to you when you got your medicine,. Some medicines come with directions on what to do if you miss your regular dose.
3. If you are still not sure, call your **pharmacist** or **doctor** for advice.
4. Work out a plan for your next dose with your pharmacist or doctor.
5. Talk with your pharmacist or doctor about any concerns you might have.

HINT: Keep the phone numbers of your pharmacist and doctor in your wallet.

University of California
San Francisco
UCSF
School of Pharmacy

California State Board of Pharmacy
1625 N. Market Blvd., Suite N-219, Sacramento, CA 95834 (916) 574-7900
UCSF Center for Consumer Self Care
3333 California Street, San Francisco, CA 94143-0613



Did You Know?

Good oral health means good overall health!

FACT: Poor oral health can cause pain, discomfort and bad breath. It can also put you at risk of serious disease, like heart disease and stroke.

FACT: If you do not brush and floss daily, the sticky film of bacteria in your mouth, called plaque, can harden into tartar and help cause gum disease (gingivitis).

FACT: If untreated, bacteria in plaque and in infected gums can travel from your mouth into your blood stream. This has been linked to clogging of arteries and damage to heart valves.

FACT: **Smoking** is a major risk factor for oral and dental diseases, including oral cancer. Tobacco reduces blood flow to the gums, lowering the supply of oxygen and nutrients needed to fight bacterial gum infection.

FACT: **People with diabetes** are more at risk to get gum disease, and this can put them at greater risk of diabetic complications.

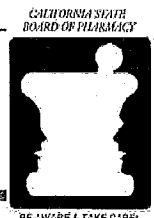
FACT: **Pregnant women** with gum disease are at higher risk of delivering early-term, low birth weight babies than women without gum disease.

To lower your risk:

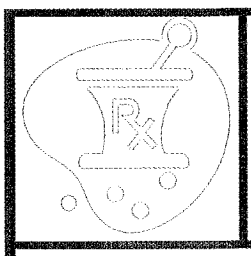
- Brush and floss your teeth daily.
- Visit your dentist regularly.
- Ask your dentist or pharmacist about the right toothpaste, toothbrush and floss for you.
- Eat a healthy diet.
- Do not smoke. If you do, be sure to visit your dentist regularly.
- If you are pregnant, be sure to eat healthy foods and maintain good oral health.
- Brush your children's teeth for them until they have the ability to do properly themselves. For example, when they can write their own name (not print), they should be able to brush their teeth with your guidance.

University of California
San Francisco
UCSF
School of Pharmacy

California State Board of Pharmacy
1625 N. Market Blvd., Suite N-219, Sacramento, CA 95834 (916) 574-7900
UCSF Center for Consumer Self Care
3333 California Street, San Francisco, CA 94143-0613



BE AWARE & TAKE CARE!
Talk to your pharmacist!



Diabetes

Engage your health team!

FACT: Diabetes can cause serious health complications including heart disease, blindness, kidney failure, and lower-extremity amputations. Diabetes is the sixth leading cause of death in the United States.

If you think you might have diabetes, visit a physician for a diagnosis. You might have SOME or NONE of the following symptoms:

- Frequent urination
- Excessive thirst
- Unexplained weight loss
- Extreme hunger
- Sudden vision changes
- Tingling or numbness in hands or feet
- Feeling very tired much of the time
- Very dry skin
- Sores that are slow to heal
- More infections than usual.

You can help prevent or postpone type 2 diabetes by taking a central role in your own self care:

- Don't smoke.
- Achieve a healthy weight and maintain it.
- Be physically active.
- Limit your intake of fat and sugar.
- Eat regular, balanced meals that include the four food groups.
- Keep your cholesterol and other blood fats within the target level.
- Maintain a normal blood pressure.

Engage your health team!

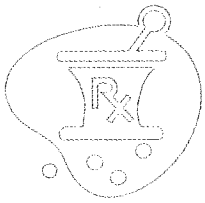
- Monitor your blood glucose regularly, as recommended by your **doctor**.
- Take your medication as prescribed. Ask your **pharmacist** about questions you may have on the use of your medicines, their safety or possible drug interactions.
- Take care of your feet by examining the skin for redness and sores. Ask your **pharmacist** for suggestions on products that can help improve your foot care.
- Make a date to visit your **doctor, dentist,** and **eye specialist** for regular check ups. Your role in making these visits is key to preventing problems.
- Consult a **dietitian** about creating balanced meals.
- If you drink alcohol, be moderate in how much you drink. Avoid drinking on an empty stomach as this can cause hypoglycemia (low blood glucose).
- If you are pregnant, ask your **doctor** about using artificial sweeteners.

University of California
San Francisco
UCSF
School of Pharmacy

California State Board of Pharmacy
1625 N. Market Blvd., Suite N-219, Sacramento, CA 95834 (916) 574-7900
UCSF Center for Consumer Self Care
3333 California Street, San Francisco, CA 94143-0613

OSP 06 97190-3

Ask Your Pharmacist



What's the deal with double dosing?

Too much Acetaminophen, that's what!

FACT: Acetaminophen is the #1 cause of liver damage in the U.S.

- Acetaminophen is found in many over-the-counter (OTC) products, like Tylenol, Anacin, Excedrin, Liquiprin, Midol, Panadol, Robitussin, Sudafed, Tavist, TheraFlu, Traiminic, Vick's, generic products, and prescription drugs (e.g., Tylenol with codeine).

FACT: If you take more than one medicine that has acetaminophen you are at risk.

FACT: Acetaminophen is the most widely used pain killer medicine in the U.S.

- It is widely used in many prescription and non-prescription products — for headache, menstrual pain, general aches and pains, fever, and other pains.
- In any given week, some 23 percent of adults (48.1 million people) report using acetaminophen-containing products.

FACT: As consumers and patients we don't read the medicine label carefully.

- 56 percent do not read what active ingredients are in their medicines.
- 80 percent say they do not read the medicine label for possible side effects.

FACT: Liver damage from too much acetaminophen *can be prevented*.

Lower Your Risk!

- Read your medicine labels. Compare the active ingredient sections.
- Do not take two different products—both containing acetaminophen, If unsure, ask you doctor or pharmacist about which medicines might be best for you.
- If you think you have taken too much acetaminophen, seek medical attention right away.
- Be especially careful with medicines you give to children. Many fever reducers and cough/cold products given to children contain acetaminophen.

Some Possible Signs of Acetaminophen Overdose

- **Body as a whole:** sweating, convulsions
- **Gastrointestinal:** diarrhea, upset stomach, appetite loss, nausea and/or vomiting
- **Nervous System:** Irritability, coma

NOTE: Symptoms may be delayed for 12 hours after acetaminophen has been swallowed.

University of California
San Francisco
UCSF
School of Pharmacy

California State Board of Pharmacy
1625 N. Market Blvd., Suite N-219, Sacramento, CA 95834 (916) 574-7900
UCSF Center for Consumer Self Care
3333 California Street, San Francisco, CA 94143-0613

OSP 06 97190-9

Topics Suggested for Consumer Fact Sheet Series

1. Different dosage form of drugs -- the ability for patients to request a specific type of product (liquid or capsule) that would best fit the patients' needs for a given type of medication. Also differences between tablespoons, mLs, cc, teaspoon measures.
2. Falls - with emphasis on medicines that put you at risk - talk to your pharmacist/read the label
3. Consumer reporting of adverse drug events -- based on FDA quote "Consumers can play an important public health role by reporting to FDA any adverse reactions or other problems with products the Agency regulates. When problems with FDA-regulated products occur, the Agency wants to know about them and has several ways for the public to make reports. Timely reporting by consumers, health professionals, and FDA-regulated companies allows the Agency to take prompt action. FDA evaluates the reports to determine how serious the problem is, and if necessary, may request additional information from the person who filed the report before taking action. "
4. Driving when you are taking medicines
5. Rebound headaches and the danger of taking too many OTC pain relievers for headaches
6. Hormone replacement therapy -- what is the current thinking?
7. Pediatric issues
8. Poison control issues
9. Ask for drug product information and labels in your native language if you cannot read English
10. Cough and cold meds and addiction issues (specifically, dextromethorophan)
11. Taking your Medicines Right (four fact sheets)
    - How to Use an Rx Label
    - How to Use an OTC Label
    - How to Use a Dietary Supplement Label
    - How to Use a Food Label
12. Take Only as Directed (three fact sheets)
    - Dangers of Double Dosing
    - Disposal of Out of Date Medicines
    - Tips on How to Take your Medicine Safely
13. Ask your Pharmacist or Doctor
    - Have a question?
    - Ask your Pharmacist for Native Language Materials/Labeling
14. Questions to Ask About your Condition or Medicine:
    - Diabetes: Questions to Ask
    - Cardiovascular Disease: Questions to Ask
    - Asthma: Questions to Ask
    - Depression: Questions to Ask

- Arthritis and Pain: Questions to Ask

15. What Can I do to Prevent Disease?
    - Regular Check Ups
    - Screening
    - What Medicare Offers
16. Childhood Illnesses and Conditions
    - Head Lice
    - Fever Reducers: Questions to Ask
    - Immunizations: Questions to Ask & Schedules
17. Questions to Ask About Your Medicines
    - What Are Drug Interactions?
    - Ask Your Pharmacist: Medicare Part D Prescription Drug Benefit
    - Medication Therapy Management – What Is It?
    - Drinking and Taking Medicines
18. Learn More about your Medicine
    - Credible Sources on the Internet

Medicine Safety

- Heading: Read the Label
  "How to Read an Rx Label"
  "How to Use an OTC Label"
  "How to Use a Dietary Supplement Label"
  "How to Use a Food Label"
- "A Medicine Chest for Traveling"
- "Drug-Drug Interactions"

Health Topics

- "Diabetes and Aspirin"
- "Asthma – Safe Use of Inhalers"
- "Immunizations"
- "Checking Your Blood Pressure"
- "Head Lice – Back to School"

Tips for Parents

- read the label
- teaspoons and tablespoons
- more is not better
- ask your pharmacist

Aspirin for Heart Attack and Stroke

- aspirin is not for everyone
- risks associated with aspirin
- what to think about before starting daily aspirin

Counterfeit Medicines

- dangers of using counterfeit medicines
- what to look for
- ask your pharmacist

Consumer Drug information on the Internet

- how to judge reliable information
- sites to trust
- where to look
- ask your pharmacist

Allergies to Medicines

- what to look for
- what to do
- before purchase, read the label – inactive ingredient section
- consumer reports to FDA (MedWatch)
- ask your pharmacist

Immunizations

- immunization schedules
- what schools require
- awareness alert that some pharmacies provide immunization services
- ask your pharmacist

Attachment 2

New Consumer Brochures

A. Prescription pricing can differ from pharmacy to pharmacy under this program. Most of the time this will occur because different drug manufacturers charge Medi-Cal different prices for the same drug.

Q. I just refilled my prescription, and it cost more than last time, why?

A. Prescription drug manufacturers change their prices periodically. Price increases occur throughout the year, and for some drugs, many times during the year. Medi-Cal updates the prices it pays for drugs in its computer weekly. If your prescription price does increase, you can ask your pharmacist if the manufacturer has increased the price.

Q. If I already have prescription coverage, will this program affect me?

A. The program covers Medicare patients who themselves pay the full drug price. If you have prescription drug coverage through an insurance plan, your pharmacy is not required to charge the insurance company the Medi-Cal price, even if you are a Medicare patient. However, if you have prescription coverage, it might be advantageous to use the program if:

- You have reached your yearly or monthly prescription maximum paid amount under your insurance program and now have to pay full price for your prescriptions.
- Your prescription insurance doesn't cover a certain drug prescribed for you.
- You have a deductible to meet before your coverage begins.

Q. Will this program affect my Medicare coverage?

A. No. This program does not affect your coverage under the Medicare program.

Q. Can I receive the Medi-Cal price from my mail order pharmacy?

A. Yes, if that pharmacy is a Medi-Cal provider.

Q. Who do I call if I believe the pharmacy is not charging me the right price, and I haven't been able to work it out with the pharmacy?

A. You can contact the California State Board of Pharmacy, Monday through Friday between the hours of 8 a.m. and 5 p.m. at (916) 574-7900.

Obtaining prices from several pharmacies may help you find the lowest cost, but it's best to get all your prescriptions from the same pharmacy. This way the pharmacist can record all the medications you are taking and what you are taking them for, and your pharmacist can tell you what to do if you have a bad reaction to a drug or find that a drug isn't working. Also, the pharmacist can check your new prescription to make sure it won't react badly with medicine you're already taking. Proper pharmaceutical care can protect your health or even save your life!

California State Board of Pharmacy

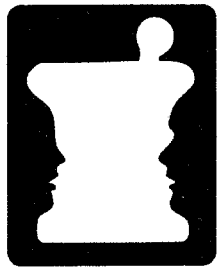
1625 N. Market Blvd, Suite N-219
Sacramento, CA 95834
(916) 574-7900
www.pharmacy.ca.gov

January 2008

Prescription Drug Discount Program for Medicare Recipients

You can to save up to 40% on the cost of your prescriptions not available under the Medicare Part D Prescription Drug benefit. All you need is your Medicare card! California law makes it possible for Medicare recipients to obtain their prescription drugs at a cost no higher than the Medi-Cal price for those drugs.

CALIFORNIA STATE BOARD OF PHARMACY



BE AWARE & TAKE CARE:
Talk to your pharmacist!

Here's how it works:

1. Show your Medicare card to the pharmacy staff.
2. Give your prescription to the pharmacy staff, and ask for the Medi-Cal prescription price. Ask if that is the lowest price the pharmacy will accept for the drug.
3. If the Medi-Cal price is the lowest price, you can pay that price, plus a small processing fee of 15 cents, for the prescribed drug. The processing fee is intended to reimburse the pharmacy for electronically checking Medi-Cal for prescription pricing information.
4. Pay for the prescription in full at the pharmacy. If you have prescription drug coverage, your insurance company is not eligible to receive the Medi-Cal price.
5. Only Medi-Cal provider pharmacies are required by law to offer and accept the Medi-Cal price as payment for prescription medication for Medicare recipients, but non-Medi-Cal pharmacies may also offer the Medi-Cal price if they choose.

Frequently Asked Questions

Q. What is the Prescription Drug Discount Program for Medicare Recipients?

A. It is a program that requires Medi-Cal provider pharmacies to charge Medicare recipients no more than the Medi-Cal price for their prescription drugs.

Q. Who is eligible?

A. Anyone who has a Medicare card is eligible. That includes seniors over age 65 and those under age 65 who are disabled and have a Medicare card. You do not have to be on Medi-Cal.

Q. Is Medi-Cal paying for my prescription?

A. No, Medi-Cal is not paying for the prescription. You, the Medicare recipient, are still responsible for paying for the prescription medication and the processing fee.

Q. Do I have to fill out any forms to take advantage of the program?

A. No. All you need is your Medicare card.

Q. Does the program work for drugs not covered under the new Medicare Part D benefit?

A. Yes. When you give your prescription to the pharmacist, show the pharmacy staff your Medicare card, and request the Medi-Cal price rate. The pharmacist will electronically check Medi-Cal for the price of the prescribed drug, and you will be eligible to buy the drug at that price, plus the 15-cent fee.

Q. How does the discount program work with telephoned prescriptions?

A. Ask the doctor's office to advise the pharmacy that you are a Medicare patient when they phone in your prescription. Then show your Medicare card when you pick up your prescription. For future prescriptions, it is also a good idea to ask your regular pharmacy to note on your record that you are a Medicare recipient.

Q. What drugs are covered?

A. Virtually every prescription medication is covered including both generic and brand name drugs; however, over-the-counter drugs and drugs that the pharmacist has to compound are not covered under this program.

Q. Can I go to any pharmacy I want to get the Medi-Cal price?

A. Only Medi-Cal pharmacy providers are required to charge a Medicare recipient no more than the Medi-Cal prescription price; however, most pharmacies in California do participate in the Medi-Cal program. Ask your pharmacy if it is a Medi-Cal provider. Some non-Medi-Cal pharmacies are willing to charge a similar prescription price.

Q. How much money will I have to pay?

A. What you pay will depend on the medication, but it will not exceed the amount Medi-Cal pays the pharmacy for the medication, plus the 15-cent processing fee.

Q. How much money will I save?

A. Again, that will depend on the medication, as well as the quantity ordered and the drug manufacturer. Several companies, with each charging a different price, may manufacture the same drug.

Q. How do I know I'm being charged the right amount?

A. Ask the pharmacist for a printout of the Medi-Cal information obtained through the pharmacy's computer. Be sure to make this request when you hand your prescription to the pharmacy staff or when the doctor's office calls in the prescription.

Q. I have called four different pharmacies and have received four different prices. Why is that?

HOW TO FILE A COMPLAINT

Complaint forms are found at www.pharmacy.ca.gov and may be filled out and submitted electronically or printed and filled out by hand. Forms filled out by hand must be sent to the California State Board of Pharmacy, 1625 N. Market Blvd., Suite N-219, Sacramento, CA 95834. The on-line complaint form can be submitted electronically.

WHAT HAPPENS TO MY COMPLAINT?

The board strives to complete most investigations within 120 days. Routine investigations may take up to 90 days, while more complex cases requiring extensive investigation may take longer.

If the complaint is within the board's jurisdiction, the complaint will be referred to staff for mediation or investigation. If the complaint is not within the board's jurisdiction, it may be closed with no action taken or referred to another agency that may have jurisdiction. A complaint could result in disciplinary action being taken against a licensee ranging from a reprimand, a citation and fine, or revocation of the license with loss of the right to practice or operate a pharmacy.

If you write to the board and request information regarding the outcome of a complaint, the board will respond in writing. The following information may be obtained:

- The date the complaint was received by the board
- A summary of the investigation
- The outcome or type of discipline

Formal disciplinary actions are a matter of public record, as are the names of licensees, their license numbers, their address of record, the date the original license was issued, and the current status (active or inactive) of that license.

CALIFORNIA STATE BOARD OF PHARMACY

FOR MORE INFORMATION ABOUT THE BOARD, LICENSING, OR THE COMPLAINT PROCESS, YOU MAY:

VISIT THE BOARD'S WEB SITE AT
WWW.PHARMACY.CA.GOV

WRITE TO THE BOARD AT
1625 N. MARKET BLVD., SUITE N-219
SACRAMENTO, CA 95834

CALL THE BOARD AT
(916) 574-7900

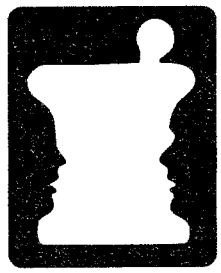
January 2008

STATE OF CALIFORNIA
dca
DEPARTMENT OF CONSUMER AFFAIRS

DO YOU HAVE A CONCERN OR COMPLAINT ABOUT A PHARMACY OR PHARMACIST?

WE WANT TO HEAR FROM YOU.

CALIFORNIA STATE BOARD OF PHARMACY



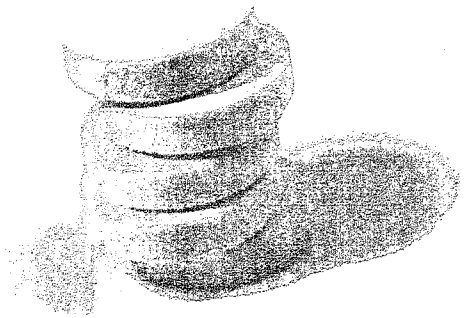
BE AWARE & TAKE CARE:
Talk to your pharmacist!

COMPLAINT RESOLUTION

A primary way the California State Board of Pharmacy (board) protects the public is through the investigation of consumer inquiries and complaints involving the care patients have received. Errors in filling prescriptions or suspected misconduct by a pharmacist may be violations of pharmacy law, and should be reported, whether or not a patient was harmed.

The board does not have jurisdiction over drug prices charged by the pharmacy or prescription billing disputes with insurance carriers.

The board advocates and enforces laws that protect the health and safety of patients, and encourages submission of complaints and inquiries from the public. Each complaint is evaluated to determine if the complaint involves a pharmacist, pharmacy, or firm regulated by the board, and whether the complaint involves a violation of California Pharmacy Law.



WHAT IS PHARMACIST MISCONDUCT?

Examples of misconduct by a pharmacist include (but are not limited to) instances where:

- The pharmacist fails to counsel you about how to take a new prescription medicine (or a prescription with changed instructions) and its possible side effects
- Someone in the pharmacy other than the pharmacist counsels you
- A pharmacist is not present and your prescription is filled by other pharmacy staff
- A pharmacist fails to maintain the confidentiality of your prescription information
- A pharmacist is under the influence of alcohol or drugs while on duty
- The pharmacy is dirty, cluttered, or looks unsanitary
- A pharmacist does not help you in obtaining a prescribed drug or device from another pharmacy, when the drug or device is out of stock
- A pharmacist fails to assist you in obtaining a prescribed medicine or device from another pharmacy, when refusing to provide the medicine for ethical, moral, or religious reasons

WHAT ARE PRESCRIPTION ERRORS?

Examples of prescription errors include (but are not limited to) instances where:

- Incorrect information is entered on the label of the medicine container
- Medicine is dispensed with the wrong drug or wrong dosage
- Medicine is refilled without proper authorization from the prescribing physician
- A generic medicine is substituted for a brand name medicine, without informing the patient of the substitution
- Medicine is filled using drugs whose expiration date has passed

Where to find more information

The board's Web site provides consumer education material, application material for licensing, and information for ensuring compliance with California Pharmacy Law. The Web site also provides information on board meetings where public comments and input are encouraged. Go to www.pharmacy.ca.gov for materials including:

- Consumer Education Material
- Applications and Forms
- Complaint Resolution process
- Publications and Newsletters
- Pharmacy Law and Regulations
- License Verification
- Licensing Requirements and Renewal Information
- Public board and committee meeting dates, agendas, meeting materials and minutes

Did you know?

