California State Board of Pharmacy
1625 N. Market Blvd, Suite N219, Sacramento, CA 95834
Phone (916) 574-7900
Fax (916) 574-8618

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

NOTICE OF MEETING and AGENDA
Communication and Public Education Committee

Contact Person: Virginia Herold
(916) 574-7911

Time: 1:00 – 3:00 p.m.
Date: January 8, 2008
Place: Santa Barbara Conference Room
Department of Consumer Affairs
1625 N. Market Boulevard, Suite N-118
Sacramento, CA 95834

This committee meeting is