Anyone interested in receiving e-mail alerts about updates to the board's Web site can join the board's e-mail notification list. Go to www.pharmacy.ca.gov, then click on "Join our e-mail list." E-mail alerts provide information regarding:

- Regulations implemented or released for public comment
- Board newsletters when they are published
- Agendas for public meetings when released
- Questions and answers about new laws
- Board actions from board meetings

Consumers and licensees may also call or write to the board:

California State Board of Pharmacy
1625 N. Market Blvd., Suite N-219
Sacramento, CA 95834

(916) 574-7900
www.pharmacy.ca.gov

January 2008

STATE OF CALIFORNIA
dca
DEPARTMENT OF CONSUMER AFFAIRS

Healthy Californians

Through Quality Pharmacists Care

CALIFORNIA STATE BOARD OF PHARMACY

BE AWARE & TAKE CARE:
Talk to your pharmacist!

Who we are

The California State Board of Pharmacy (board) serves the public as a consumer protection agency. The board is part of the Department of Consumer Affairs, which is in the executive branch of California's government. The Governor is at the top of the executive branch.

The board consists of 13 members, appointed to four-year terms. Members can serve only two consecutive terms. There are seven pharmacists and six public members appointed to the board. The Governor appoints the seven pharmacists, as well as four of the public members. The Senate Rules Committee and the Speaker of the Assembly each appoint one public member. Public members are individuals who are not licensed by the board.

Members of the board appoint the executive officer, who directs board operations and oversees a staff of more than 55 people. The staff includes over 20 pharmacists who inspect licensed premises and investigate suspected violations of pharmacy law. The board is self-funded through licensing fees, and receives no tax money from the General Revenue Fund of California.

How we protect the public

The board develops and enforces regulations to protect the public from the misuse and diversion of prescription drugs from pharmacies. The board licenses pharmacists, pharmacist interns, pharmacy technicians, and designated representatives (those involved with wholesaling medicine and medical devices, but who do not hold a pharmacist license).

The board also regulates firms that distribute medicine and medical devices in California. These firms include community pharmacies, hospital pharmacies, clinics, out-of-state pharmacies that fill prescriptions and deliver them to patients in California, and wholesalers who ship medicines into California.

To become a licensed pharmacist, an individual must graduate from an accredited pharmacy school, pass two examinations, and complete experience in both community and hospital pharmacies. In addition, continuing education is required for a pharmacist to renew his or her license.

Did you know?

Information regarding license status and official actions taken in connection with a licensee, if known, are disclosed to the public upon request. Go to www.pharmacy.ca.gov for instructions about how to request this information in writing. You can obtain:

- Licensee Name
- License Number
- Name of Licensed Facility Owner (including the corporation name and corporate officers) and the Pharmacist-in-Charge
- Address of Record
- Date the original License was issued
- License Expiration Date
- Current License Status
- Letters of Admonishment
- Citations
- Referrals for formal Disciplinary Action
- Accusation/Petition to Revoke Probation
- Board Decisions
- Temporary Restraining Order
- Automatic Suspension Order
- Summary Suspension Order
- Interim Suspension Order
- Penal Code 23 license restrictions

What we do

Under California law, the board's mandate is consumer protection. The board oversees those that compound, dispense, store, ship, or handle prescription drugs and medical devices to patients and practitioners in California. Currently, the board licenses over 100,000 pharmacists, pharmacies, and other individuals and businesses who are involved in these activities. The board sets standards and licenses only those who comply with these standards, to ensure practitioners and licensed premises comply with legal requirements and follow essential components.

The board ensures that pharmacists provide patients with quality pharmacist care when dispensing prescribed medicine, providing medication and education information, and when monitoring therapeutic outcomes resulting from their decisions.

Becoming a Licensed Pharmacist in California
An Insider's View

■ **Virginia Herold**
Executive Office, California State Board of Pharmacy

The California State Board of Pharmacy licenses pharmacists in California. The goal of licensing is consumer protection: the board is required to ensure that before practicing pharmacy, every applicant meets the minimum requirements. Once proof of achievement of the requirements is provided to and approved by the board, the board issues the individual a pharmacist license.

Pharmacy is regulated at the state level, so states have their own licensure requirements, although most states have similar requirements. Each requirement has a purpose. The requirements themselves have their origin in California statutory laws (enacted by the Legislature) or in regulations (rules promulgated by the board).

For many applicants, the process will take four to five months. For others it will take six months, and for a few, longer than six months. Most applicants can take steps to minimize the timeframe required to become licensed to the shorter end of the range. This article describes these steps.

Here are the basic components (note: please use the directions for the online examination application to provide you with the specifics of each component). The more complete your application is when you submit it, the shorter the process will be for you.

I. Becoming Eligible to take the Examinations

1. **Education:** each applicant must be either:
   - A graduate of an ACPE-accredited school of pharmacy, or
   - If a foreign-educated pharmacist, certified by the Foreign Pharmacy Graduate Education Committee.
2. **Experience:** each applicant must provide proof of experience working as an intern pharmacist or if licensed in another state, experience as a pharmacist. Satisfactory evidence of experience must be one of the following:
   - 1,500 hours of intern experience provided on affidavits available from the board if registered in California as an intern.
   - 1,500 hours of intern experience earned as a pharmacist intern in another state - these hours must be certified by the board of pharmacy in the state where the hours were earned.
   - Proof of licensure as a pharmacist in another state for one year – this requires a license certification from the board of pharmacy in the state where the individual is licensed.
3. **Criminal Background Check:** All pharmacist applicants must undergo a criminal background check by submitting fingerprints for evaluation by the California Department of Justice and Federal Bureau of Investigation. Even if you have previously submitted prints to the California board for an intern or pharmacy technician license, you must submit new prints with the classification of "pharmacist" listed on the fingerprint form. There are two ways to submit fingerprints:
   - If you are located in California, you must submit prints via LiveScan. This is faster, and the California Department of Justice is insistent that LiveScan be used for those residing in California.
   - If you are outside California, request that the board mail you fingerprint cards. You need to submit two cards along with a separate fee (made payable to the board).
4. **License Verification:** we require a license verification from every state in which you are licensed as a pharmacist. The state boards of pharmacy in the respective states need to provide these certifications.

II. Being made Eligible for the Examinations

Once the board has a complete application, the board will make you eligible to take the CPJE and NAPLEX exams. We will send you a letter notifying you that you are "eligible," and how to schedule your CPJE and NAPLEX exams. You can take the exams in any order.

- The board does provide some leeway for fingerprint clearances: if we have proof you have submitted prints for a pharmacist license, we will make you eligible without having the background clearances (however, you will not be licensed until we receive the clearances).
- If you passed the NAPLEX after January 1, 2004, you will not need to retake this examination if NABP can transfer the score to California. Contact NABP (www.nabp.net) for more information on how to share prior NAPLEX scores with California.
- Unless we have a quality assurance review (see below) underway for the CPJE, we will mail the scores to you typically within 14 days of when you take the exams.

III. Becoming Licensed

After the board has the two passing scores on the required examinations, the board will send you a green sheet titled "Request for Issuance of Pharmacist License." You will be asked for a license fee and advised of any deficiencies remaining in your application. Typically the only deficiencies at this stage are results to the background clearances. If you believe that you have already

corrected the deficiency, use the "Contact Us" feature from the board's website to email us or attach a note to the green sheet when you return it to the board.

We try to process these applications very quickly. The fastest way to know you are licensed is to use the license verification feature on the website (http://www.pharmacy.ca.gov/verify_lic.htm) and checking your name. Once your name appears as a licensed pharmacist, you are licensed. California law provides that verification of licensure from the website is proof you are licensed. You will receive a green, wallet-size license in about 8 weeks (another agency prints and mails these for the board). The large wall license will be mailed within four months.

TIPS for faster and smoother processing, remember:

1. Use one of the processes we suggest for verifying that the board received your application.
2. Status checks are a problem for the board to perform. It diverts limited staff away from processing activities to simply answering a question for someone. We will not generally respond to status inquiries on applications that are less than 60 days old with the board. Instead we direct staff to process applications. Please be patient – and use a technique listed elsewhere in this article to make certain you know we received your application.
3. However, there are times when applicants need to reach us. Use the appropriate email address under "Contact Us" on the website. Certainly email the board if it has been more than 60 days, and you have heard nothing from the board – this is a problem you need to call to our attention. Also, if it has been more than 30 days after you believe your deficiency has been corrected, contact us.
4. If you receive a letter advising you that the board is missing some items (what we call a "deficiency letter") – this truly means we do not have the listed items. To get through the system faster, you need to provide the item, even if you may think we already have it. So what is most often missing?
   - Transcripts from colleges with the pharmacy degree posted (these must come directly from the school of pharmacy to the board). Oddly, some colleges do not post the PharmD degree to transcripts until 2-3 months after graduation.
   - Fingerprint clearances are sometimes a problem (we run both federal and state background checks). Sometimes we need to ask applicants to resubmit prints because something is preventing the board from receiving the documentation; the board will contact you if additional information is required.
   - Intern hours are missing or less than the 1,500 hours required.
5. Make certain your name matches identically on your government identification, with your social security card and with your name of record that you file with the board (this is the name that will appear on your pharmacist license). Identically means identically (see the board's website for more ir tion). Resolving name conflicts is the one area whe should not wait 60 days before resolving the problem.
6. The board periodically conducts quality assurance rev the CPJE. When this occurs, no CPJE scores are releas the assessment is completed. The board makes ever to release scores as soon as we can, but a quality assurance check usually runs 2-3 months or until approximately 400 individuals take the test. We know this is frustrating, but it is necessary. We post this information on the website.
7. Background checks - if you have a prior conviction, you need to disclose it in the required place on the application and describe it fully. (You need to do this if you have reported the conviction on prior applications.) Even if you think a conviction has been expunged or set aside and dismissed, the clearance check usually picks up these records. If you state you have no convictions and yet a background check shows you do, this will be come an "enforcement issue." Enforcement issues will delay the processing of your application or issuance of a license until all enforcement matters are resolved (typically this adds at least two months).

What can you do?

1. Submit as complete an application as you can. This means you should submit in one package:
   - All required application forms
   - The required fee
   - Proof of at least 1,500 hours of intern experience
   - Verifications of pharmacist licensure from all states in which you are licensed
   - LiveScan Receipt showing submission of your fingerprints or if you are out-of-state, enclosing the fingerprint cards and additional processing fee.
2. How to verify the board has received your application:
   - Enclose a self-addressed, stamped post card, or simply an envelope addressed to you with your application package. Board staff will mail these to you when the board receives your application – so you know we have your application.
   - Check to see if the bank has cashed your check. The board cashes all checks it receives very quickly – within two working days of receipt. If the check has been cashed, we received your application.
3. Contact us if it has been more than 60 days since you submitted your application and you have heard nothing from the board, or more than 30 days since you have taken steps to correct a deficiency and you have had no response from the board.

The board wants all qualified applicants to become licensed as quickly and effortlessly as possible. Use the information above to aid you in getting though the process as expediently as possible. ◆

Attachment 3

Text Required on the Notice to Consumers Poster

§ 1707.2. Notice to Consumers and Duty to Consult.

(f) In every pharmacy subject to the provisions of Business and Professions Code Section 4122, there shall be prominently posted in a place conspicuous to and readable by prescription drug consumers the following notice:

> "NOTICE TO CONSUMERS"
> At your request, this pharmacy will provide its current retail price of any prescription without obligation. You may request price information in person or by telephone.
>
> Ask your pharmacist if a lower-cost generic drug is available to fill your prescription.
>
> Prescription prices for the same drug vary from pharmacy to pharmacy. One reason for differences in price is differences in services provided.
>
> Before taking any prescription medicine, talk to your pharmacist; be sure you know:
>
> > What is the name of the medicine and what does it do?
> > How and when do I take it – and for how long? What if I miss a dose?
> > What are the possible side effects and what should I do if they occur?
> > Will the new medicine work safely with other medicines and herbal supplements I am taking?
> > What foods, drinks or activities should I avoid while taking this medicine?

Ask your pharmacist if you have additional questions.

(g) In addition to the "NOTICE TO CONSUMERS" referred to in subdivision (f), every pharmacy subject to the provisions of Business and Professions Code §4122 shall prominently post in a place conspicuous to and readable by prescription drug consumers the following notice:

Know your rights under California law concerning medicine and devices prescribed to you.

> You have the right to receive medicine and devices legally prescribed to you, unless:
> 1. The medicine or device is not in stock in the pharmacy,
> 2. The pharmacist, based upon his or her professional judgment determines providing the item:
>
> - is against the law,
> - could cause a harmful drug interaction, or
> - could have a harmful effect on your health

This pharmacist may decline to fill your prescription for ethical, moral or religious reasons, but the pharmacy is required to help you get the prescription filled at this or another nearby pharmacy timely.

The pharmacy may decline to provide the medicine or device if it is not covered by your insurance or if you are unable to pay for the item or any copayment you owe.

If the pharmacy is unable to fill your prescription, you are entitled to have the prescription returned to you or transferred to another nearby pharmacy. Ask about our procedure to help you get an item that we don't have in stock.

Any questions? Ask the pharmacist!

Attachment 4

Senate Bill 472 (Corbett, Chapter 470, Statutes of 2007)

Senate Bill No. 472

CHAPTER 470

An act to add Section 4076.5 to the Business and Professions Code, relating to pharmacy.

[Approved by Governor October 11, 2007. Filed with Secretary of State October 11, 2007.]

LEGISLATIVE COUNSEL'S DIGEST

SB 472, Corbett. Prescription drugs: labeling requirements.

Existing law, the Pharmacy Law, provides for the licensure and regulation of the practice of pharmacy by the California State Board of Pharmacy in the Department of Consumer Affairs. Existing law prohibits a pharmacist from dispensing a prescription, except in a container that meets certain labeling requirements.

This bill would require the board to promulgate regulations that require, on or before January 1, 2011, a standardized, patient-centered, prescription drug label on all prescription medication dispensed to patients in California. The bill would require the board to hold special public meetings statewide in order to seek information from certain groups, and would require the board to consider specified factors in developing the label requirements. The bill would require the board to report to the Legislature on or before January 1, 2010, on its progress at the time of the report, and to report to the Legislature on or before January 1, 2013, on the status of implementation of the requirements.

Because a knowing violation of the Pharmacy Law constitutes a crime, and because the above-described provisions would impose additional duties under that law, this bill would impose a state-mandated local program.

The California Constitution requires the state to reimburse local agencies and school districts for certain costs mandated by the state. Statutory provisions establish procedures for making that reimbursement.

This bill would provide that no reimbursement is required by this act for a specified reason.

The people of the State of California do enact as follows:

SECTION 1. This act shall be known and may be cited as the California Patient Medication Safety Act.

SEC. 2. The Legislature hereby finds and declares all of the following:

(a) Health care costs and spending in California are rising dramatically and are expected to continue to increase.

(b) In California, prescription drug spending totaled over $188 billion in 2004, a $14 billion dollar per year spending increase from 1984.

(c) Prescription drug cost continues to be among the most significant cost factors in California's overall spending on health care.

(d) According to the Institute of Medicine of the National Academies, medication errors are among the most common medical errors, harming at least 1.5 million people every year.

(e) Up to one-half of all medications are taken incorrectly or mixed with other medications that cause dangerous reactions that can lead to injury and death.

(f) Approximately 46 percent of American adults cannot understand the label on their prescription medications.

(g) Ninety percent of Medicare patients take medications for chronic conditions and nearly one-half of them take five or more different medications.

(h) Nearly six out of 10 adults in the United States have taken prescription medications incorrectly.

(i) The people of California recognize the importance of reducing medication-related errors and increasing health care literacy regarding prescription drugs and prescription container labeling, which can increase consumer protection and improve the health, safety, and well-being of consumers.

(j) The Legislature affirms the importance of identifying deficiencies in, and opportunities for improving, patient medication safety systems in order to identify and encourage the adoption of structural safeguards related to prescription drug container labels.

(k) It is the intent of the Legislature to adopt a standardized prescription drug label that will be designed by the California State Board of Pharmacy for use on any prescription drug dispensed to a patient in California.

SEC. 3. Section 4076.5 is added to the Business and Professions Code, to read:

4076.5. (a) The board shall promulgate regulations that require, on or before January 1, 2011, a standardized, patient-centered, prescription drug label on all prescription medicine dispensed to patients in California.

(b) To ensure maximum public comment, the board shall hold public meetings statewide that are separate from its normally scheduled hearings in order to seek information from groups representing consumers, seniors, pharmacists or the practice of pharmacy, other health care professionals, and other interested parties.

(c) When developing the requirements for prescription drug labels, the board shall consider all of the following factors:

(1) Medical literacy research that points to increased understandability of labels.

(2) Improved directions for use.

(3) Improved font types and sizes.

(4) Placement of information that is patient-centered.

(5) The needs of patients with limited English proficiency.

(6) The needs of senior citizens.

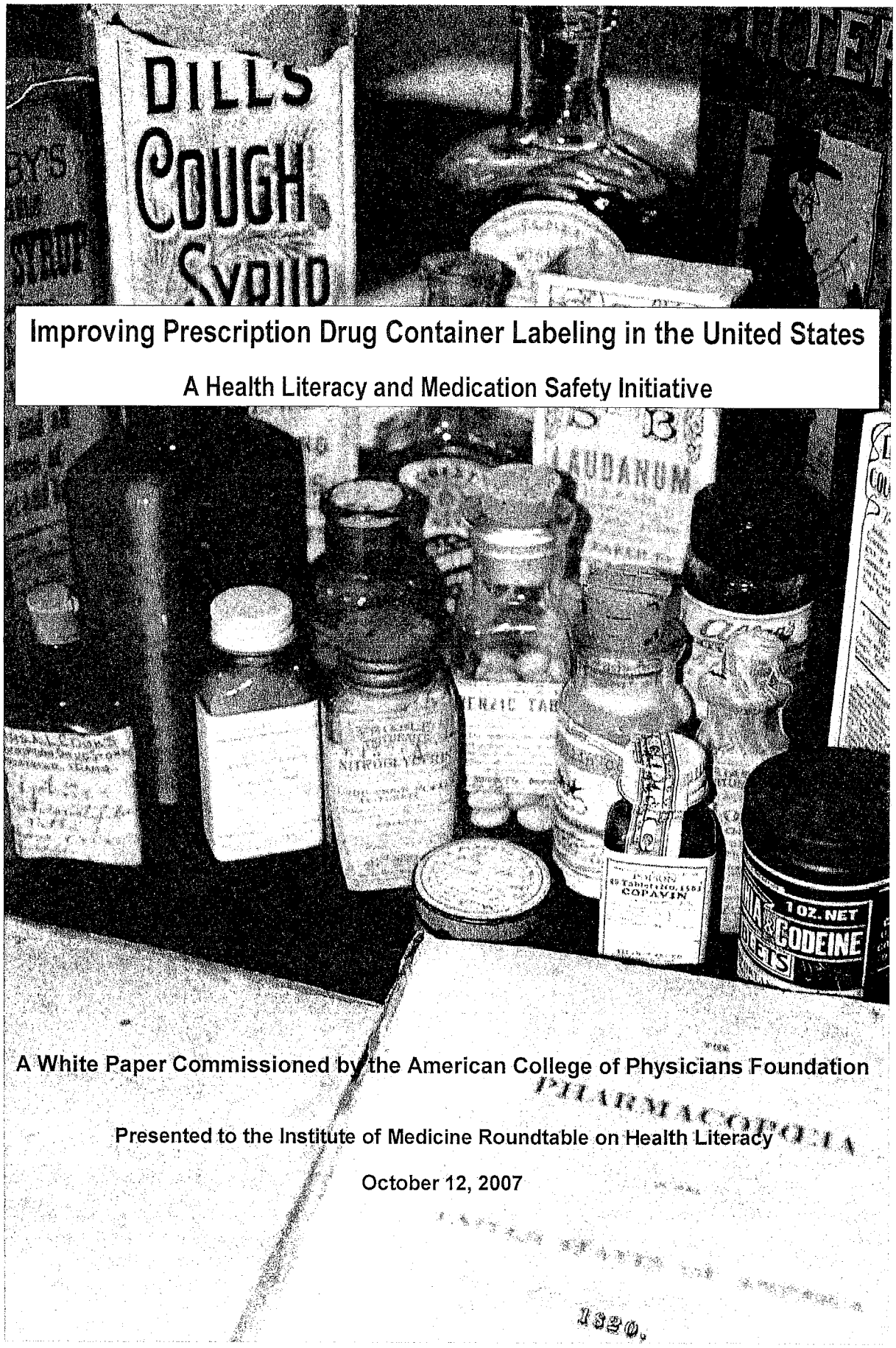
(7) Technology requirements necessary to implement the standards.

(d) (1) On or before January 1, 2010, the board shall report to the Legislature on its progress under this section as of the time of the report.

(2) On or before January 1, 2013, the board shall report to the Legislature the status of implementation of the prescription drug label requirements adopted pursuant to this section.

SEC. 4. No reimbursement is required by this act pursuant to Section 6 of Article XIII B of the California Constitution because the only costs that may be incurred by a local agency or school district will be incurred because this act creates a new crime or infraction, eliminates a crime or infraction, or changes the penalty for a crime or infraction, within the meaning of Section 17556 of the Government Code, or changes the definition of a crime within the meaning of Section 6 of Article XIII B of the California Constitution.

O



Improving Prescription Drug Container Labeling in the United States

A Health Literacy and Medication Safety Initiative

A White Paper Commissioned by the American College of Physicians Foundation

Presented to the Institute of Medicine Roundtable on Health Literacy

October 12, 2007

Report Presented on Behalf of the ACPF Medication Labeling Technical Advisory Board

Committee Co-Chairs:

Michael S. Wolf, PhD, MPH *Feinberg School of Medicine, Northwestern University*

Ruth M. Parker, MD *Emory University School of Medicine*

Members:

Carolyn Clancy, MD *Agency for Healthcare Research and Quality*

Frank Frederico, RPh *Institute for Healthcare Improvement*

Charles Ganley, MD *Food and Drug Administration*

William H. Shrank, MD MSHS Brigham and Women's Hospital; *Harvard Medical School*

Scott Smith, PhD PharmD *Agency for Healthcare Research and Quality*

Roger Williams, MD *U.S. Pharmacopeia*

Alastair Wood, MD *Symphony Capital, LLC*

Albert Wu, MD MPH *Johns Hopkins Bloomberg School of Public Health*

ACPF Staff:

Robert L. Harnsberger, MBA, VP/COO *American College of Physicians Foundation*

Jean A. Krause, EVP/CEO *American College of Physicians Foundation*

Acknowledgements:

John Swann, PhD *Food and Drug Administration*

Diane Wendt *Smithsonian Institution*

Special Thanks:

Stacy Cooper Bailey, MPH *Northwestern University*

Kara Jacobson, MPH *Emory University*

TABLE OF CONTENTS

Executive Summary	4-5
Prologue	6
Drug Container Labeling as a Matter of Medication Safety	7-8
The Patient Perspective	9-14
A Health Literacy Concern	9-10
Sources of Patient Medication Information	10-12
Health Literacy and Medication Safety	12-13
A Broken System	14-18
The Prescriber	14
The Dispensing Pharmacy	15-17
Health Information Technology	17-18
A Brief History of Drug Labeling	19-26
Early Attention to Drug Labels	19-23
Beyond the Bottle: The Learned Intermediary	23-25
The Modern Drug Label: Contents and Oversight	25-26
Setting Standards: An Evidence-Based Drug Container Label	27-29
Specific Report Recommendations	30-33
Conclusions	34
References	35

EXECUTIVE SUMMARY

According to the Institute of Medicine (IOM) 2006 report, Preventing Medication Errors, more than half a million adverse drug events (ADEs) occur in the United States each year in outpatient settings. Problems with prescription drug (Rx) labeling were cited as the cause of a large proportion of outpatient medication errors and ADEs, as patients may unintentionally misuse a prescribed medicine due to improper understanding of instructions. Recent health literacy research has highlighted the alarmingly high prevalence of patients misunderstanding seemingly simple instructions and warnings placed on Rx container labels. The elderly, those with limited literacy skills, and individuals managing multiple medication regimens were found to be at greater risk for making errors in interpreting container label instructions.

The ability to understand Rx container label instructions is critical, both as *health literacy* and *medication safety* concerns. This is especially true since other sources of patient medication information are insufficient. Prior studies have found that physicians and pharmacists frequently miss opportunities to adequately counsel patients on newly prescribed medicines. Other supplementary sources, such as patient information leaflets and Medication Guides dispensed with the prescribed medicine are too complex and written at a reading level unsuitable for the majority of patients to comprehend. As a result, these materials are often ignored. While all of these sources are best viewed as a *system* of patient information, the Rx container label is particularly important as it is often the sole source of specific instructions received and repeatedly used by patients on how to self-administer medicines.

Despite its potential value, there are clear problems with Rx container labels. Minimal standards and regulations exist regarding their content and format, and Rx labels can vary by dispensing pharmacy. Specific dosage instructions on the container label are dependent on what the prescribing physician writes, as well as how the pharmacist interprets these instructions. While the format and content of Rx container labels may differ between and within local and national pharmacies, all share the common attribute of being unnecessarily complex

and not offering a patient-friendly interface. Instead, the greatest emphasis is placed on provider-directed content.

This report reviews in detail the problem with Rx container labels in the United States. The 'best practices' in drug container labeling are summarized. Recommendations are offered to guide medical and pharmacy practice, and related state and federal policy. The overall objective of this paper is to move forward a set of evidence-based, Rx container label standards that will minimize patient confusion and promote patient awareness of how to use a prescribed medicine safely and effectively, thereby reducing risk of medication error.

Table 1. Primary Findings

Finding 1	*Inadequate patient understanding of prescription medication instructions and warnings is prevalent and a significant safety concern.*
Finding 2	*Lack of universal standards and regulations for medication labeling is a 'root cause' for misunderstanding and medication error.*
Finding 3	*An evidence-based set of practices should guide all label content and format.*
Finding 4	*Instructions for use on the container label are especially important for patients and should be clear and concise. Language should be standardized to improve patient understanding for safe and effective use.*
Finding 5	*Drug labeling should be viewed as part of an integrated system of patient information. Improvements are needed beyond the container label, and other sources of consumer medication information should be targeted.*
Finding 6	*Health care providers are not adequately communicating to patients, either orally or in print, about prescribed medicines. More training is needed to promote best practices for writing prescriptions and counseling patients.*
Finding 7	*Support is necessary for research on drug labeling and to identify 'best practices' for patient medication information.*

PROLOGUE

Since 2002, the American College of Physicians Foundation (ACPF) has sought to address the problem of limited health literacy by developing initiatives to mitigate the impact of this highly prevalent problem on health outcomes. The issue of inconsistent and confusing medication information and labeling soon became a primary target of the ACPF health literacy agenda. A few projects were commissioned by the ACPF, and informal activities were spearheaded to engage experts and stakeholders from academia, industry, and government. In September 2006, a meeting was held in Washington D.C. to discuss the ACPF's medication labeling initiatives and to suggest next steps for ACPF. The overall objective of the meeting was to consolidate an understanding of the broad problem of inadequate patient understanding of medication labels, and to identify a specific course of action to improve drug labeling in the United States. The meeting served as a timely response to Institute of Medicine (IOM) reports, released in July and September 2006, which targeted medication error and drug safety, respectively. Participants at this meeting included national experts in health literacy, patient safety, pharmacology, and pharmacy policy and practice. The Agency for Healthcare Research and Quality (AHRQ), the Institute of Medicine (IOM), and the Food and Drug Administration (FDA) were represented.

Participants reviewed the nature and extent of the problems surrounding medication labeling, particularly for prescription drugs. Summaries were provided from the July 2006 IOM report, Preventing Medication Errors, the FDA over-the-counter (OTC) consumer education initiatives, an ACPF-commissioned medication labeling systematic literature review, and recent health literacy research studies. Herein, this white paper presents the ACPF perspective on the current prescription medication *container* labeling system, with a focus on improving the format, content, and dosage and use instructions on the container label.

PRESCRIPTION DRUG CONTAINER LABELING: A MEDICATION SAFETY CONCERN

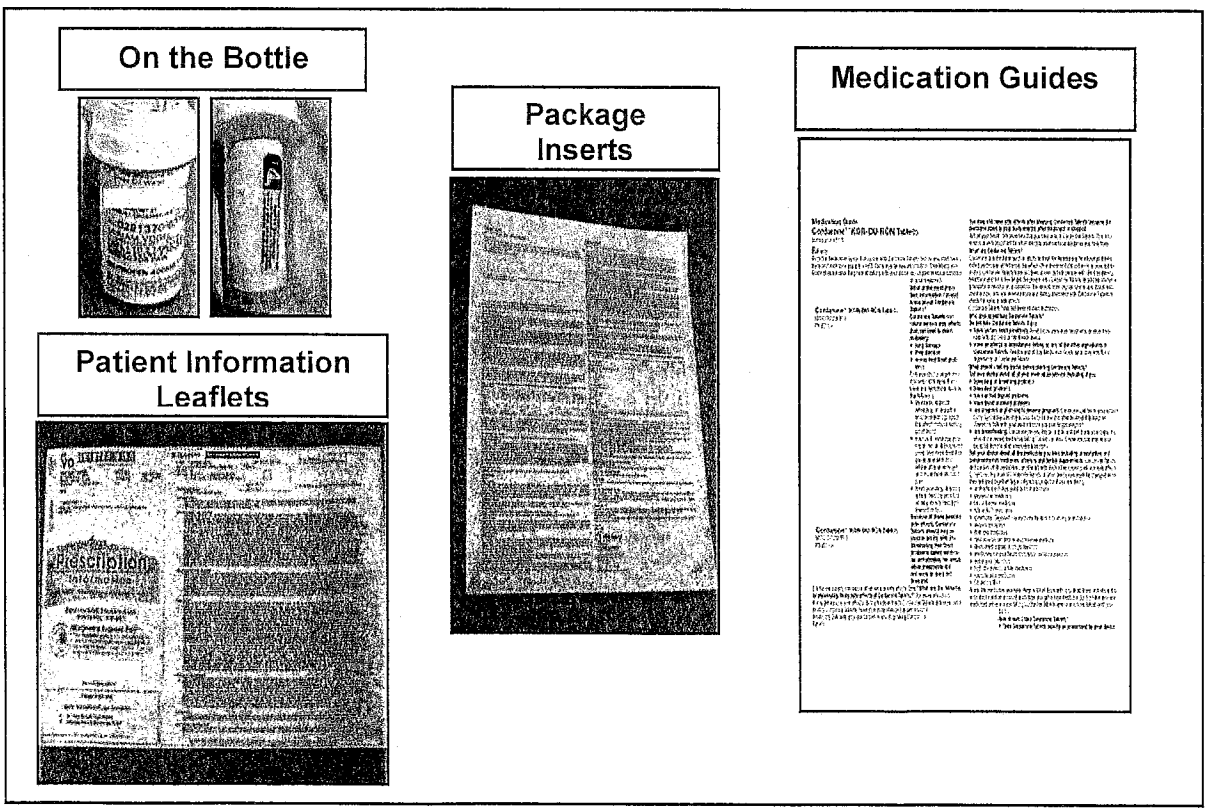
Patient safety remains one of the most important objectives for health care providers and organizations.[1-5] Medication errors, in particular, are the most common form of mistakes that lead to patient injury, hospitalization, and death.[6-19] According to the recent IOM report, Preventing Medication Errors, approximately 1.5 million preventable adverse drug events occur each year; more than one third of these take place in outpatient settings at a cost approaching $1 billion annually.[20] Both physicians and patients identify this as an area of serious concern, as a growing number of adults self-administer prescription medicines each year. Errors in ambulatory care are likely to increase as patients are self-managing a greater number of prescription and over-the-counter (OTC) medications. Two thirds of all adults use prescription drugs, representing 16 percent ($73 billion) of all health care expenditures.[21] According to the Medical Expenditures Panel Survey (MEPS), the average number of prescription medications filled annually by adults in the United States increased between 1996 and 2003 from 7 to 10 prescriptions. Among adults over 65 years of age, the average number of prescriptions filled increased from 19 to 27 medicines during this same time period.[21] Further complicating the problem, elderly patients are cared for by an average of 8 different health providers, each of whom may use different instructions for the same dosing frequencies . A clear understanding of the existing failures has therefore been sought to reduce the potential for costly errors in the future.

There is a limited body of evidence detailing the possible causes of outpatient medication error. Attention to the causes of error has most often been directed to the role of the health care provider or the system in causing errors during the prescribing, ordering, dispensing or administering of a medicine.[1] This may be an appropriate focus for inpatient hospital or nursing home settings, where most studies investigating medication error have been conducted.[15-19] However, studies estimate that many outpatient medication errors occur when patients themselves fail to administer a medicine as intended.[6,7,13,14,22,23] For ambulatory care, the

patient, rather than the provider, is ultimately responsible for correctly administering a medicine as prescribed. In this setting, the processes of quality control and monitoring of medication use shift from provider to patient.[14]

Given the formative role patients must play in promoting medication safety in outpatient settings, it is instructive to understand current processes that can help an individual learn how to use prescribed medicines appropriately. These include both verbal and written communication about taking medication; it is the tangible, written sources that comprise drug container labeling that are of special interest to this report. Figure 1 provides a breakdown of what specifically is meant by the broader term of 'drug labeling'. The prescription container label warrants special attention, as it often may be the only prescription drug information seen and used repeatedly by patients. As this report will detail, container labels for prescription drugs have been undervalued and neglected, despite their critical importance in conveying instructions for use to patients.

Figure 1. Components of Drug Labeling.



THE PATIENT PERSPECTIVE

The past 100 years have led to a fractured system of delivering adequate assurances of instructions for safe and effective use of prescription drugs to patients. In the past decade, the health literacy movement in the United States has placed greater attention on the responsibility of the health care system to support patients' ability to read, understand, and act on health information. Health literacy emphasizes the unique value of container labeling for prescription drugs as a patient source of essential health information, vital for drug safety and efficacy.

A Health Literacy Concern

Recent studies have highlighted *limited health literacy* as a potential risk factor for higher rates of outpatient medication error that are the result of improper dosing administration.[20,22,24] Health literacy, as defined by the IOM report A Prescription to End Confusion and accepted by the National Library of Medicine is the "degree to which individuals have the capacity to obtain, process, and understand basic health information and services needed to make appropriate health decisions."[24] An estimated one third to one half of adults in the United States – as many as 90 million Americans - possess limited health literacy skills, and may have trouble understanding and acting on health materials. Information in less familiar print contexts, such as prescription container labels, may be confusing and more difficult to comprehend for less literate patients.[25]

According to the National Assessment of Adult Literacy (NAAL) of 2003, 14% of U.S. adults possess skills in the lowest level of prose and document literacy ('below basic'), and 22% are at the lowest level for quantitative literacy.[25] These individuals can perform only the most simple, concrete tasks associated with each of these domains. However, those with only 'basic' literacy proficiency have limited abilities and are likely to be hindered in routine daily activities. Considering individuals with basic and below basic skills combined, as many as 34% to 55% of adults in the U.S. have limited literacy skills. Estimates are significantly higher among the

elderly; 60% of individuals over the age of 65 have limited levels of prose and document literacy.[25]

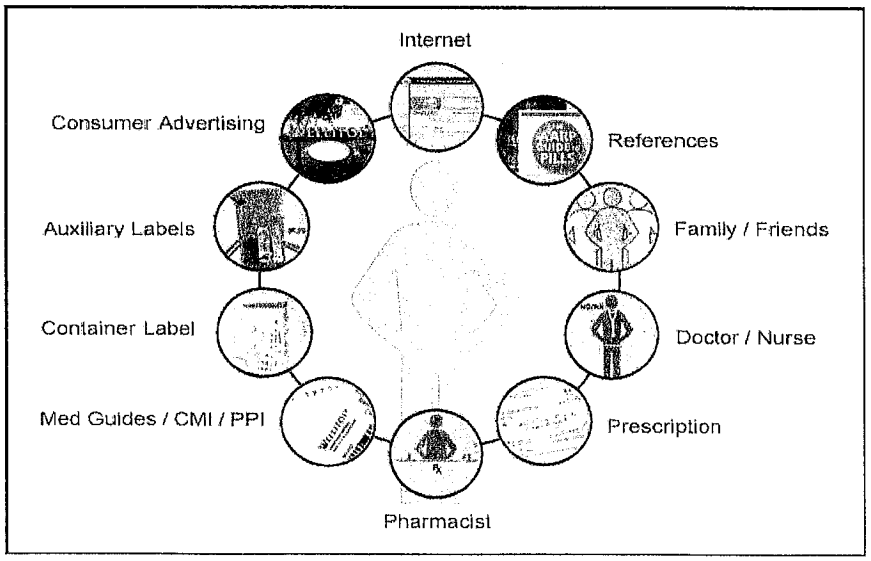
Yet reading fluency and the full range of literacy skills are likely to vary with an individual's familiarity with the content of the text.[26-28] Health materials and encounters often use difficult and unfamiliar medical terms.[29] Therefore, the estimates of limited health literacy using the NAAL general literacy assessment may underestimate the problem. As a response to this concern, the NAAL 2003 included a health literacy assessment designed to measure respondents' abilities to locate and understand health-related information and services. The health literacy assessment reported average health literacy scores on a scale of 100 to 500, with 500 representing the highest possible score. The assessment also reported results by grouping respondents with similar scores into performance levels based on health literacy ability. The performance levels designated by the assessment were: below basic, basic, intermediary, and proficient.[30] Results from the health literacy assessment showed the average health literacy scores of Americans to be lower than the average general literacy scores of adults, as measured by the NAAL. Those over 65 years of age had a health literacy mean score of 214 (the lowest average score; threshold between below basic and basic proficiency) compared to a mean score of 256 for adults between the age of 25 and 39 (the highest average score).[30] The conclusion remains the same: millions of U.S. adults – especially the elderly - lack the health literacy skills that enable them to effectively use complex health materials and accomplish more challenging health-related tasks.

Sources of Patient Prescription Medication Information

The IOM Health Literacy report emphasized that the problem of limited health literacy cannot be viewed solely as a patient issue.[24] Rather, health literacy is a duality, reflecting both individual capability and the complexity of demands placed upon the individual by the health care system. This perspective is equally valid for medication labeling in the United States. While patients

must have cognitive capacity and proficiency to read and understand labels, and apply dosage/usage instructions for proper medicine-taking behaviors, the manner in which the current health care system delivers necessary medication information to patients is inadequate. Understanding the sources available to patients and their deficits provides for a comprehensive picture of current health system failures and remedies. The existing continuum of sources of patient medication information begins at the moment a prescription is issued to the patient by the physician (see Figure 2). Physicians, with legal responsibilities to deliver instructions on proper medication use, have repeatedly been found to be ineffective in this role.[31-35] Research has shown physicians frequently miss opportunities to counsel their patients on how to self-administer their medicines.[31,34] Health literacy studies have also highlighted that many physicians do not communicate health and treatment information in a manner that can be understood by patients with limited literacy skills.[36-38] A written prescription will be passed on to patients, yet these are typically written with unfamiliar shorthand, often in Latin, and therefore of little use to patients.[1,39,40]

Figure 2. Sources of Patient Medication Information.



CMI = Consumer Medication Information; PPI = Patient Package Insert

If the patient leaves the physician office without the knowledge needed to correctly implement the prescribed regimen, the pharmacist, at the point of dispensing medicines, would be next in line to counsel patients. Studies have shown that pharmacists also often fail to orally communicate detailed information to patients to support their adherence with prescribed regimens.[32,33,35] The last opportunity for counseling is the container label and accompanying print materials (container label, patient package inserts, consumer medication information, Medication Guides), which have been found to be long, complex, and written at a level too difficult for a majority of patients, regardless of literacy level, to comprehend and use.[38,42-46]

Without accurate and available formal sources of information, individuals may seek out informal sources to learn about their medicines. Informal sources might include social networks (family, informal caregivers, friends), the internet and other reference materials. No assurances can be made to the quality, accuracy, or readability of the information provided within these sources, as their content is not regulated.[41,42,47-49]

Health Literacy and Medication Safety

Numerous studies have found limited health literacy to be significantly associated with a poorer understanding of medication names, indications, and instructions.[50-59] More recently, health literacy skills have been linked to requisite knowledge necessary for adherence to treatment regimens.[22,23,60] Recently, health literacy was specifically identified within a seminal report released by the National Council for Patient Information and Education (NCPIE).[61] The report refers to health literacy as a national concern with regard to patient understanding, safe use, and proper adherence to medication regimens.[61]

A current and well-publicized body of research has focused on the ability of patients to read, understand, and demonstrate instructions on prescription medication container labels.[22,23] This line of inquiry has also been supported by parallel work in human factors research, which

has more broadly investigated similar measures, mostly among the elderly.[62-68] Davis, et al conducted a multi-site study among adults receiving primary care at community health centers and found a high prevalence of patients, especially those with limited literacy, misunderstanding seemingly simple dose instructions provided on the primary label of medication containers.[22] In this study, 46% of adults misunderstood at least one prescription container label they encountered. The problem extends to the auxiliary sticker labels that provide accompanying warnings and instructions for use of the medicine (see Figure 2).[23,60] Other studies demonstrated that over half (53%) of patients, especially those with limited literacy, had difficulty interpreting text and icons commonly used on auxiliary warning instructions.[23]

Beyond the container label, another recent study also found accompanying medication information materials that provide indications for use and precautions are not useful for most patients, particularly those with limited health literacy.[46] This includes consumer Medication Guides that are required by the FDA to accompany certain prescribed medicines that have been identified as having serious public health concerns.[69-75] Patients with limited health literacy were significantly more likely to report not having reviewed these materials. These findings are supported by earlier research studies that suggested consumer medication materials are too difficult for many patients to read.[76-77] As a result, the patient information leaflets that accompany many prescription medications may be ignored.

Patients with limited health literacy may possess less knowledge of how to take their medicines not only as a result of difficulty with medicine labeling, but due to more limited interactions with health care providers and use of fewer alternative sources of informational support (i.e. internet, reference guides).[78] Prior research found patients with limited literacy skills to be more likely to report their physician as their sole source of health information, including for medicines taken for a chronic disease. Individuals with limited literacy are also less likely to seek out information or ask for clarification during medical encounters as a result of feelings of shame and concern over stigma for their poor reading ability.[79-81]

A BROKEN SYSTEM

The problems associated with prescription container labeling are ultimately the result of an apparent lack of standards and regulatory oversight. This results in patients receiving medications with highly variable labels, which they frequently do not understand. This is an issue of patient safety and successful therapeutic outcomes. Current drug prescribing and dispensing practices allow for variability in container labels. A lack of integration among the existing health information systems that support an increasing number of prescribers and the majority of dispensing pharmacies also add to labeling difficulties.

The Prescriber

The container label offers perhaps the only written documentation of dosage/usage instructions for the patient, which is imparted through the physician's prescription. In most pharmacies today, whatever the physician writes is what is transcribed onto the container label. Although there may be a finite number of ways a prescription can be written, the same dose and frequency schedule for a prescribed drug may be written in several different ways (i.e. every twelve hours, twice daily, in the morning and evening, at 8am and 5pm, etc.). Physicians also use a variety of Latin abbreviations to identify drug dose and frequency, rendering the prescription uninterpretable to most patients. This becomes especially problematic as many patients, especially the elderly, may have more than one health care provider prescribing medicine. It is unclear if physicians and other prescribing health care providers receive adequate training in writing prescriptions. Although electronic prescribing offers options for enhanced safety, it is still necessary to determine what physician prescribing notations optimize patients' safe and effective use of their medications.

The Dispensing Pharmacy

The contents of labels are also highly variable depending on which pharmacy a patient selects. In a recent study, data were gathered from identically written prescriptions filled for four commonly prescribed drugs (atorvastatin, alendronate, trimethoprim-sulfamethoxazole, ibuprofen) in 6 different pharmacies (2 chains, 2 independents, and 2 grocery stores) in four diverse cities.[82] Evaluation of the format of labels on filled prescriptions suggests that labels are not designed to optimize patient understanding of medication administration directions or warnings. The largest item on nearly all of the labels was the pharmacy logo. The average font size was also largest for the pharmacy logo, followed by medication instructions, and drug name. Auxiliary instruction and warning stickers averaged a much smaller font size (6.5 point), too small for many older patients to see without magnification.

Additionally, the label items that were emphasized were useful to identify the pharmacy and to enhance the practice of the pharmacist, but not to help patients safely and appropriately administer medication. Typographic cues (bolding, highlighting, use of color), recommended by health literacy experts to draw attention to important text, were more commonly used for the pharmacy name or logo and other items related to the pharmacy (prescription number, refill status, and quantity). Rather than emphasizing the information patients need to take their medications safely and appropriately, current label design focuses on pharmacy brand recognition and assisting the pharmacist.

Substantial variability was also seen in the content of the labels, especially on whether or not warning/instruction stickers were used. In the reported study, between 8% and 25% of containers did not include any warning or instruction stickers. Among those that did, the variability in the content of the stickers was alarming. For the medications filled at each pharmacy, few warnings or instructions were present on more than half of the labels purchased. Among atorvastatin labels, only 42% included a warning about pregnancy, and less than 20% included directions about taking with food, taking with water, following directions precisely, and

checking with a physician before starting other medications. 58% of alendronate containers included stickers instructing the patient not to lie down for 30 minutes after taking. Other warnings concerning important drug interactions and swallowing the drug whole were present on less than a third of labels. Ibuprofen containers had a broad range of warnings, but no single warning was consistently included on more than half of labels. Findings from this study suggest there is high variability in the format and content of container labels across dispensing pharmacies. More importantly, very few labels are currently designed to optimize appropriate and safe prescription medication use.

Variability also extends to how pharmacies translate physician medication instructions. In a follow-up study, researchers investigated how dosage instructions, written with common Latin abbreviations, were interpreted by various pharmacies.[40] Considerable differences were noted (see Table 2). Among the 85 labels evaluated, dose frequency was omitted on 6% of instructions ("Take 1 tablet for cholesterol").[40] Administration timing was explicitly stated on only 2% of instructions ("in the morning"). All four prescriptions noted earlier were written with an indication, yet pharmacies transcribed this onto 38% of labels. The prescription for alendronate stated to not lie down for at least 30 minutes after taking; this was transcribed with 50% of instructions. A total of 27% of the translated instructions had a Lexile reading grade level above a high school level.[23]

Table 2. Physician-Written Prescriptions and Pharmacy Interpretations.

Prescription	Examples of Pharmacy 'Sig' Interpretations
Lipitor 10 mg tabs Take one tab QD Dispense #30 Indication: for high cholesterol No refills	- "Take one tablet daily." - "Take 1 tablet by mouth for high cholesterol." - "Take one (1) tablet(s) by mouth once a day." - "Take one tablet by mouth every day for high cholesterol."
Fosamax 5 mg tabs Take one tab QD Dispense #30 Indication: osteoporosis prevention Do not lie down for at least 30 minutes	- "Take 1 tablet by mouth daily." - "Take one tablet by mouth every day for osteoporosis prevention. Do not lie down for at least 30 minutes after taking." - "Take 1 tablet every day, 30 minutes before breakfast with a glass of water. Do not lie down." - "Take one tablet every day."
Bactrim DS tabs Take one tab BID Dispense #6 Indication: UTI No refills	- "Take one tablet by mouth twice daily for UTI" - "Take one tablet by mouth twice daily for urinary tract infection." - "Take 1 tablet by mouth 2 times a day." - "Take 1 tablet twice daily for 3 days."
Ibuprofen 200 mg tabs Take 1-2 tabs TID PRN pain Dispense #30 No refills	- "Take 1 to 2 tablets by mouth as needed for pain." - "Take 1 to 2 tablets by mouth three times daily as needed for pain." - "Take 1 to 2 tablets by mouth as needed for pain ** Not to exceed 4 times a day" - "Take 1 to 2 tablets 3 times a day as needed for pain."

Health Information Technology

Tremendous advances have been made in the use of health information systems that support the prescribing and dispensing of medication. The 2006 IOM report, The Future of Drug Safety, directs attention to e-prescribing and the importance of health technologies for surveillance of errors and events but also to rapidly communicate risk information.[83] As more medical practices are incorporating electronic health records, many of these systems are now setting standard

'sig' messages for prescribing medications for efficiency and patient safety purposes.[84] At the point of dispensing, pharmacy systems also have been using information systems to support drug labeling. This includes default standards for translating prescriber instructions and including auxiliary warnings, with set parameters for label content and format.[85,86] Currently, the Agency for Healthcare Research and Quality (AHRQ), Center for Medicare and Medicaid Studies (CMS), and National Coalition for Prescription Drug Programs have been working to develop a finite list of standard, codified 'sig' lines to improve care and efficiency specifically for electronic prescribing practices.[87] A major problem that has been recognized by these organizations is the discordance between the uniform practices being developed through electronic health records at the point of prescribing and those systems in place within a majority of pharmacies in the U.S.. Linking the technology on both sides to ease communication and avoiding a need for interpretation at dispensing will be an essential goal for achieving a truly standard, integrated system of patient medication information.

A BRIEF HISTORY OF DRUG LABELING

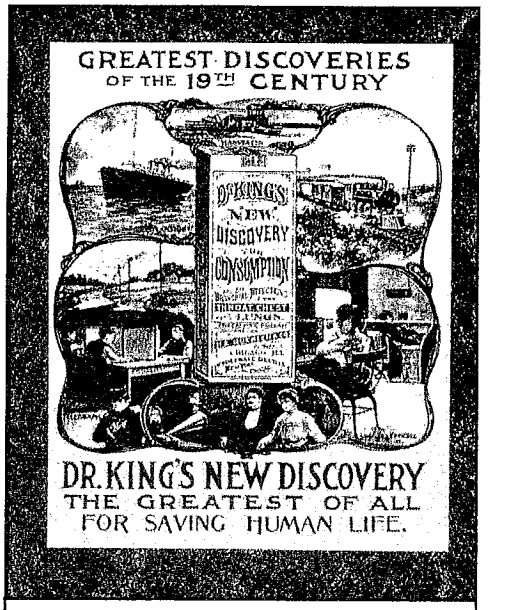
The looming problem of prescription drug container labeling is best appreciated after having a basic understanding of the relevant historical events leading up to the present circumstances. Since the formal establishment of the modern Food and Drug Administration (FDA) as a regulatory agency in 1906, four recurring themes related to drug labeling are apparent. First, oversight of drug labeling has always been a focus of the FDA, and the agency's role has gradually evolved with expanding regulatory power. Second, labeling for prescription-only medicines, in particular, is based on the assumption that physicians and other prescribers adequately communicate medication instructions to patients. Third, FDA-issued requirements for prescription drug container labeling practices are exceptionally vague. Finally, container labels for prescription-only medicines are primarily governed at the state level, and most states offer minimal guidance.

Early Attention to Drug Labeling

Instructional labels attached to vials containing the various medicines available have been in existence for centuries. Prior to the turn of the 20th century, drug container labels were designed for physician-pharmacist communication; they contained minimal content typically written in Latin abbreviations.[88] The United States Pharmacopeia (USP) was formed in 1820 to create a system of standards that would ensure quality control and drug safety. At that time, only 217 drugs met the criteria for inclusion as "most fully established and fully understood".[89] With the few possible exceptions of certain state regulations, there were no laws in place governing what could or could not be stated on the container label.[88] The Pure Food and Drugs Act of 1906 was the beginning of many federal legislative responses to promote accurate and safe practices in the labeling and marketing of drugs.

The federal government response was warranted by an increasing incidence of consumer reports and investigations of patent or 'quack' medicines. Many widely-used products

were ineffective, addictive, or even lethal.[88] This new law focused on the regulation of product labeling rather than pre-market approval. The passage of the Pure Food and Drugs Act marked the beginning of the modern era of the FDA, and with this legislation came the beginning of a limited set of federal labeling standards. Specifically, drugs defined with standards of strength, quality and purity in the USP could not be sold in any other condition unless the variations from the standards were plainly stated on the label.[88] The new law required the contents and quantity of food and drug products be clearly identified on the label attached to the container or package. Drug labels could not be false or misleading, and the presence and amount of eleven dangerous ingredients, including alcohol, heroin, and cocaine, had to be listed on the label.[88]



Dr. King's New Discovery was promoted as a major advance in science, in this case as a life-saving treatment. Yet it offered no ingredient disclosure. (Photo, FDA History Office)

What follows throughout the early decades of the 20th century is a pattern of extending federal regulatory oversight for drugs, with two distinct classifications now emerging: over-the-counter and prescription-only. This was primarily driven by a growing number of cases of unintentional drug addiction and harm. The Harrison Narcotics Act of 1914 required pharmacies to be licensed (at a cost) to dispense narcotics, and for these drugs to require a physician prescription.[90] Prior to this time, pharmacists usually followed physician recommendations and any pertinent state laws concerning dispensing practices. Problems began to emerge when physicians complained about the ability of pharmacists to dispense refills to patients for prescribed medicines without the authorization of the physician. The Harrison Act initiated the

early distinction in federal statutes between the modern classifications of prescription and over-the-counter medicines, but only for a distinct class of drugs.

With growing concern over a new class of sulfa drugs among other new therapeutic agents, the Food, Drug, and Cosmetics Act of 1938 (FDCA) further grounded the FDA as an agent of public health, deeming many more new drugs too much of a hazard for self-medication and requiring a physician's prescription for use.[90] New labeling requirements were issued with the FDCA, requiring drug labels to explicitly state to consumers all ingredients, adequate directions for use, and to include warnings of potential dangers if not administered appropriately. With the new law, manufacturers had to submit a "New Drug Application" (NDA) before the drug would be approved by the FDA. The NDA had to include information about the drug and its safety, along with prescribing information. If a medicine had a narrow therapeutic margin with apparent risks, making it difficult to detail adequate instructions for safe use, the FDA's regulations required the drug label to include a statement restricting access by mandating that the drug be dispensed only through a physician's prescription. Specifically the following statement was to be included on the label: "To be used only by or on the prescription of a physician".[90] This is referred to as the prescription legend, which is still required on prescription medicine container labels to this day (although this statement was shortened to 'Rx Only' in 2000).

An early permutation of a prescription legend. (Photo, FDA history office)

Within two months of the passage of the FDCA, the FDA began to identify drugs such as the sulfas that could not be labeled for safe use directly by the patient--they would require a prescription from a physician. Labeling manufacturers were increasingly recognized as a serious problem. Drugs that were viewed as safe for over-the-counter use were marketed as

prescription-only to avoid liability in the container/package labeling requirements for detailed instructions for use and safety warnings.[90] Laws remained unclear for prescription labeling, specifically, as the FDA assumed that physicians and pharmacists were orally communicating necessary usage directions and warnings to patients for prescribed medicines. Hence, less attention was given to the labeling on prescription drug containers or any accompanying marketing literature provided by the manufacturer. In addition, variable refill restrictions made it still possible for an individual to continue a prescription medicine, and manufacturers advertised directly to consumers to recommend their product to friends.[90] To confuse matters more, different manufacturers of the same drug often would take contradictory approaches to marketing their medicine to patients. One label might state the drug was for prescription use only, while another would be promoted for over-the-counter sale.

The Durham-Humphrey Amendment of 1951 helped put an end to some of the consumer confusion left in the wake of the FDCA, by compiling a list of medicines of the day that should be dispensed only with a physician's prescription.[90] The Amendment also established a broad outline for what constituted a prescription drug, as those medicines that were 1) habit forming, 2) toxic thereby requiring physician supervision, or 3) new drugs approved by the FDA with safety precautions.[90] Refills were addressed and these required physician authorization in the Durham-Humphrey Amendment, along the regulatory assumption of the FDA. Over-the-counter medicines were required to have adequate label instructions and warnings to instill safe use by the consumer,

The practice by some pharmacists of refilling prescriptions without the prescriber's authorization, particularly for dangerous drugs such as barbiturates and amphetamines, lead to the Durham-Humphrey Amendment to the 1938 Act. (Photo, FDA history office)

without physician consultation. However, this was not necessary for prescription-only drugs, as again it was expected access required physician consultation and information would be delivered verbally at that time. Interestingly, the Durham-Humphrey Amendment still left the ultimate determination of whether a drug would be prescription or over-the-counter to the drug manufacturer's discretion.[90]

Beyond the Bottle: The Learned Intermediary

In 1966, a pharmaceutical liability suit, *Sterling Drug Inc. v. Cornish,* established the physician as the "learned intermediary" with responsibility to communicate drug warnings passed on by the manufacturer to patients.[91] According to the learned intermediary doctrine, a prescription drug manufacturer fulfills its legal duty to warn a patient by adequately warning the prescribing physician. Of note, the duty to warn only the physician (and not the patient) is an exception to the general rule of law that adequate warning must reach the ultimate consumer in order for the manufacturer to avoid product liability in the case of harm. As the number of drugs labeled prescription only increased, manufacturers continued to maintain autonomy over labeling practices for these drugs. With the physician as learned intermediary, it was not viewed as necessary for prescription medicine labels to meet what constituted adequate written instructions and warnings for patients, as required under the FDCA.

With an increasingly litigious climate and society demanding more public disclosure, the need for consumer-directed prescription drug information was recognized. The Fair Packaging and Labeling Act of 1966 continued the FDA legacy of demanding honest and informative product labeling from the manufacturers themselves.[92] In line with a much earlier 1948 Supreme Court ruling in *Kordel v. United States* that stated supplementary materials not physically attached to the drug container could still be viewed as part of the product label, the Fair Packaging and Labeling Act mandated the inclusion of patient-directed package inserts written in lay language for all prescription drugs. This was to give patients more detailed instructions

and warnings about a prescribed drug's risks and benefits, in light of container label space limitations. By the end of 1968, the first 'patient package insert', or accompanying drug information sheet was issued for the asthma inhalant isoproterenol.[93] Not until 1970 with the issuance of a package insert for oral contraceptives did this requirement draw public attention.[88]

In 1979, the FDA attempted to require drug manufacturers to create patient package inserts for all prescription drugs. The FDA quickly revoked this regulation in 1981 after receiving criticism for the program by industry and health care provider organizations. In its place, drug manufacturers made a good faith agreement to 'self-regulate' the industry, and generate "consumer medication information" (CMI) to be distributed with prescription medicines. In 1995, the Medication Guides program was unveiled at the FDA, which required the industry to generate yet another patient information form, for certain prescription drugs deemed to be of "serious public health concern".[88] Medication Guides are similar to the earlier patient package inserts, and are now the only consumer-directed materials for prescription drugs with explicit standards in place for their development, and to which the FDA still maintains regulatory oversight. Since 1995, more than 50 prescription medications and/or drug classes have been required to include Medication Guides. With the onset of this program, the definition of drug labeling had now expanded to include the container label, package insert, consumer medication information, and Medication Guide. The prescribing information, or 'prescriber's insert', that has been required by law since 1938 for prescription-only medicines, is technically part of the label but is directed to the physician rather than the patient.

In 1997, The Keystone Dialogue, initiated by the Department of Health and Human Services and including the FDA, pharmacist associations, and the National Association of Boards of Pharmacy, was charged with developing an action plan for improving drug labeling. Recommendations targeted improvements in the reading ease of consumer medication information in order for these print materials to be accessible and useful. The published report called for consumer medication information to be written at a sixth to eighth grade level and for

improved format and organization.[75] These were recommendations only, as a review of FDA-approved materials a decade later found little improvement in the quality of patient information.

The most recent labeling effort by the FDA to ensure patient understanding of appropriate prescription drug use was the June 30, 2006 revision of 21 CFR 201.56 and 201.57, "Requirements on Content and Format of Labeling for Human Prescription Drug and Biological Products". While the new law had the patient in mind, its provisions reflect the powerful role of the learned intermediary in providing essential information to the ultimate medication consumer. Revisions specifically targeted modifications to the prescriber's insert label directed to physicians. According to the new law, all inserts must contain a *Highlights* section summarizing drug benefits and risks, as well as a table of contents. Another new section, *Patient Counseling Information*, is also now included in inserts to help summarize for physicians what information about a particular drug should be conveyed to patients. This was the first change to the package insert in 25 years. However, the package insert is aimed at educating physicians rather than patients, and these changes will likely offer little relief to patients when they pick up their prescriptions at the pharmacy.[94]

The Modern Drug Container Label: Contents and Oversight

Under 21 CFR 201 of the FDCA, the FDA now requires the following information be present on the prescription drug container label: drug name, pharmacy name and address, serial/lot number of the prescription, prescribing physician name, patient name, and instructions for use. State boards of pharmacy may impart their own additional standards for container label content and format. To date, only minimal regulations have been added by states, although enough to require national pharmacy chains to generate 31 different label styles across the 50 states.

Without explicit FDA regulatory guidance, it still remains unclear what constitutes 'adequate' label instructions and warnings according to the FDCA for the more than 13,000 FDA-approved prescription medicines in use today. With the recent dominance of direct-to-

consumer advertising and the 1999 ruling in *Perez v. Wyeth Laboratories, Inc.,* the pharmaceutical industry has had to assume greater liability to directly warn consumers, beyond the learned intermediary, of any potential risks associated with using a particular medicine.[91] Such risks have usually been conveyed through the prescriber's insert (for providers) and CMI (for patients), and not directly on the container label, due to space issues.

With limited space on the primary container label which detail dosage/use instructions, auxiliary 'warning' stickers had been included with bottles as early as the late 1950s. These secondary container labels provided special instructions and precautions, often given orally to patients by the pharmacist, to support safe patient administration. However, no regulations have existed regarding the use of these auxiliary stickers either. Despite the potential value of these stickers, the accuracy of the specific instructional and/or precautionary messages has not been confirmed through any systematic process derived in pharmacological evidence.

SETTING STANDARDS: AN EVIDENCE-BASED DRUG CONTAINER LABEL

While limited, there is evidence available to detail 'best practices' for improving dosage/usage instructions written by the prescribing physician, and the format and content of prescription medication container labels designed by the dispensing pharmacy.[95] Perhaps most importantly, the use of standard and more explicit dosage/usage instructions can improve patients' functional understanding of how and when to take a medicine (i.e. take two tablets by mouth twice daily vs. take 4 tablets a day vs. take 2 tablets in the morning, and take 2 tablets in the evening).[22] Shrank and colleagues summarized known evidence for best practices in labeling format and content, such as: increasing font size, using clear and simple language, using headers, and placing a more appropriate emphasis on organizing label content around what is most important for patients (i.e. drug name, dose, dosage/usage instructions, patient name, doctor name, quantity, refill information) instead of the provider content (i.e. pharmacy name/logo, phone number, national drug code number).[95]

The field of health literacy also offers appropriate recommendations on how best to present print medication information to lower literate audiences. For instance, sans sarif font should be used, avoidance of all capital letters for words and phrases, and using numbers instead of the text equivalent (i.e. 2 instead of "two").[22,95] When possible, text should be as large as 12 point font to display patient dosage/usage instructions. Icons for drug warnings have previously been found to be confusing for many older patients and those with limited literacy skills, and should be minimized in practice. A complete list of evidence-based, recommended standards for format, content, and instruction is detailed in Table 3.

Table 3. Description of Standards for an Enhanced Rx Container Label.

Proposed Standard	Description
1. *Use explicit text to describe dosage/interval in instructions.*	Dosage/usage instructions must clearly separate dose from interval, and provide the explicit frequency of the drug (i.e. "take 4 tablets each day. Take 2 tablets in the morning, and 2 tablets in the evening" vs. "take two tablets by mouth twice daily"). These explicit dose/use instructions will be standardized by the pharmacy to avoid physician variability for the same dose frequency.
2. *Use a universal medication schedule (UMS) to convey and simplify dosage/use instructions.*	A universal medication schedule ("UMS") can help patients identify and support the explicit text dosage/usage instructions, following a familiar format to cue patients (i.e. a pill organizer external aid; with standard intervals for taking medicines: breakfast, lunch, dinner, bedtime).
3. *Organize 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 medicine instructions. Patient-directed content will be at the top of the label, while provider-directed content will be placed at the bottom of the label. Drug name and specific dosage/usage instructions will be placed in greatest prominence.
4. *Include distinguishable front and back sides to the label.*	The Rx container label should have two distinct sides – a front (primary) and back (auxiliary) side on the bottle. The primary label will contain patient information (drug name, dose, dosage/usage instructions, patient name, doctor name, quantity, refill information) and provider content (pharmacy name/logo, phone number, national drug code #). The back should contain all appropriate warning and instruction messages and icons, supplanting the use of stickers.
5. *When possible, include indication for use.*	While Rx approval status and confidentiality may limit inclusion of indications for use, prior studies suggest this is very helpful to patients.
6. *Simplify language, avoiding unfamiliar words/medical jargon.*	Language on the label, will avoid the use of unclarified medical jargon, and common terms and sentences will be used only. While readability formulas and software are not recommended for short excerpts of text such as what is included on Rx labels, the principles established by the Suitability Assessment of Materials by Doak, Doak, and Root for maintaining simple language can guide the simplification process. Feedback should also be sought from consumers.
7. *Improve typography, use larger, sans serif font.*	A standard for minimum font size (12 pt) will be set for patient name, drug name, and specific dosage-usage instructions (both in text and in matrix). Health literacy and adult education researchers recommend the use of Sans-Serif font (i.e. Arial) to more clearly present print text information to new adult learners. Patient information on front and back labels will be 12 pt font. Use of all capital letters should be avoided; the first letter of words in text will be capitalized only.

Table 3 continued.

8. *When applicable, use numeric vs. alphabet characters.*	Our recent research efforts (see Section C), and a prior study, provide evidence that presenting numbers instead of the text equivalent (i.e. 2 vs. two) was more helpful to patients for understanding and more rapidly processing dosage/usage instructions.
9. *Use typographic cues (bolding and highlighting) for patient content only.*	Bolding and highlighting will be used for patient-centered information only. Drug name and dose will be highlighted, dosage/usage instructions bolded.
10. *Use horizontal text only.*	Several national pharmacy chains place text for warning and instruction messages vertical to the Rx label; requiring the patient to turn the bottle to read. This may create further difficulty among older adults. Only include horizontal text on the label.
11. *Use a standard icon system for signaling and organizing auxiliary warnings and instructions.*	Work towards a standard set of icons, or consider a single icon to flag patients that a warning exists for the prescribed medicine. Warnings will use 12 point font.

Current FDA Over-The-Counter (OTC) product labeling standards may provide additional guidance to future strategies to be taken with prescription medications. OTC products, such as "Drug Facts", have already been developed with health literacy considerations in mind, utilize a standard format, and have been marketed to the public, increasing their familiarity and usability. While not all OTC labeling standards are applicable for prescription medicines, patients would likely benefit from a more familiar and consistent format, especially if this could extend to dosage/usage instructions.

SPECIFIC REPORT FINDINGS

Ideally, medication labeling should be viewed as a system of information, with key components communicated to the prescriber, the dispenser, and ultimately to patients. The work of this group has used the lens of health literacy to target patients' critical need for clear and concise prescription medication instructions to support safe and effective use. Based on the evidence and potential impact for reducing confusion that may lead to medication error, standardization of the container label's content and format, including dosage instructions, is proposed as a primary evidence-based finding that the committee viewed as necessary for resolving the current prescription labeling problem. It is anticipated that several measures will be required to address the development of low literacy-appropriate patient information leaflets and Medication Guides, and provider education and training programs to increase medication counseling and best practices for writing prescriptions.

The findings of this report support the exploration into a standard label format that may potentially include set key intervals (i.e. morning, noon, evening, bedtime) that can most precisely identify dose frequency. Currently, preliminary research activities are under way by members of the committee to investigate the efficacy of a matrix visual aid on the container label to improve patient comprehension of dosage instructions. However, before this or any other standards can be recommended, perspectives from pharmacology, pharmacy and from prescribing clinicians should be sought. More research is needed to support future actions to be taken with regard to prescription medication labeling, and all modifications to the existing labeling format should be properly evaluated.

The Committee concluded with the following findings:

1. **Inadequate patient understanding of prescription medication instructions and warnings is prevalent and a significant safety concern.** Health literacy research has highlighted the high prevalence of patient misunderstanding of dosage instructions and auxiliary warnings placed on Rx container labels. The elderly, those with limited literacy, and individuals managing multiple medication regimens are at greater risk for misinterpreting prescription instructions.

2. **Lack of universal standards and regulations for medication labeling is a 'root cause' for medication error.** More than a third of all reported adverse drug events occur in ambulatory care settings, where patients primarily assume quality control over prescription medication administration. Patient misuse is a common occurrence, and the clarity and complexity of medication dose/use instructions varies greatly by dispensing pharmacy. State and federal agencies involved in consumer medication information and labeling are not united in efforts to provide regulatory guidance.

3. **An evidence-based set of practices should guide all label content and format.** A major problem for prescription drug labeling relates to content inclusion. Efforts need to be directed at minimizing information placed on the label container, particularly auxiliary instructions supporting the safe use of the product. Only warnings and instructions that are supported by pharmacological evidence, or that are otherwise thought to significantly aid the patient in self-administration should be placed on the label. If a warning or instruction message is to be recommended for a specified drug to be on the container label, then it should be required. This would limit the existing variability between and within pharmacies.

4. **Instructions for use on the container label are especially important for patients and should be written in the most clear, concise manner. Language should be standardized to improve patient understanding for safe and effective use.** Variability and confusion regarding prescription drug label dosage/usage instructions is especially problematic. While auxiliary warning and instructions may vary by pharmacy, the actual instructions for dosage and use for a medicine will often vary by prescribing physician. Explicit instructions that segregate dose (number of pills to be taken at one time) from frequency (number of times per day) are more helpful to patients. Standardized, evidenced base dosage/usage instructions with limited variability would provide patients with more useful information, and offer improved drug safety for patients. A universal medication schedule would further simplify medication-taking behavior.

5. **Drug labeling should be viewed as an integrated system of patient information. Improvements are needed beyond the container label, and other sources of consumer medication information should be targeted.** Consumer-directed materials that accompany the pill bottle container currently do not meet acceptable standards set for the design of health information for patients with limited literacy skills. Medication Guides, patient information leaflets, and other supplementary sources of medication information should follow the same patient-oriented schema for presenting content as the container label, and be simplified following current health literacy principles. Patients need to be involved in the re-design of these materials, and considerations of re-design should focus on all the components of the label as a system of information.

6. **Health care providers are not adequately communicating to patients, either orally or in print, for prescribed medicines. More training is needed to promote best practices for writing prescriptions and counseling patients.** Physicians, nurses, physician assistants and pharmacists have previously been reported as missing opportunities to adequately counsel patients on how to administer prescribed regimens. While recent FDA actions mandate content in the package insert to aid providers on what to convey to patients about specified medicines, additional training and quality improvement efforts are needed to ensure the occurrence of these practices.

7. **Research support is necessary to advance the science of drug labeling and identify 'best practices' for patient medication information.** Ultimately, funds should be allocated to support research that can systematically review the scientific evidence and detail the necessary content for inclusion on prescription container warning labels and supplementary patient medication information materials. Likewise, health services and human factors research is needed to test new labeling strategies that incorporate known 'best practices' and determine whether the changes can improve patient understanding, behaviors, and even health outcomes.

CONCLUSION

The ACPF Medication Labeling Technical Advisory Board has proposed several changes for prescription drug labeling, perhaps most notable being that dosage/usage instructions on the container label be a critical and primary focus for establishing clear standards. The importance of the container label should be reiterated as the most tangible and repeatedly used source of prescription drug instructions for use. In fact, it may be the 'last line' of informational support on how and when to take a prescribed medicine. The Advisory Board agreed that prescription medication labeling should be viewed as a *system of information*, and additional efforts must also seek to standardize and improve labeling beyond the primary prescription container label.

It is anticipated that this report will engage policymakers, researchers, and clinicians to work toward an integrated and standard system of patient medication information. The IOM report Preventing Medication Error issued a call to action to improve patient-directed medication information, including labeling and provider-patient communication. To go one step beyond the report, an agenda should be detailed that targets the prescription drug container label, and then works to integrate other formal information sources. Lessons from both the field of health literacy and human factors design should be observed. Above all, lessons from the field of health literacy underscore the need for this work to be done with patients as partners in the process, ensuring the best deliverables possible.

REFERENCES

1. Institute of Medicine. *To err is human: Building a safer health system.* Kohn L, Corrigan J, Donaldson M, editors. Washington, D.C.: National Academy Press; 2000.
2. Altman DE, Clancy C, Blendon RJ. Improving patient safety--five years after the IOM report. *N Engl J Med* 2004; 351: 2041-3.
3. Blendon RJ, DesRoches CM, Brodie M, Benson JM, Rosen AB, Schneider E, et al. Views of practicing physicians and the public on medical errors. *N Engl J Med.* 2002; 347:1933-40.
4. Vincent C. Understanding and responding to adverse events. *N Engl J Med* 2003; 348:1051-6.
5. Leape LL. Reporting of adverse events. *N Engl J Med* 2002; 347:1633-8.
6. Elder NC, Dovey SM. Classification of medical errors and preventable adverse events in primary care: a synthesis of the literature. *J Fam Pract* 2002; 51: 927-32.
7. Gandhi TK, Weingart SN, Borus J, Seger AC, Peterson J, Burdick E, et al. Adverse drug events in ambulatory care. *N Engl J Med* 2003; 348: 1556-1564.
8. Gurwitz JH, Field TS, Harrold LR, Rothschild J, Debellis K, Seger A, et al. Incidence and preventability of adverse drug events among older persons in the ambulatory setting. *JAMA* 2003; 289: 1107-1116.
9. Forster AJ, Murff HJ, Peterson JF, Gandhi TK, Bates DW. The incidence and severity of adverse events affecting patients after discharge from the hospital. *Ann Intern Med* 2003;138: 161-7.
10. Hammons T, Piland NF, Small SD, Hatlie MJ, Burstin HR. Ambulatory patient safety. What we know and need to know. *J Ambul Care Manage* 2003; 26:63–82.
11. Gandhi TK, Burstin HR, Cook EF, et al. Drug complications in outpatients. *J Gen Intern Med* 2000; 15:149–54.

12. Dovey SM, Meyers DS, Phillips RL, et al. A preliminary taxonomy of medical errors in family practice. *Qual Saf Health Care* 2002; 11:233–8.

13. Plews-Ogan ML, Nadkarni MM, Forren S, Leon D, White D, Marineau D, et al. Patient safety in the ambulatory setting. A clinician-based approach. *J Gen Intern Med* 2004; 19:719-25.

14. Budnitz DS, Layde PM. Outpatient drug safety: new steps in an old direction. *Pharmacoepidemiol Drug Saf*; Apr 24, 2006 [Epub ahead of print- is this still the case?].

15. Bates DW, Spell N, Cullen D, Burdick E, Laird N, Peterson L, et al. The costs of adverse drug events in hospitalized patients. *JAMA* 1997; 277:307-311.

16. Poon EG, Cina JL, Churchill W, Patel N, Featherstone E, Rothschild JM. Medication dispensing errors and potential adverse drug events before and after implementing bar code technology in the pharmacy. *Ann Intern Med* 2006; 145:426-34.

17. Barker KN, Flynn EA, Pepper GA, Bates DW, Mikeal RL. Medication errors observed in 36 health care facilities. *Arch Intern Med* 2002;162:1897-903.

18. Barker KN, Mikeal RL, Pearson RE, Illig NA, Morse ML. Medication errors in nursing homes and small hospitals. *Am J Hosp Pharm* 1982; 39: 987-91.

19. Gurwitz JH, Field TS, Judge J, Rochon P, Harrold LR, Cadoret C, et al. The incidence of adverse drug events in two large academic long-term care facilities. *Am J Med* 2005; 118:251-8.

20. Institute of Medicine. *Preventing Medication Errors*. Aspden P, Wolcott J, Bootman L, Cronenwett LR (eds). Washington D.C., National Academy Press, 2006.

21. Medical Expenditure Panel Survey [on-line]. Available at http://www.meps.ahrq.gov. Accessed January 3, 2007.

22. Davis TC, Wolf MS, Bass PF, Tilson H, Neuberger M, Parker RM. Literacy and misunderstanding of prescription drug labels. *Ann Intern Med* 2006; 145: 887-94.

23. Davis TC, Wolf MS, Bass PF, Middlebrooks M, Kennan E, Baker DW, Bennett CL, Durazo-Arvizu R, Savory S, Parker RM. Low literacy impairs comprehension of prescription drug warning labels. *J Gen Intern Med* 2006; 21: 847-851.

24. Institute of Medicine. Health Literacy: A prescription to end confusion. Nielsen-Bohlman L, Panzer A, Kindig DA, editors. Washington, D.C., National Academy Press 2004.

25. Kutner M, Greenberg E, Baer J. A first look at the literacy of America's adults in the 21st century. National Center for Education Statistics, U.S. Department of Education, 2005.

26. Baker DW. The meaning and the measure of health literacy. *J Gen Intern Med* 2006: 21: 878-883.

27. DeWalt DA, Pignone MP. Reading is fundamental: the relationship between literacy and health. *Arch Intern Med* 2005 Sep 26;165(17):1943-4.

28. Rudd RE, Renzulli D, Pereira A, Daltroy L. Literacy demands in health care settings: the patient perspective, in Schwartzberg JG, VanGeest JB, Wang CC (eds.): Understanding health literacy: Implications for medicine and public health. Chicago, IL, AMA Press, 2004, pp. 69-84.

29. Castro CM, Wilson C, Schillinger D. Babel- should this Babble? Babble: Physicians' use of unclarified medical jargon with patients who have type 2 diabetes and limited health literacy. In press- still in press?, *Am J Health Behav* 2007.

30. Kutner, M., Greenberg, E., Jin, Y., & Paulsen, C. (2006). The Health Literacy of America's Adults: Results from the 2003 National Assessment of Adult Literacy (NCES 2006-483). U.S. Department of Education. Washington, DC: National Center for Education Statistics.

31. Tarn DM, Heritage J, Paterniti DA, Hays RD, Kravitz RL, Wenger NS. Physician communication when prescribing new medications. *Arch Intern Med* 2006; 166:1855-62.

32. Morris LA, Tabak ER, Gondel K. Counseling patients about prescribed medications: 12-year trend. *Med Care* 1997; 35: 996-1007.

33. Metlay JP, Cohen A, Polsky D, Kimmel SE, Koppel R, Hennessy S. Medication safety in older adults: home-based practice patterns. *J Am Geriatr Soc* 2005; 53: 976-982.

34. Sleath B, Roter D, Chewning B, et al. Asking questions about medication: analysis of physician-patient interactions and physician perceptions. *Med Care* 1999; 37:1169-73.

35. Stevenson FA, Cox K, Britten N, et al. A systematic review of the research on communication between patients and health care professionals about medicines: the consequences for concordance. *Health Expect* 2004; 7: 235-45.

36. Schillinger D, Piette J, Grumbach K, Wang F, et al. Closing the loop: Physician communication with diabetic patients who have low health literacy. *Arch Intern Med* 2003:163: 83-90.

37. Weiss BD, Coyne C, and Michielutte, R., et al. Communicating with patients who have limited literacy skills: Consensus statement from the National Work Group on Literacy and Health. *J Family Practice* 1998, 46:168-176.

38. Davis TC, Williams MV, Branch, Jr., WT, Green KW. Explaining illness to patients with limited literacy. In: Whaley, Bryan B. (ed.). Explaining Illness: Research, Theory, and Strategies. Mahway, New Jersey: Larence Erlbaum Associates, 2000: 123-146.

39. Dunn EB, Wolfe JJ. Let go of Latin! Vet Hum Toxicol 2001; 43: 235-6.

40. Wolf MS, Shrank WH, Choudry NK, Agnew-Blais J, Parker RM, Shekelle P. Variability in Pharmacy Interpretations of Physician Prescriptions. *Under review, Journal of General Internal Medicine.*

41. Wallace LS, Roskos SE, Weiss BD. Readability characteristics of consumer medication information for asthma inhalation devices. *J Asthma* 2006; 43:375-8.

42. Wallace LS, Rogers ES, Turner LW, Keenum AJ, Weiss BD. Suitability of written supplemental materials available on the Internet for nonprescription medications. *Am J Health Syst Pharm* 2006 Jan 1;63(1):71-8.

43. Kang E, Fields HW, Cornett S, Beck FM. An evaluation of pediatric dental patient education materials using contemporary health literacy measures. *Pediatr Dent* 2005; 27: 409-13.

44. Kaphingst KA, Zanfini CJ, Emmons KM. Accessibility of web sites containing colorectal cancer information to adults with limited literacy. *Cancer Causes Control* 2006; 17:147-51.

45. Weintraub D, Maliski SL, Fink A, Choe S, Litwin MS. Suitability of prostate cancer education materials: applying a standardized assessment tool to currently available materials. *Patient Educ Couns* 2004; 55:275-80.

46. Wolf MS, Davis TC, Shrank W, Neuberger M, Parker RM. A critical review of FDA-approved Medication Guides. *Pat Educ Counsel* 2006; 62: 316-22.

47. Peterson G, Aslani P, Williams KA. How do consumers search for and appraise information on medicines on the Internet? A qualitative study using focus groups. *J Med Internet Res* 2003; 5: e33.

48. Batchlor E, Laouri M. Pharmaceutical promotion, advertising, and consumers. *Health Aff* 2003; Jan-Jun Suppl: W3-109-11.

49. Rosenthal MB, Berndt ER, Donohue JM, Frank RG, Epstein AM. Promotion of prescription drugs to consumers. *N Engl J Med* 2002; 346: 498-505.

50. Wolf MS, Davis TC, Arozullah A, Penn R, Arnold C, Bennett CL. Relationship between literacy and HIV treatment knowledge among individuals enrolled in HAART regimens. *AIDS Care* 2005; 17: 863-873.

51. Wolf MS, Davis TC, Cross JT, Marin E, Green KM, Bennett CL. Health literacy and patient knowledge in a Southern U.S. HIV clinic. *Int J STD AIDS* 2004; 15: 747-752.

52. Davis TC, Fredrickson DD, Potter L, Brouillette R, Bocchini AC, Williams MV, Parker RM. Patient understanding and use of oral contraceptive pills in a southern public health family planning clinic. *South Med J* 2006; 99:713-8.

53. Dowse R, Ehlers MS. The influence of education on the interpretation of pharmaceutical pictograms for communicating medicine instructions. *Intern J Pharm Pract* 2003; 11: 11-18.

54. Insel K, Morrow D, Brewer B, Figueredo A. Executive function, working memory, and medication adherence among older adults. *J Gerontol B Psychol Sci Soc Sci* 2006: 61: 102-107.

55. Stilley CS, Sereika S, Muldoon MF, Ryan CM, Dunbar-Jacob J. Psychological and cognitive function: predictors of adherence with cholesterol lowering treatment. *Ann Behav Med* 2004: 27: 117-124.

56. Gazmararian JA, Kripalani S, Miller MJ, Echt KV, Ren J, Rask K. Factors associated with medication refill adherence in cardiovascular-related diseases: a focus on health literacy. *J Gen Intern Med* 2006; 21:1215-1221.

57. Kalichman SC, Ramachandran B, Catz S. Adherence to combination antiretroviral therapies in HIV patients of low health literacy. *J Gen Intern Med* 1999; 14:267-273.

58. Chia LR, Schlenk EA, Dunbar-Jacob J. Effect of personal and cultural beliefs on medication adherence in the elderly. *Drugs Aging* 2006; 23:191-202.

59. Brown M, Frost R, Ko Y, Woosley R. Diagramming patients' views of root causes of adverse drug events in ambulatory care: an online tool for planning educational research. *Pat Educ Counsel* 2006; 62: 302-315.

60. Wolf MS, Davis TC, Bass PF, Tilson H, Parker RM. Misunderstanding prescription drug warning labels among patients with low literacy. *Am J Health System Pharm* 2006; 63: 1048-55.

61. National Council on Patient Information and Education (NCPIE) [on-line]. Available at: http://www.talkaboutrx.org/. Accessed August 15, 2007.

62. Morrow DG, Leirer VO, Sheikh J. Adherence and medication instructions: review and recommendations. *J Am Geriatric Soc* 1988; 36: 1147-1160.

63. Park DC, Jones TR. Medication adherence and aging. In Fisk AD, Rogers WA (eds) Handbook of Human Factors and the Older Adult (pp.257-287), San Diego, CA: Academic Press, 1997.

64. Rice GE, Okun MA. Older readers' processing of medical information that contradicts their beliefs. *J Gerontol: Psych Sci* 1994: 49: 119-128.

65. Gien L, Anderson JA. Medication and the elderly: a review. *J Geriatric Drug Ther* 1989; 4: 59-89.

66. Park DC, Morrell RW, Frieske D, Blackburn AB, Birchmore. Cognitive factors and the use of over-the-counter medication organizers by arthritis patients. *Human Factors* 1991; 33: 57-67.

67. Park DC, Morrell RW, Frieske D, Kincaid D. Medication adherence behaviors in older adults: effects of external cognitive supports. *Psychol & Aging* 1992; 7: 252-256.

68. Morrow DG. Elder's schema for taking medication: implications for instructional design. *J Gerontol Psych Sci* 1991; 46: 378-385.

69. Prescription drug product labeling: FDA Medication Guide requirements. Final rule. Fed Regist 1998; 63: 66378-400.

70. Medication Guides for Prescription Drug Products. Code of Federal Regulations 2004 ed. Title 21; Pt 208: 111-114.

71. Status of Useful Written Prescription Drug Information for Patients; Docket No 00N-0352. Federal Register 65 (28 April 2000): 7022.

72. American Pharmaceutical Association. Committee Policy Report on Health Literacy 2001-2002.

73. American Society of Health-System Pharmacists. ASHP Guidelines on Pharmacist-Conducted Patient Education and Counseling. Medication Therapy and Patient Care: Organization and Delivery of Services- Guidelines 1997; 192-4.

74. The American Pharmaceutical Association and APhA Foundation: Pharmacy and You: www.pharmacyandyou.org.- accessed on February 28, 2007.

75. Keystone Center. 1996. The final report of the Keystone national policy dialogue on food, nutrition, and health. Keystone, CO and Washington, DC.

76. Krass I, Svarstad BL, Bultman D. Using alternative methodologies for evaluating patient medication leaflets. *Patient Educ Couns* 2002; 47: 29-35.

77. Gustafsson J, Kalvemark S, Nilsson G, et al. Patient information leaflets: patients' comprehension of information about interactions and contraindications. *Pharm World Sci* 2005; 27: 35-40.

78. Wolf MS, Davis TC, Cross JT, Marin E, Green KM, Bennett CL. Health literacy and patient knowledge in a Southern U.S. HIV clinic. *Int J STD AIDS* 2004; 15: 747-752.

79. Wolf MS, Williams MV, Parker RM, Parikh NS, Nowlan AW, Baker DW. Patient's shame and attitudes toward discussing the results of literacy screening. *Journal of Health Communication, in press 2007.*

80. Baker DW, Parker RM, Williams MV, Pitkin K, Parikh NS, Coates W, Imara M. The health care experience of patients with low literacy. *Arch Fam Med* 1996;5:329-34.

81. Parikh NS, Parker RM, Nurss JR, Baker DW, Williams MV. Shame and health literacy: the unspoken connection. *Patient Educ Couns* 1996;27:33-9.

82. Shrank WH, Agnew-Blais J, Choudry N, Wolf MS, Kesselheim A, Avorn JL, Shekelle. The variability and poor quality of medication container labels: A prescription for confusion. *In press, Archives of Internal Medicine.*

83. Institute of Medicine. The future of drug safety: promoting and protecting the health of the public. Baciu A, Stratton K, Burke S, editors. Washington, D.C.: National Academy Press; 2006.

84. Epic Company [on-line]. Available at http://www.epicsystems.com/Company/About.php. Accessed August 20, 2007.

85. Medi-Span [on-line]. Available at http://www.medispan.com. Accessed August 20, 2007.

86. National Council for Prescription Drug Programs [on-line] Available at http://www.ncpdp.org. Accessed August 20, 2007.

87. Electronic Prescribing Initiative eHealth Initiative. Electronic Prescribing: Toward Maximum Value and Rapid Adoption. Recommendations for optimal design and implementation to improve care, increase efficiency and reduce costs in ambulatory care. Agency for Healthcare Research and Quality (AHRQ); Washington DC, April 14, 2004.

88. Swann J. Evolution of the drug label. *Food, Drug, Cosm Med Device L Digest* 1998; 15: 23-31.

89. US Pharmacopeia History [on-line]. Available at http://www.usp.org/aboutUSP/history.html. Accessed February 8, 2007.

90. Swann J. The FDA and the practice of pharmacy: prescription drug regulation before 1968, in Spillane JF, Erlen J (eds.): Federal drug control: The evolution of policy and practice. New York, NY, Haworth Press, 2004, pp 145-166.

91. Gemperli MP. Rethinking the role of the learned intermediary: the effect of direct-to-consumer advertising on litigation. JAMA 2000; 284:2241.

92. 33 Fed. Reg. 8812 (1968) (codi_ed at 21 C.F.R. ~201.305).

93. Public Law 93-608, 3 Nov. 1966, 80 U. S. Stat.

94. Avorn J, Shrank W. Highlights and a hidden hazard--the FDA's new labeling regulations. N Engl J Med. 2006 Jun 8;354(23):2409-11.

95. Shrank WH, Avorn J, Rolón C, Shekelle P. The Effect of the Content and Format of Prescription Drug Labels on Readability, Understanding and Medication Use: A Systematic Review. Ann Pharmacother. 2007 May;41(5):783-801.

EXECUTIVE SUMMARY

According to the Institute of Medicine (IOM) 2006 report, Preventing Medication Errors, more than half a million adverse drug events (ADEs) occur in the United States each year in outpatient settings. Problems with prescription drug (Rx) labeling were cited as the cause of a large proportion of outpatient medication errors and ADEs, as patients may unintentionally misuse a prescribed medicine due to improper understanding of instructions. Recent health literacy research has highlighted the alarmingly high prevalence of patients misunderstanding seemingly simple instructions and warnings placed on Rx container labels. The elderly, those with limited literacy skills, and individuals managing multiple medication regimens were found to be at greater risk for making errors in interpreting container label instructions.

The ability to understand Rx container label instructions is critical, both as *health literacy* and *medication safety* concerns. This is especially true since other sources of patient medication information are insufficient. Prior studies have found that physicians and pharmacists frequently miss opportunities to adequately counsel patients on newly prescribed medicines. Other supplementary sources, such as patient information leaflets and Medication Guides dispensed with the prescribed medicine are too complex and written at a reading level unsuitable for the majority of patients to comprehend. As a result, these materials are often ignored. While all of these sources are best viewed as a *system* of patient information, the Rx container label is particularly important as it is often the sole source of specific instructions received and repeatedly used by patients on how to self-administer medicines.

Despite its potential value, there are clear problems with Rx container labels. Minimal standards and regulations exist regarding their content and format, and Rx labels can vary by dispensing pharmacy. Specific dosage instructions on the container label are dependent on what the prescribing physician writes, as well as how the pharmacist interprets these instructions. While the format and content of Rx container labels may differ between and within local and national pharmacies, all share the common attribute of being unnecessarily complex

and not offering a patient-friendly interface. Instead, the greatest emphasis is placed on provider-directed content.

This report reviews in detail the problem with Rx container labels in the United States. The 'best practices' in drug container labeling are summarized. Recommendations are offered to guide medical and pharmacy practice, and related state and federal policy. The overall objective of this paper is to move forward a set of evidence-based, Rx container label standards that will minimize patient confusion and promote patient awareness of how to use a prescribed medicine safely and effectively, thereby reducing risk of medication error.

Table 1. Primary Findings

Finding 1	*Inadequate patient understanding of prescription medication instructions and warnings is prevalent and a significant safety concern.*
Finding 2	*Lack of universal standards and regulations for medication labeling is a 'root cause' for misunderstanding and medication error.*
Finding 3	*An evidence-based set of practices should guide all label content and format.*
Finding 4	*Instructions for use on the container label are especially important for patients and should be clear and concise. Language should be standardized to improve patient understanding for safe and effective use.*
Finding 5	*Drug labeling should be viewed as part of an integrated system of patient information. Improvements are needed beyond the container label, and other sources of consumer medication information should be targeted.*
Finding 6	*Health care providers are not adequately communicating to patients, either orally or in print, about prescribed medicines. More training is needed to promote best practices for writing prescriptions and counseling patients.*
Finding 7	*Support is necessary for research on drug labeling and to identify 'best practices' for patient medication information.*

Report Presented on Behalf of the ACPF Medication Labeling Technical Advisory Board

Committee Co-Chairs:

Michael S. Wolf, PhD, MPH *Feinberg School of Medicine, Northwestern University*

Ruth M. Parker, MD *Emory University School of Medicine*

Members:

Carolyn Clancy, MD *Agency for Healthcare Research and Quality*

Frank Frederico, RPh *Institute for Healthcare Improvement*

Charles Ganley, MD *Food and Drug Administration*

William H. Shrank, MD MSHS Brigham and Women's Hospital; *Harvard Medical School*

Scott Smith, PhD PharmD *Agency for Healthcare Research and Quality*

Roger Williams, MD *U.S. Pharmacopeia*

Alastair Wood, MD *Symphony Capital, LLC*

Albert Wu, MD MPH *Johns Hopkins Bloomberg School of Public Health*

ACPF Staff:

Robert L. Harnsberger, MBA, VP/COO *American College of Physicians Foundation*

Jean A. Krause, EVP/CEO *American College of Physicians Foundation*

Acknowledgements:

John Swann, PhD *Food and Drug Administration*

Diane Wendt *Smithsonian Institution*

Special Thanks:

Stacy Cooper Bailey, MPH *Northwestern University*

Kara Jacobson, MPH *Emory University*

Simplifying Medication Scheduling
Can We Confuse Patients Less?

Alastair J.J. Wood MD

Taking Medicines Requires Knowing

- What to take
- How many pills to take
- When to take them

© Alastair J.J. Wood

Successful Drug Therapy Requires

- Physician
  - Correct choice of drug
  - Correct choice of dosage
  - Correctly writing Rx
- Pharmacist
  - Correctly understanding Rx
  - Correctly transcribing Rx to bottle
  - Correctly transmitting information to patient

© Alastair J.J. Wood

Successful Drug Therapy Requires

- Patient
  - Access to medicines
  - Correct use of medicines
    - Correct understanding of instructions
    - Correct implementation of instructions
    - Integration of multiple medicines into schedule
    - Actually taking medicine(s)

© Alastair J.J. Wood

Correctly Taking Medication

- Much much harder than it looks!
  - When do I take them?
  - How much do I take?
    - How many tablets?
  - Which medicines do I take when?

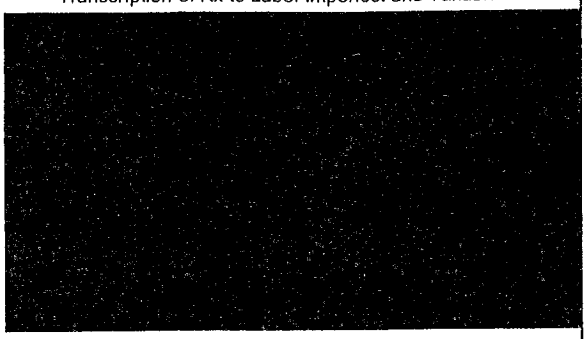
© Alastair J.J. Wood

Variability in Label Instructions "Take 1 pill a day"

- Prescriber
  - Inter—different prescribers write it 44 ways!
  - Intra—same prescriber multiple ways!
- Pharmacist
  - Inter—different pharmacists transcribe same sig differently
  - Intra—same pharmacists transcribe it differently at different times

© Alastair J.J. Wood

Transcription of Rx to Label Imperfect and Variable



© Alastair J.J. Wood

Wolf, et al., submitted 2007

Container Label Variability Varies by Pharmacy

- **Most prominent**
  - **Pharmacy name**
  - **Pharmacy phone number**
  - **Refill number**
- **Less prominent/less clear**
  - **Patient instructions**

© Alastair J.J. Wood

Patient Understanding Imperfect

- **46%** of patients misinterpret 1 or more Rx instructions on labels

Wolf MS, et al. Pat Ed Counsel 2007; 67: 293-300

© Alastair J.J. Wood

Patient Understanding Imperfect

Dosage Instruction	Interpretation
Take one teaspoonful by mouth three times daily	Take three teaspoons daily
	Take three table spoons every day
	Drink it three times a day

Wolf MS, et al. Pat Ed Counsel 2007; 67: 293-300

© Alastair J.J. Wood

Patient Understanding Imperfect

Dosage Instruction	Interpretation
Take one tablet by mouth twice daily for 7 days	Take two pills a day
	Take it for 7 days
	Take one every day for a week
	I'd take a pill every day for a week

Wolf MS, et al. Pat Ed Counsel 2007; 67: 293-300

© Alastair J.J. Wood

Patient Understanding Imperfect

Dosage Instruction	Interpretation
Take two tablets by mouth twice daily	Take it every 8 hours
	Take it every day
	Take one every 12 hours

Wolf MS, et al. Pat Ed Counsel 2007; 67: 293-300

© Alastair J.J. Wood

Patient Understanding Imperfect

Dosage Instruction	Interpretation
Take one tablet in the morning and one at 5 pm	I would take it every day at 5 o'clock Take it at 5 p.m.

Wolf MS, et al. Pat Ed Counsel 2007; 67: 293-300

© Alastair J.J. Wood

Current Situation Unsatisfactory Need For Radical Change

- Prescriptions unclear
- Transcription of Rx to label imperfect
- Patient understanding of label poor
- Variability excessive
- Complexity excessive

© Alastair J.J. Wood

Patient's Day

- 7am
- 8am
- 9am
- 10am
- 11am
- Noon
- 1pm
- 2pm

3pm
4pm
5pm
6pm
7pm
8pm
9pm
10pm

© Alastair J.J. Wood

Patient's Day
TID Med

◆ 7am	X	4pm	
◆ 8am		5pm	
◆ 9am		6pm	
◆ 10am		7pm	
◆ 11am		8pm	
◆ Noon		9pm	
◆ 1pm		10pm	
◆ 2pm		11pm	X
◆ 3pm	X		

© Alastair J.J. Wood

Patient's Day
TID Med & QID Med

◆ 7am	X	4pm	
◆ 8am	X	5pm	
◆ 9am		6pm	
◆ 10am		7pm	X
◆ 11am		8pm	
◆ Noon		9pm	
◆ 1pm	X	10pm	
◆ 2pm		11pm	X X
◆ 3pm	X		

© Alastair J.J. Wood

Patient's Day
TID Med & QID Med BID Med

◆ 7am	X	4pm	
◆ 8am	X	5pm	
◆ 9am	X	6pm	
◆ 10am		7pm	X
◆ 11am		8pm	
◆ Noon		9pm	X
◆ 1pm	X	10pm	
◆ 2pm		11pm	X X
◆ 3pm	X		

© Alastair J.J. Wood

Patient's Day
TID Med & QID Med BID Med
8 episodes/day!!!

◆ 7am	X	4pm	
◆ 8am	X	5pm	
◆ 9am	X	6pm	
◆ 10am		7pm	X
◆ 11am		8pm	
◆ Noon		9pm	X
◆ 1pm	X	10pm	
◆ 2pm		11pm	X X
◆ 3pm	X		

© Alastair J.J. Wood

Proposal
Universal Medication Schedule UMS

- Breakfast time
- Lunch time
- Supper time
- Bed time

© Alastair J.J. Wood

Proposal
Universal Medication Schedule UMS

- As far as possible all medicines should be slotted into the Universal Medication Schedule
  - Breakfast time
  - Lunch time
  - Supper time
  - Bed time

© Alastair J.J. Wood

Patient's Day
TID Med

- Breakfast time T
- Lunch time T
- Supper time
- Bed time T

© Alastair J.J. Wood

Patient's Day
TID Med & QID Med

- Breakfast time T Q
- Lunch time T Q
- Supper time Q
- Bed time T Q

© Alastair J.J. Wood

Patient's Day
TID Med & QID Med BID Med

- Breakfast time T Q B
- Lunch time T Q
- Supper time Q B
- Bed time T Q

© Alastair J.J. Wood

Patient's Day

TID Med & QID Med BID Med

8 episodes/day reduced to 4/day

- Breakfast time T Q B
-
- Lunch time T Q
- Supper time Q B
- Bed time T Q

© Alastair J.J. Wood

Proportion of Patients' Rxs Covered

- Review of 346,844 oral prescriptions
  - Once a day 51%
  - Twice a day 19%
  - Three times a day 5%
  - Four times a day 2%
  - TOTAL 77%
  - As directed/As needed 15%
  - TOTAL 92%
  - Five or more times a day 1%
  - Other 7%

Wolf, MS personal communication, October 2007

© Alastair J.J. Wood

Patient Understanding of UMS

Randomized Trial (Comprehension Testing)

- 500 patients, 2 sites (Chicago, Shreveport)
- BID, TID, QD prescriptions tested
  - Enhanced text only
  - Standard label
  - UMS label
- UMS 5x better comprehension compared to standard label ($p<0.001$)

© Alastair J.J. Wood

Wolf, MS et al. personal communication, 2007

Patient Understanding of UMS Compared to Standard Label

5x better comprehension compared to standard label ($p<0.001$)

© Alastair J.J. Wood

Wolf, MS et al. personal communication, 2007

Standard Dosing Times On Prescriptions

Alastair Wood, MD
1234 Springfield Drive
Nashville, TN 54321
(302) 432-4234

1. _____	2. _____	3. _____
Dose: _____	Dose: _____	Dose: _____
Take for: _____	Take for: _____	Take for: _____
Schedule: Breakfast / Lunch / Dinner / Bedtime	Schedule: Breakfast / Lunch / Dinner / Bedtime	Schedule: Breakfast / Lunch / Dinner / Bedtime
Additional Instructions: ☐ Take with a meal ☐ Swallow whole ☐ Do not drink alcohol ☐ Limit your time in the sun ☐ Other _____	Additional Instructions: ☐ Take with a meal ☐ Swallow whole ☐ Do not drink alcohol ☐ Limit your time in the sun ☐ Other _____	Additional Instructions: ☐ Take with a meal ☐ Swallow whole ☐ Do not drink alcohol ☐ Limit your time in the sun ☐ Other _____

© Alastair J.J. Wood

Standard Dosing Times On Containers

Glyburide 50mg 09/26/2007
This medicine is for Michael Wolf
To treat Diabetes
Prescribed by Ruth Parker, MD
Filled by Target Pharmacy
123 State Street
St. Paul, MN 12345
(312) 123-4567
You have 11 refills
Refer to Rx# 789-3452-1-0

Take 2 tablets in the morning and 2 tablets at bedtime

Breakfast	Lunch	Dinner	Bedtime
2			2

- Take with a meal
- Swallow tablet whole
- Do not drink alcohol

© Alastair J.J. Wood

Benefits

- Patients, physicians, pharmacists use the same schedule
- Variability in Rx reduced
- Variability in transcription of Rx reduced
- Patients understanding improved
- Patient adherence improved
- Therapeutic outcome improved

© Alastair J.J. Wood

Benefits

- Universal Prescription pads
- Universal labels
- Universal medicine reminder boxes
- Uniform medication schedules in pivotal clinical trials for FDA approval
- Consistent format across all domains
- Reduction in errors/variability

© Alastair J.J. Wood

Potential Objections
Drug concentration variability

- Concentrations actually vary enormously among individuals—Biological variability
- Product variability
- Brand/Generic Variability
  - FDA requirement for brand/generic equivalence
    - only requires that for peak and average concentrations (AUC) "90% CI between 80%-125% of branded product"

© Alastair J.J. Wood

FDA Definition of Equivalence

- 90 % confidence intervals for peak and average concentrations (AUC) must lie within

  80%-125% of those of branded product

© Alastair J.J. Wood

Potential Objections
Drug concentration variability

- Within patient variability will be improved by Uniform Medication Schedule
  - And that is what matters!
- Across patient variability is already greater than change produced by UMS
- No physician actually knows when meds taken

© Alastair J.J. Wood

Uniform Medication Schedule

- Simplifies dosing schedule
- No loss of efficacy
- Improves patient understanding
- Improves patient adherence
- Reduces errors
- Reduces variability
- Improves outcome

© Alastair J.J. Wood

Attachment 5

Board of Pharmacy's and DCA's New Web Sites

CA.GOV DEPARTMENT OF CONSUMER AFFAIRS
BOARD OF PHARMACY

GOVERNOR SCHWARZENEGGER
Visit his Website

REBUILD YOURLIFE

CALIFORNIA STATE BOARD OF PHARMACY

WELCOME TO THE BOARD OF PHARMACY

- Information for Licensees
- Information for Consumers
- Information for Applicants
- Online Services
- Laws and Regulations
- Written Information and Publications
- About the Board and Public Meetings
- Pending Decisions and Opportunities for Public Participation

QUICK HITS

- Verify a License
- Change of Address
- License Renewal
- File a Complaint
- Board Meetings
- Contact Us
- Join Our E-Mail List
- Newsletter - The Script
- Medicare Part D Info
- What's New
- Department of Consumer Affairs

Visit the Flex Your Power Website

Energy efficiency and conservation information. Find incentives/rebates, technical assistance, retailers, product guides, case studies and more.

Save a child with AMBER ALERT

AMBER ALERT empowers law enforcement, the media and the public to combat abduction by sending out immediate information.

CONTACT US

1625 N Market Blvd, N219
Sacramento, CA 95834
Phone (916) 574-7900
Fax (916) 574-8618

CA.GOV CALIFORNIA DEPARTMENT OF CONSUMER AFFAIRS

STATE OF CALIFORNIA
dca
DEPARTMENT OF CONSUMER AFFAIRS

REBUILD YOURLIFE

Call Toll-Free 1-800-952-5210

QUICK HITS

- Boards and Bureaus
- Identity Theft
- License Verification
- Automotive Repair
- Smog Check
- Landlord Tenant
- Media Room
- Employment Opportunities
- Consumer Services Center

SELECT YOUR LANGUAGE

Español 中文
한국어 Русский
Tagalog Việt ngữ

DCA Outreach Events

Breathe Easier

JUST RELEASED - Visit the New Consumer Services Center

I AM A CONSUMER AND NEED:

- To File a Complaint
- To Verify a License
- The Consumer Connection Magazine
- To Sign-up for Consumer Updates
- Product Recalls
- Senior Resources
- The DCA Outreach Event Calendar
- 2008 Tax Tips

More

I AM A LICENSEE AND NEED:

- To Renew My License Online
- Search for a Board or Bureau by Profession
- License Verification

More

BUSINESS FUNCTIONS:

- Employment Opportunities
- Reports
- Small Business Liaison
- Consumer Campaigns
- What We Do and How We Do it
- Boards/Bureaus
- Board Members Information

More

Visit the Flex Your Power Website

Energy efficiency and conservation information. Find incentives/rebates, technical assistance, retailers, product guides, case studies and more.

Save a child with AMBER ALERT

AMBER ALERT empowers law enforcement, the media and the public to combat abduction by sending out immediate information.

Attachment 6

Consumer Articles

Travel

- Travel News
- Travel Alerts
- For U.S. Citizens
- For Non-U.S. Citizens
- Clearing CBP
- Trusted Traveler Programs
- For Travel Industry Personnel
- Wait Times - Airport and Border
- Pleasure Boats & Private Flyers
- CBP Search Authority
- Customer Service

Report Suspicious Activity to 1-800-BE-ALERT

Medication/Drugs

print

The Federal Food, Drug, and Cosmetic Act (the Act) prohibits persons from importing into the United States any prescription drug that has not been approved for sale by the United States Food and Drug Administration (FDA), or which is adulterated or misbranded within the meaning of the Act. Moreover, in those instances where a United States manufacturer makes an FDA-approved prescription drug and sends it abroad, the Act also prohibits any person other than the original manufacturer from importing the drug back into the United States. **Thus, in virtually all instances, individual citizens are prohibited from importing prescription drugs into the United States.**

FDA Enforcement Policy Regarding the Personal Importation of Violative Drugs

The FDA has developed guidance entitled "Coverage of Personal Importations" which sets forth the FDA enforcement priorities with respect to the personal importation of unapproved new drugs by individuals for their personal use. Under this guidance, as an exercise of enforcement discretion, FDA may allow an individual entering the United States to import a three month supply of an unapproved drug if all of the following conditions are met:

1. The intended use of the drug is for a serious condition for which effective treatment may not be available domestically;
2. The drug will not be distributed commercially by the importer;
3. The product is considered not to represent an unreasonable risk;
4. The individual seeking to import the product affirms in writing that the drug is for the patient's own use and provides the name and address of the doctor licensed in the United States responsible for his or her treatment with the product, or provides evidence that the product is for the continuation of a treatment begun in a foreign country.

The FDA is responsible for pharmaceutical admissibility determinations. If you have any questions as to whether a specific pharmaceutical may be imported into the United States, please contact the FDA, Division of Import Operations and Policy, at **(301) 443-6553**.

If you have any questions regarding the importation of a controlled substance into the United States, please contact the Drug Enforcement Administration, Office of Diversion Control, International Drug Unit, at **(202) 307-2414**.

see also:

in Restricted/Prohibited Goods:

Prohibitions on Cuban Cigars

Restricted/Prohibited Goods for All Travelers

Restricted/Prohibited Goods by Country

Bird smugglers to receive higher fines

"Don't Smuggle Me...I Could Be Sick" (pdf - 247 KB.)

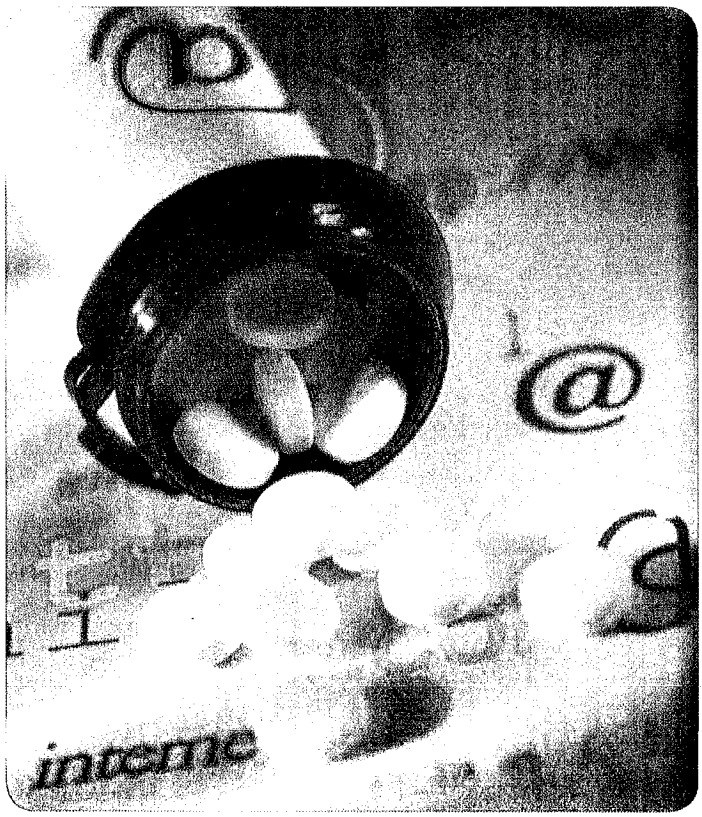
on cbp.gov:

Prohibited and Restricted Items

on the web:

FDA Warns Consumers Not to Buy or Use Prescription Drugs from Various Canadian Websites that Apparently Sell Counterfeit Products

The Possible Dangers of Buying Medicine Online



Comstock

Although counterfeit drugs may look exactly like real FDA-approved drugs, they are not legitimate and are of unknown quality and safety.

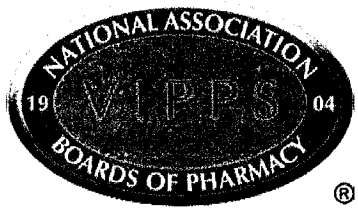
The Food and Drug Administration cannot warn people enough about the possible dangers of buying medications online. Some Web sites sell medicine, such as prescription and over-the-counter drugs, that may not be safe to use and could put people's health at risk. The current system of federal and state safeguards for protecting consumers from using inappropriate or unsafe drugs has generally served the country well. But FDA says that the best way consumers can protect themselves is to become educated about safe online shopping.

SET YOUR SITES HIGH

Buying such prescription and over-the-counter drugs online from a company you don't know means you may not know exactly what you're getting. While many Web sites are operating legally and offering convenience, privacy, and the safeguards of traditional procedures for dispensing drugs, consumers must be wary of "rogue Web sites" that aren't operating within the law. A Web site can look very sophisticated and legitimate but actually be an illegal operation.

These sites often sell unapproved drugs, or if they market approved drugs, they often sidestep required practices meant to protect consumers. Some Web sites sell counterfeit drugs. Although counterfeit drugs may look exactly like real FDA-approved drugs, they are not legitimate and are of unknown quality and safety. If you're considering buying medicine over the Internet, look for Web sites with practices that protect you. If there is no way to con-

People can be confident that Web sites that are VIPPS-approved are legitimate. Legitimate pharmacies that carry the VIPPS® seal are listed at www.vipps.info



tact the Web site pharmacy by phone, if prices are dramatically lower than the competition, or if no prescription from your doctor is required, you should be especially wary.

Safe Web sites should

- Be located in the United States.
- Be licensed by the state board of pharmacy where the Web site is operating (visit *www.nabp.info* for a list of state boards of pharmacy).
- Have a licensed pharmacist available to answer your questions.
- Require a prescription from your doctor or other health care professional who is licensed to prescribe medicines.
- Provide contact information and allow you to talk to a person if you have problems or questions.

The National Association of Boards of Pharmacy's (NABP) Verified Internet Pharmacy Practice Sites™ Seal, also known as VIPPS® Seal, gives a seal of approval to Internet pharmacy sites that apply and meet state licensure requirements and other VIPPS® criteria.

People can be confident that Web sites that are VIPPS-approved are legitimate. Legitimate pharmacies that carry the VIPPS® seal are listed at *www.vipps.info*

Unsafe Web sites

- Typically don't know your medical history or the details about your current illness or condition.
- Send you drugs with unknown quality or origin.
- Could give you the wrong medicine or another dangerous product for your illness.
- May sell prescription drugs even without a prescription—this is against the law!
- May not protect your personal information.

KNOW YOUR MEDICINES

Before you get any new medicine for the first time, talk to your doctor about any special steps you need to take to fill your prescription. In addition

- Any time you get a prescription refilled, check the physical appearance: color, texture, and shape of the drug. Even if all of these characteristics appear to be okay, there may be a problem if the medication doesn't taste like it has in the past.
- Pay special attention to altered or unsealed containers or changes in product packaging.
- Alert your pharmacist, or whoever is providing treatment, if you notice any differences or anything unusual about the product packaging.
- Make sure that you only use drugs that have been prescribed by your health care provider who is licensed in the United States to prescribe medications.

Be aware that some medicines sold online

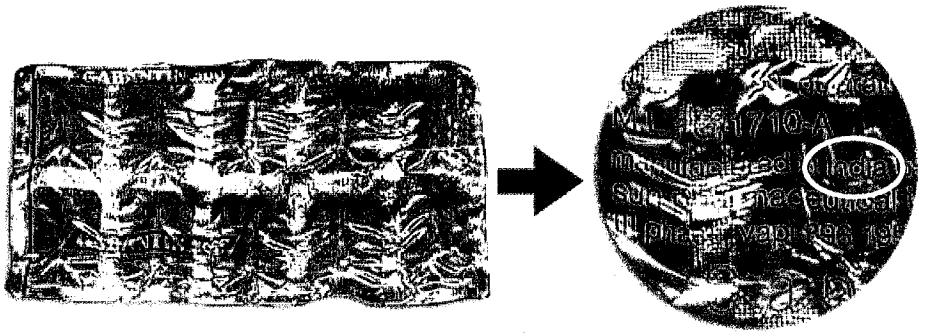
- Are too old, too strong or too weak.
- Aren't FDA-approved.
- Aren't made using safe standards.
- Aren't safe to use with other medicines or products.
- Aren't labeled, stored, or shipped correctly.

BEWARE OF COUNTERFEIT MEDICINE

Counterfeit drugs are fake or copycat medicines that can be difficult to identify. The deliberate and fraudulent practice of counterfeiting can apply to both brand name and generic products, where the identity of the source is often mislabeled in a way that suggests it is the authentic approved product. Counterfeit drugs may

- Be contaminated.
- Not help the condition or disease the medicine is intended to treat
- Lead to dangerous side effects.
- Contain the wrong active ingredient.
- Be made with the wrong amounts of ingredients.
- Contain no active ingredients at all or contain too much of an active ingredient.
- Be packaged in phony packaging that looks legitimate.

For example, counterfeit versions of the FDA-approved weight loss drug Xenical, which contains the active ingredient orlistat, recently were obtained by three consumers from two different Web sites. The agency announced in May 2007 that none of the capsules that the consumers received contained orlistat. In fact, laboratory analysis showed that one capsule actually contained sibutramine, which is the active ingre-



Drugs purchased over the Internet by an American patient who was told that the products were manufactured in the United States and were being sold from Canada. The drugs he actually received are fake "knockoffs" from India.

dient in Meridia, a prescription drug also approved by FDA to help obese people lose weight and maintain weight loss.

Using medication that contains an active ingredient other than what was prescribed by your licensed health care provider is generally unsafe.

FDA also became aware recently of a number of people who placed orders over the Internet for

- Ambien (zolpidem tartnate)
- Xanax (alprazolam)
- Lexapro (escitalopram oxalate)
- Ativan (lorazepam)

Instead of the intended drug, several customers received a product that contained haloperidol, a powerful anti-psychotic drug. As a result, some sought emergency medical treatment for symptoms such as difficulty in breathing, muscle spasms and muscle stiffness—all problems that can occur with haloperidol.

FDA continues to be proactive in aggressively protecting consumers from counterfeit drugs. The agency is working with drug manufacturers, wholesalers, and retailers to identify and prevent counterfeit drugs. FDA also has created an internal task force to explore the use of modern technologies and other measures that will make it more difficult for counterfeit drugs to get mixed up with, or deliberately substituted for, safe and effective drugs.

Generally, medications that have not been purchased with a prescription from a state-licensed pharmacy located in the United States may be unsafe and ineffective. But remember, even those drugs that are purchased from a state-licensed pharmacy Web site cannot be guaranteed safe and effective.

PROTECT YOURSELF

- Only buy from state-licensed pharmacy sites based in the U.S. (preferably from VIPPS-certified sites, when possible).
- Don't buy from sites that sell prescription drugs without a prescription.
- Don't buy from sites that offer to prescribe a medication for the first time without a physical exam by your doctor.
- Check with your state board of pharmacy or the NABP to see if an online pharmacy has a valid pharmacy license and meets state quality standards.
- Sites ending in ".com" are usually commercial sites selling products (they may be either legitimate or rogue sites). Sites that end in ".gov" (government), ".edu" (universities or medical schools), and ".org" (not-for-profit groups) may be good sources of health information.
- Use legitimate Web sites that have a licensed pharmacist to answer your questions.
- Look for privacy and security policies that are easy to find and easy to understand.
- Don't give any personal information, such as a social security number, credit card information, or medical or health history, unless you are sure the Web site will keep your information safe and private.
- Make sure that the site will not sell your personal information, unless you agree.
- Report Web sites that may be problematic. You can do this by visiting *www.fda.gov/buyonline* and clicking on "Notify FDA about problem websites."

ALERT: For a list of drugs that you should NOT buy online because of special safety restrictions, visit *www.fda.gov/cder/consumerinfo/dontBuyonNet.htm* FDA

Graphic version in PDF format

Buying Prescription Medicine Online:
A Consumer Safety Guide

Buying your medicine online can be easy.

Just make sure you do it safely.

The Internet has changed the way we live, work and shop. The growth of the Internet has made it possible to compare prices and buy products without ever leaving home. But **when it comes to buying medicine online, it is important to be very careful**. Some websites sell medicine that may not be safe to use and could put your health at risk.

Some websites that sell medicine:

- aren't U.S. state-licensed pharmacies or aren't pharmacies at all
- may give a diagnosis that is not correct and sell medicine that is not right for you or your condition
- won't protect your personal information

Some medicines sold online:

- are fake (counterfeit or "copycat" medicines)
- are too strong or too weak
- have dangerous ingredients
- have expired (are out-of-date)
- aren't FDA-approved (haven't been checked for safety and effectiveness)
- aren't made using safe standards
- aren't safe to use with other medicine or products you use

- aren't labeled, stored, or shipped correctly

MEET AND TALK WITH YOUR DOCTOR

- **Talk with your doctor** and have a physical exam before you get any new medicine for the first time.
- **Use ONLY medicine that has been prescribed** by your doctor or another trusted professional who is licensed in the U.S. to write prescriptions for medicine.
- **Ask your doctor** if there are any special steps you need to take to fill your prescription.

These tips will help protect you if you buy medicines online:

KNOW YOUR SOURCE to make sure it's safe

Make sure a website is a state-licensed pharmacy that is located in the United States. Pharmacies and pharmacists in the United States are licensed by a state's board of pharmacy. Your state board of pharmacy can tell you if a website is a state-licensed pharmacy, is in good standing, and is located in the United States. Find a list of state boards of pharmacy on the National Association of Boards of Pharmacy (NABP) website at www.nabp.info.

The NABP is a professional association of the state boards of pharmacy. It has a program to help you find some of the pharmacies that are licensed to sell medicine online. Internet websites that display the seal of this program have been checked to make sure they meet state and federal rules. For more on this program and a list of pharmacies that display the Verified Internet Pharmacy Practice Sites™ Seal, (VIPPS® Seal), go to www.vipps.info.

Look for websites with practices that protect you

A safe website should:

1. **be located in the United States and licensed by the state board of pharmacy where the website is operating (check www.nabp.info for a list of state boards of pharmacy)**
2. **have a licensed pharmacist to answer your questions**
3. **require a prescription from your doctor or other health care professional who is licensed in the United States to write prescriptions for medicine**
4. **have a way for you to talk to a person if you have problems**

BE SURE YOUR PRIVACY IS PROTECTED

Look for privacy and security policies that are easy-to-find and easy-to-understand.

Don't give any personal information (such as social security number, credit card, or medical or health history), unless you are sure the website will keep your information safe and private.

Make sure that the site will not sell your information, unless you agree.

PROTECT YOURSELF AND OTHERS

Report websites you are not sure of, or if you have complaints about a site.

Go to www.fda.gov/buyonline and click on "Notify FDA about problem websites."

Buying your medicine online can be easy. Just make sure you do it safely.

For more information on buying medicines and medical products over the Internet, go to www.fda.gov and click on "Buying Medicines Online," or go directly to www.fda.gov/buyonline.

For related information, go to:

Imported medicine www.fda.gov/importeddrugs
Counterfeit medicine www.fda.gov/counterfeit
Generic drugs www.fda.gov/cder/ogd

U.S. Department of Health and Human Services | Food and Drug Administration
www.fda.gov
1-888-INFO-FDA (1-888-463-6332)

In cooperation with the

National Council on Patient Information and Education
www.talkaboutrx.org

Consumer Education: Buying Medicines and Medical Products Over the Internet

Back to Top Back to Consumer Education

Date created: January 11, 2005; Updated October 4, 2006

U.S. Food and Drug Administration • Center for Drug Evaluation and Research

Consumer Education

Graphic version in PDF format

Looks can be deceiving.

The medicine you buy from outside the United States may be unsafe or ineffective.

Don't risk your health.

Things you should know about purchasing medicines from outside the United States.

If you buy foreign medicine from an Internet site, from a storefront business that offers to order medicine for you, or during visits outside the United States, you are taking a risk. The U.S. Food and Drug Administration (FDA) cannot guarantee the safety of these medicines.

QUALITY ASSURANCE CONCERNS. Medicines that have not been approved for sale in the United States may not have been manufactured under quality assurance procedures designed to produce a safe and effective product.

COUNTERFEIT POTENTIAL. Some imported medicines - even those that bear the name of a U.S.-approved product - may, in fact, be counterfeit versions that are unsafe or even completely ineffective.

PRESENCE OF UNTESTED SUBSTANCES. Some imported medicines and their ingredients, although legal in foreign countries, may not have been evaluated for safety and effectiveness in the United States. These products may be addictive or contain other dangerous substances.

RISKS OF UNSUPERVISED USE. Some medicines, whether imported or not, are unsafe when taken without adequate medical supervision. You may need a medical evaluation to ensure that the medicine is appropriate for you and your condition. Or, you may require medical checkups to make sure that you are taking the medicine properly, it is working for you, and that you are not having unexpected or life-threatening side effects.

LABELING AND LANGUAGE ISSUES. The medicine's label, including instructions for use and possible side effects, may be in a language you do not understand and may make medical claims or suggest specific uses that have not been adequately evaluated for safety and effectiveness.

LACK OF INFORMATION. An imported medicine may lack information that would permit you to be promptly and correctly treated for a dangerous side effect caused by the medicine.

Remember, medicines you buy outside the U.S. may be unsafe or ineffective.

It's not worth risking your health!

If you have any questions about the use of any medicine, FDA encourages you to contact your physician, your local pharmacist or the board of pharmacy for the state in which you live.

U.S. Department of Health and Human Services
Food and Drug Administration
www.fda.gov/importeddrugs
1-888-INFO-FDA

Consumer Education: Buying Medicine From Outside the United States

Back to Top Consumer Education

FDA/Center for Drug Evaluation and Research
Last Updated: April 8, 2004
Originator: OTCOM/DLIS
HTML by SJW

Looks Can Be Deceiving: The Risks Of Buying Medicines From Across The Border Or Around The World

(NAPS)—When it comes to buying medicines, the U.S. Food and Drug Administration (FDA) believes that nothing is more important than safety.

With this in mind, FDA is warning consumers not to purchase medications from foreign countries, including Canadian Internet pharmacies. Non-FDA approved products sold from these outlets can be risky and dangerous. The FDA's warning follows a recent announcement by the government of Canada that it cannot assure the safety or effectiveness of medicines being purchased by U.S. consumers from Canada.

In the U.S., FDA sets high standards to ensure that medicines are high quality, safe, and effective products. Around the world, FDA is considered the world's gold standard. Because of FDA's efforts and science-based decisions, millions of Americans can get the medicines they need and be assured of their safety and effectiveness when they buy from pharmacies and pharmacists licensed and located in the United States.

Outside the U.S., all bets are off. When buying medicines online or from so-called "store-front" pharmacies, consumers enter the world of what could be unsafe and risky products. Prescription medicines bought outside of the U.S. may be old, poorly manufactured, improperly stored or even counterfeit (fake or tampered with). Crooked people from around the world are shipping counterfeit, dangerous and illegal medicines every day. This safety gap is real: the World Health Organization has determined that more than 80 percent of medicines are counterfeit in some countries.

Bottom line: Buying medicines from outside the U.S. is risky business. Don't take the risk.

To make sure that an Internet site or pharmacy is a state-licensed pharmacy, is in good standing, and is located in the United States, check with your state board of pharmacy or with the National Association of Boards of Pharmacy (NABP) at www.nabp.net.

Consumer Education: Buying Medicine From Outside the United States

Back to Top Back to Consumer Education

Date created: August 26, 2004; Updated October 4, 2006

Kaiser Daily Health Policy Report

Thursday, December 13, 2007

Coverage & Access

Survey Looks at Parents' Views of OTC Cold and Cough Medications for Children Under Age Six After Recent Safety Concerns

A new survey from NPR, the Kaiser Family Foundation and the Harvard School of Public Health examined parents' views in light of recent concerns about the safety and effectiveness of giving over-the-counter cold and cough medications to children, NPR's "Morning Edition" reports. An FDA advisory committee in October recommended that drug makers stop marketing OTC cold medications for use in children under age six. The recommendation came after six clinical trials by a group of pediatricians showed that OTC cold medications are no more effective than a placebo in relieving cold symptoms. About three children die each year after taking cold medications, and the deaths have been linked to potential overdoses, according to "Morning Edition."

Eighty-six percent of parents are aware of the safety concerns with the medications, the survey said. According to the survey, 58% of parents think OTC cold and cough medications are "somewhat safe" for children between ages two and six, while 23% of parents believe the medications are "very safe" (Aubrey, "Morning Edition," NPR, 12/13).

The survey indicates that many parents are not sure whether they should continue to use cold and cough medications for their children under age six. According to the survey:

- 34% of parents with children under age six said they have at least temporarily stopped using OTC cold and cough medications since concerns about the treatments arose;
- 15% of parents with children ages two to six say they plan to stop using such medications;
- 30% of such parents said they plan to continue to use the treatments; and
- 28% of parents with pre-elementary school children said they have not decided what to do, and other parents responded that they were not aware of the recent safety concerns or had never given their children OTC cold and cough medications.

The survey also looked at who parents trust when making decisions about the safety of OTC cold and cough medications in their children. According to the survey 71% of parents with children under age six trust pediatricians "a lot," while half of parents said they have confidence in pharmacists. Finally, only 29% of such parents said they have a lot of trust in FDA (NPR/Kaiser Family Foundation/Harvard School of Public Health joint release, 12/13).

Sixty-two percent of parents with children under age six said their doctor has recommended using OTC cold or cough medicines for their children ("Morning Edition," NPR, 12/13).

The survey was conducted by telephone from Nov. 15 to Nov. 25 and includes responses from 1,522 adults, with an oversample of parents with young children. The survey has a margin of sampling error of plus or minus three percentage points for the full sample and plus or minus five percentage points for parents with young children (NPR/Kaiser Family Foundation/Harvard School of Public Health joint release,

12/13).

The survey is available online.

The "Morning Edition" segment also is available online.

HARVARD
School of Public Health

Toplines

NPR/Kaiser Family Foundation/Harvard School of Public Health

Children's OTC Cold Medicines: The Public, and Parents, Weigh In

December 2007

Methodology

The NPR/Kaiser Family Foundation/Harvard School of Public Health survey, *Children's OTC Cold Medicines: The Public, and Parents, Weigh In,* is part of a series of projects about health-related issues by NPR (National Public Radio), the Henry J. Kaiser Family Foundation, and the Harvard School of Public Health. Representatives of the three organizations worked together to develop the survey questionnaire and to analyze the results, with NPR maintaining sole editorial control over its broadcasts on the surveys. The survey research team included Mollyann Brodie, Ph.D., Claudia Deane, M.A., and Liz Hamel from the Kaiser Family Foundation; Professor Robert Blendon, Sc.D., and John Benson, M.A. of the Harvard School of Public Health; and Anne Gudenkauf, Joe Neel, Allison Aubrey, and Joanne Silberner from NPR.

Fieldwork was done by telephone Nov. 15 – 20, suspended for the Thanksgiving holiday, and then completed Nov. 25, 2007, among a nationally representative sample of 1,522 randomly selected respondents ages 18 and over, including an oversample of parents of young children, by ICR/International Communications Research. Interviews were conducted in English and Spanish. Sizes of the relevant populations and their associated margins of sampling error are:

	N	*Margin of sampling error*
Total population	1,522	+/- 3 percentage points
Parent of child <18	759	+/- 5 percentage points
Parent of child <6	572	+/- 5 percentage points

For results based on smaller subsets of respondents the margin of sampling error is somewhat higher.

Please note: (1) Table percentages may not add to 100% due to rounding. (2) Values less than 0.5% are indicated by an asterisk (*). (3) "Vol." indicates that a response was volunteered by the respondent and not an explicitly offered choice. (4) Sampling error is only one of many potential sources of error in this or any other public opinion poll.

(INTERVIEWER READ) My first question is about over-the-counter medicines. These are drugs that you can buy without a prescription, like cough medicines, or painkillers like aspirin, Motrin or Tylenol. Over-the-counter drugs do NOT include vitamins and herbal medicines.

1. Overall, how confident are you in the safety of over-the-counter drugs sold in the United States? Would you say you are very confident, somewhat confident, not too confident, or not at all confident?

Total	Parents	Parents of child <6	
41	**40**	**34**	Very confident
43	**48**	**50**	Somewhat confident
8	**7**	**11**	Not too confident
5	**5**	**5**	Not at all confident
2	**1**	**1**	Don't know
*	--	--	Refused

(INTERVIEWER READ) As you may know, the Food and Drug Administration, or FDA, is the federal agency responsible for regulating over-the-counter medicines sold in the U.S.

2. One of the FDA's main roles is to make sure that over-the-counter drugs are safe for consumer use. Do you think that the FDA should also be in charge of determining whether over-the-counter medicines are effective, pulling drugs from the market if they determine they don't work well, or do you think that consumers and their doctors should decide for themselves whether over-the-counter medicines seem effective for them?

Total	Parents	Parents of child <6	
43	**43**	**45**	The FDA should also be in charge
51	**51**	**50**	Consumers and their doctors should decide for themselves
6	**5**	**4**	Don't know
*	*	**1**	Refused

(INTERVIEWER READ) Now thinking specifically about over-the-counter medicines that are targeted for use by children...

3. Overall, how confident are you in the safety of children's over-the-counter drugs sold in the United States? Would you say you are very confident, somewhat confident, not too confident, or not at all confident?

Total	Parents	Parents of child <6	
22	**25**	**21**	Very confident
42	**48**	**49**	Somewhat confident
19	**15**	**16**	Not too confident
12	**11**	**13**	Not at all confident
5	**1**	**1**	Don't know
*	--	--	Refused

4. Do you think that pharmaceutical companies do enough testing to ensure that over-the-counter drugs for children are safe and effective, or do you think they do not do enough testing on these drugs?

Total	Parents	Parents of child <6	
35	**40**	**37**	Do enough testing
52	**48**	**53**	Do not do enough testing
12	**11**	**10**	Don't know
1	*	**1**	Refused

(ROTATE VERBIAGE IN PARENS)

5. As far as you know, do pharmaceutical companies test over-the-counter drugs for children (more thoroughly) than they test similar drugs for adults, (less thoroughly), or about the same amount?

Total	Parents	Parents of child <6	
12	**11**	**14**	More thoroughly
15	**14**	**14**	Less thoroughly
57	**61**	**57**	About the same amount
17	**14**	**15**	Don't know
*	*	*	Refused

6. Are you the parent of any children under age 18 living at home, or not?

Total	Parents	Parents of child <6	
36	**100**	**100**	Yes
64	--	--	No
--	--	--	Don't know
--	--	--	Refused

7. Are any of your children now living with you... (INSERT FIRST ITEM)? Are any of them (INSERT NEXT ITEM)?
(INTERVIEWER NOTE: IF RESPONDENT IS CLEAR ON CHILDREN'S AGES, I.E. "I have two children aged 3 and 5", ENTER CODE 1 IN APPROPRIATE ITEM AND ENTER CODE 2 FOR OTHER WITHOUT ASKING)

a. Under age 2
b. At least two years old but under 6 years old
c. At least 6 years old but under 12 years old
d. At least 12 years old but under 18 years old

6/7. Combo Table based on total respondents

Total	Parents	Parents of child <6	
36	**100**	**100**	Parent
17	**48**	**100**	Any children age 0 to under 6
8	**23**	**48**	Any children under age 2
14	**39**	**80**	Any children age 2 to under 6
18	**52**	**--**	No children age 0 to under 6
64	**--**	**--**	Not a parent
--	**--**	**--**	Don't know
--	**--**	**--**	Refused

(SCRAMBLE ITEMS)

8. Please tell me how much you trust each of the following sources to provide accurate information about the safety and effectiveness of over-the-counter medicines for children. (First,) what about (INSERT)?
(READ FIRST TIME, THEN READ FOR EVERY 3RD ITEM; ALWAYS READ FOR ITEM c: Do you trust them a lot, somewhat, not too much, or not at all to provide accurate information about over-the-counter medicines for children?

Based on total parents (N = 759)

Parents	A lot	Some	Not too much	Not at all	Don't know	Refused
a. Your child's doctor	**76**	**21**	**3**	*	*	--
b. Your pharmacist	**58**	**34**	**6**	**1**	**1**	*
c. Your family and friends	**29**	**47**	**15**	**8**	**1**	--
d. The FDA – that is, the Food and Drug Administration	**29**	**55**	**9**	**6**	**1**	--
e. Advertisements for over-the-counter medicines	**4**	**41**	**29**	**26**	*	*
f. The information about the product included in packages of over-the-counter medicine	**32**	**53**	**10**	**5**	*	--
g. National organizations of pediatricians	**41**	**45**	**6**	**4**	**4**	*

Based on total parents with at least one child under age 6 (N = 572)

Parents of child <6	A lot	Some	Not too much	Not at all	Don't know	Refused
a. Your child's doctor	**71**	**25**	**2**	**1**	*	--
b. Your pharmacist	**50**	**41**	**6**	**2**	**1**	*
c. Your family and friends	**24**	**49**	**17**	**9**	**1**	--
d. The FDA – that is, the Food and Drug Administration	**29**	**55**	**11**	**4**	**1**	--
e. Advertisements for over-the-counter medicines	**3**	**42**	**28**	**26**	*	*
f. The information about the product included in packages of over-the-counter medicine	**27**	**55**	**12**	**5**	*	--
g. National organizations of pediatricians	**41**	**47**	**4**	**4**	**3**	**1**

9. Last time you bought an over-the-counter drug that your child had never taken before, how confident were you that you had enough information about the drug? Would you say very confident, somewhat confident, not too confident, or not at all confident?

Parents	**Parents of child <6**	
33	**29**	Very confident
49	**52**	Somewhat confident
11	**11**	Not too confident
3	**5**	Not at all confident
3	**2**	Don't know
1	**1**	Refused
N=759	**N=572**	

10. Have you ever used over-the-counter cold or cough medicines for your children under two, or not?

Based on total parents of children under 2 (N = 254)

Parents of child <2	
56	Yes
42	No
2	Don't know
*	Refused

10a. Has your child's doctor ever specifically recommended that you use an over-the-counter cold or cough medicine for your children under two, or not?

Based on total parents of children under 2 (N = 254)

Parents of child <2	
45	Yes
52	No
3	Don't know
--	Refused

11. Thinking about your children aged 2 to under 6, have you ever used over-the-counter cold or cough medicines for them since they turned two, or not?

Based on total parents of children 2 to under 6 (N = 473)

Parents of child 2 to <6	
79	Yes
20	No
1	Don't know
--	Refused

11a. Has your child's doctor ever specifically recommended that you use an over-the-counter cold or cough medicine for your children aged two to under six, or not?

Based on total parents of children 2 to under 6 (N = 473)

Parents of child 2 to <6	
64	Yes
33	No
3	Don't know
--	Refused

(SCRAMBLE; ITEM c SHOULD ALWAYS BE LAST)

12. For each, tell me if this is a major reason, a minor reason or not a reason why you have used over-the-counter cold or cough medicines for your children: What about (READ ITEM)?

Based on total parents of children under 6 who have ever used OTC cold or cough medicines (N = 439)

Parents of child < 6	Major reason	Minor reason	Not a reason	Don't know	Refused
a. To help your child sleep better	**34**	**28**	**38**	*	--
b. To relieve your child's cold symptoms, including coughing	**78**	**17**	**4**	*	--
c. To make sure that you, as a parent, get some sleep	**10**	**24**	**66**	*	--

13. Would you say you understand whether over-the-counter cold and cough medicines are safe and effective for use in your own children, or would you say you are confused about this?

Parents	Parents of child <6	
64	**61**	Understand
34	**37**	Confused
2	**2**	Don't know
*	*	Refused
N=759	**N=572**	

14. In your own view, how effective are children's over-the-counter cold and cough medicines in relieving cold symptoms for (INSERT): very effective, somewhat effective, not too effective, or not at all effective?
(INTERVIEWER NOTE: This question is asking about children generally, not necessarily about your own children)

Based on total parents (N = 759)

Parents	Very effective	Somewhat effective	Not too effective	Not at all effective	Don't know	Refused
a. Children under age 2	**13**	**53**	**18**	**9**	**7**	*
b. Children age two to under six years old	**16**	**60**	**12**	**5**	**7**	*

Based on total parents with at least one child under age 6 (N = 572)

Parents of child <6	Very effective	Somewhat effective	Not too effective	Not at all effective	Don't know	Refused
a. Children under age 2	**14**	**52**	**16**	**10**	**7**	*
b. Children age two to under six years old	**18**	**60**	**10**	**4**	**8**	*

15. In your own view, how effective are children's over-the-counter cold and cough medicines in helping (INSERT) get a good night's sleep: very effective, somewhat effective, not too effective, or not at all effective?
(INTERVIEWER NOTE: This question is asking about children generally, not necessarily about your own children)

Based on total parents (N = 759)

Parents	Very effective	Somewhat effective	Not too effective	Not at all effective	Don't know	Refused
a. Children under age 2	**20**	**47**	**13**	**10**	**10**	*
b. Children age two to under six years old	**23**	**52**	**11**	**6**	**8**	*

Based on total parents with at least one child under age 6 (N = 572)

Parents of child <6	Very effective	Somewhat effective	Not too effective	Not at all effective	Don't know	Refused
a. Children under age 2	**17**	**47**	**13**	**14**	**9**	*
b. Children age two to under six years old	**18**	**53**	**11**	**7**	**9**	**1**

16. In your own view, how safe are children's over-the-counter cold and cough medicines for (INSERT)? Would you say...?
(INTERVIEWER NOTE: This question is asking about children generally, not necessarily about your own children)

Based on total parents (N = 759)

Parents	Very safe	Somewhat safe	Not too safe	Not at all safe	Don't know	Refused
a. Children under age 2	**19**	**47**	**19**	**12**	**3**	--
b. Children age two to under six years old	**25**	**56**	**11**	**5**	**3**	*

Based on total parents with at least one child under age 6 (N = 572)

Parents of child <6	Very safe	Somewhat safe	Not too safe	Not at all safe	Don't know	Refused
a. Children under age 2	**17**	**47**	**18**	**14**	**4**	--
b. Children age two to under six years old	**23**	**58**	**9**	**5**	**5**	*

(ROTATE VERBIAGE IN PARENS)

16b. All in all, thinking back over the past several years, would you say your views on the safety of children's over-the-counter cold and cough medicines have become more (negative), more (positive), or would you say they have stayed about the same?

Parents	**Parents of child <6**	
36	**35**	More negative
10	**9**	More positive
52	**55**	Stayed about the same
1	*	Don't know
*	--	Refused
N=759	**N=572**	

17. Lately there has been some discussion of the safety and effectiveness of over-the-counter cold and cough medicines for younger children among groups such as the FDA, drug manufacturers, pediatricians, and in the news. Would you say you have heard a lot, some, not too much or nothing at all about this?

Total	**Parents**	**Parents of child <6**	
28	**31**	**31**	A lot
36	**37**	**37**	Some
19	**18**	**18**	Not too much
16	**12**	**14**	Nothing at all
1	**1**	--	Don't know
*	--	--	Refused

(SCRAMBLE ITEMS)

18. As a result of hearing about these discussions on the safety and effectiveness of over-the-counter cold and cough medicines for children, have you done any of the following things in recent weeks, or not? Have you (INSERT), or not?

a. Talked to friends or fellow parents about this issue
b. Talked to your child's doctor about this issue
c. Gone online to learn more about this issue
d. Talked to a pharmacist about this issue
e. Stopped using these medications

17/18. Combo Table

Parents	Parents of child <6	
87	**86**	Have heard discussions of the safety/effectiveness of cold/cough medicines for younger children
44	**47**	Talked to friends/fellow parents
25	**28**	Talked to your child's doctor
22	**21**	Gone online to learn more
13	**14**	Talked to a pharmacist
30	**34**	Stopped using these medications
12	**14**	Have not heard discussions of the safety/effectiveness of cold/cough medicines for younger children
1	**--**	Don't know
--	**--**	Refused
N=759	**N=572**	

(ROTATE ITEMS 1 AND 2)

19. Thinking specifically about your child or children who are under age 2, which of the following best describes your reaction to the recent news about the safety and effectiveness of over-the-counter cold and cough medicines:

1 You plan to stop giving your children these medicines
2 You plan to continue giving your children these medicines
3 You haven't decided what you will do
4 You have never used these medicines for your child and don't plan to
5 (Vol.) Never used but may/will use in the future

7a/17/19. Combo Table based on total parents of children under 2 (N = 254)

Parents of child <2	
85	Have heard discussions of the safety/effectiveness of cold/cough medicines for younger children
16	Plan to stop giving your children these medicines
20	Plan to continue giving your children these medicines
26	Haven't decided what you will do
22	Have never used these medicines for your child and don't plan to
1	(Vol.) Never used but may/will use in the future
15	Have not heard discussions of the safety/effectiveness of cold/cough medicines for younger children
--	Don't know
--	Refused

(IF RESPONDENT ANSWERED Q.19, READ ALTERNATE VERBIAGE IN PARENS)
(ROTATE ITEMS 1 AND 2 IN SAME ORDER AS Q.19)

20. Thinking specifically about your child or children who are aged 2 to under six, which of the following best describes your reaction to the recent news about the safety and effectiveness of over-the-counter cold and cough medicines:
(Thinking specifically about your child or children who are aged 2 to under six, which of the following best describes your reaction?)

7b/17/20. Combo Table based on total parents of children 2 to < 6 (N=473)

Parents of child 2 to < 6	
85	Have heard discussions of the safety/effectiveness of cold/cough medicines for younger children
15	Plan to stop giving your children these medicines
30	Plan to continue giving your children these medicines
28	Haven't decided what you will do
9	Have never used these medicines for your child and don't plan to
1	(Vol.) Never used but may/will use in the future
15	Have not heard discussions of the safety/effectiveness of cold/cough medicines for younger children
--	Don't know
--	Refused

(ROTATE 1-3/3-1)
(P.N. – WHEN ROTATING 1-3, USE 1ST VERBIAGE IN PARENS; WHEN ROTATING 3-1 USE 2ND VERBIAGE IN PARENS)

21. If the FDA were to put a label on children's cold and cough medicines saying that they have been found to be safe but there is no evidence that they actually work in relieving children's cold symptoms, would you (READ LIST)?

Parents	Parents of child <6	
27	**22**	Probably NOT use (these medicines/them) for your child
45	**49**	Probably use them if your doctor recommends them for your child
27	**28**	Probably use (them/these medicines) if they seemed to work for your family
1	**1**	Don't know
1	*	Refused
N=759	**N=572**	

DEMOGRAPHICS

(ROTATE ITEMS IN PARENS)

22. Generally speaking, do you usually think of yourself as: (a Democrat), (a Republican), an independent or what?
INTERVIEWER IF REFUSED READ: We understand and respect that this information is private, we ask only for research purposes, and all your answers are confidential.

Total	Parents	Parents of child <6	
31	**28**	**25**	Democrat
23	**26**	**25**	Republican
31	**33**	**35**	Independent
2	**2**	**2**	Do not vote/None
1	*	**1**	Something else
6	**6**	**7**	Don't know
5	**4**	**5**	Refused

23/23a. What is your age?

Total	Parents	Parents of child <6	
20	**19**	**34**	18-29
39	**67**	**58**	30-49
23	**11**	**6**	50-64
16	**2**	**2**	65+
--	--	--	Don't know
1	*	*	Refused

23b. What is your current employment status – do you work full-time for pay, work part-time for pay, or are you a homemaker, a student, retired, currently unemployed, or what?

Total	Parents	Parents of child <6	
60	**71**	**63**	Employed (NET)
50	**62**	**54**	Work full-time for pay
10	**9**	**9**	Work part-time for pay
10	**18**	**26**	A homemaker
4	**2**	**4**	A student
16	**2**	**2**	Retired
5	**2**	**3**	Currently unemployed
2	**2**	**2**	Disabled
2	**2**	*	Other
--	--	--	Don't know
1	**1**	**1**	Refused

24. Are you of Hispanic origin or background?

25. Are you White Hispanic or Black Hispanic?

26. Are you white, black, or some other race?

Race Summary Table

Total	Parents	Parents of child <6	
67	61	57	White (non-Hispanic)
11	12	12	Black (non-Hispanic)
3	1	2	Asian (non-Hispanic)
13	20	23	Hispanic (NET)
9	14	16	White Hispanic
3	3	4	Black Hispanic
1	2	3	Hispanic unspecified
3	4	5	Some other race
*	--	--	Don't know
3	2	1	Refused

27. What is the last grade of school you completed?

28. (Asked of those who say they graduated college) Was that an associate's degree, a bachelor's degree, or what?

Total	Parents	Parents of child <6	
4	5	6	8th grade or less
11	7	11	Some high school
31	29	29	Graduated high school
27	29	25	Some college
13	15	14	College graduate
13	13	13	Post-graduate training
*	*	*	Don't know
2	1	1	Refused

29. Are you: (READ LIST)

Total	Parents	Parents of child <6	
56	73	72	Married and living with your spouse
7	8	15	Living with a partner but not married
2	4	3	Separated
8	6	2	Divorced
6	1	*	Widowed
17	6	8	Never married
--	--	--	Don't know
2	2	*	Refused

30/30a Last year, that is in 2006, what was your total family income from all sources, BEFORE taxes? Just stop me when I get to the right category.

Total	Parents	Parents of child <6	
14	**12**	**17**	Less than $20K
11	**10**	**13**	$20K but less than $30K
8	**8**	**9**	$30K but less than 40K
9	**8**	**9**	$40K but less than $50K
9	**9**	**9**	$50K but less than $60K
11	**15**	**11**	$60K but less than $80K
8	**11**	**10**	$80K but less than $100K
12	**15**	**13**	$100K or more (NET)
7	**10**	**8**	$100 to under $150K
3	**2**	**3**	$150K to under $200K
2	**3**	**2**	$200K or more
5	**4**	**4**	Don't know
13	**8**	**5**	Refused

32. REGION

Total	Parents	Parents of child <6	
19	**18**	**17**	Northeast
22	**20**	**21**	North central
36	**36**	**37**	South
22	**26**	**25**	West

33. RECORD METRO STATUS FROM SAMPLE:

Total	Parents	Parents of child <6	
33	**32**	**29**	Urban
45	**48**	**49**	Suburban
22	**20**	**21**	Rural

D01. RESPONDENT GENDER

Total	Parents	Parents of child <6	
46	**43**	**45**	Male
54	**57**	**55**	Female

HARVARD
School of Public Health

The Henry J. Kaiser Family Foundation

Headquarters
2400 Sand Hill Road
Menlo Park, CA 94025
Phone: (650) 854-9400 Fax: (650) 854-4800

Washington Offices and Barbara Jordan Conference Center
1330 G Street, NW
Washington, DC 20005
Phone: (202) 347-5270 Fax: (202) 347-5274

www.kff.org

Additional copies of this publication (#7725) are available on the Kaiser Family Foundation's website at www.kff.org.

NPR (National Public Radio) is an internationally acclaimed producer and distributor of noncommercial news, talk, and entertainment programming. A privately supported, not-for-profit membership organization, NPR serves a growing audience of 26 million Americans each week in partnership with more than 860 independently operated, noncommercial public radio stations. Each NPR Member Station serves local listeners with a distinctive combination of national and local programming. With original online content and audio streaming, NPR.org offers hourly newscasts, special features and ten years of archived audio and information.

The Kaiser Family Foundation is a non-profit, private operating foundation dedicated to providing information and analysis on health care issues to policymakers, the media, the health care community, and the general public. The Foundation is not associated with Kaiser Permanente or Kaiser Industries.

Harvard School of Public Health is dedicated to advancing the public's health through learning, discovery, and communication. More than 300 faculty members are engaged in teaching and training the 800-plus student body in a broad spectrum of disciplines crucial to the health and well being of individuals and populations around the world. Programs and projects range from the molecular biology of AIDS vaccines to the epidemiology of cancer; from risk analysis to violence prevention; from maternal and children's health to quality of care measurement; from health care management to international health and human rights.

SignOnSanDiego.com
THE SAN DIEGO UNION-TRIBUNE

PRINT THIS

Time for Medicare Part D choice

By Jane Glenn Haas
MCT NEWS SERVICE

December 4, 2007

Now is the time when everyone on Medicare gets to make choices about prescription-drug coverage.

Until the end of the year, Medicare Part A and B recipients may choose from among 57 prescription-drug plans offered by 23 organizations.

Sound daunting? Let's make it simple. Or, at least, simpler.

If you are part of a Medicare Advantage Plan or HMO plan for your medical coverage, chances are you already have prescription coverage through these plans. But those who are in Medicare supplemental insurance plans or have certain types of retiree policies or other coverage face a "puzzling" time, says Julie Schoen, legal counsel and community education specialist for the Health Insurance Counseling and Advocacy Program (HICAP), a service of the Council on Aging of Orange County.

"The average person (signing up for a Medicare Part D plan) will pay about $20 a month premium," she says.

QUESTION: Doesn't sound too bad. What's the confusion?

ANSWER: For most people, there is none. Medicare Part D is a prescription-drug benefit for Medicare recipients. But the policy offerings change annually.

The average this year in Orange County is a $20 premium, a deductible of $275, and prescription-drug coverage of 25 percent of Medicare costs up to $2,510.

But for the first time, there is no coverage after you reach that limit in drug costs.

Whoa! Why the limit in drug coverage?

There's a gap – called the doughnut hole – for drug costs from $2,511 to $5,726. In other words, if you're in the gap, you pay out of pocket – with no reimbursement – $3,215. After you pay that out, 5 percent of your costs are then covered.

For the first two years of Medicare Part D, there were plans covering the gap. None are available this year.

How much do most people spend on prescription drugs annually?

Most people seem to stay close to the limit of Medicare Part D coverage of $2,510. And if you are taking generics, this can work well. But for someone who takes brand-name drugs for a specific illness, for example, there is no avoiding paying through the "gap." You just have to get through it.

Easier said than done for some of us.

There are patient-assistance programs. HICAP can help you with these and other questions.

What should people do first?

People with Medicare should reassess their plan to make sure that it's still the right one and that it will continue to meet their needs for 2008.

Gather the list of medications you take, review your current plan, research other plans that service your area and do some comparison shopping. Be sure to make a decision before Dec. 31.

The National Council on Aging, through their Web site, Medicare.gov, says to change by Friday to make sure you receive all your prescriptions by Jan. 1.

That makes sense. But be careful. Remember, if you are in an HMO, do nothing or you can disenroll yourself from your plan.

▪Jane Glenn Haas writes for The Orange County Register. E-mail her at jghaascox.net

»Next Story»

Find this article at:
http://www.signonsandiego.com/uniontrib/20071204/news_1c04medicare.html

☐ Check the box to include the list of links referenced in the article.

© Copyright 2007 Union-Tribune Publishing Co. ? A Copley Newspaper Site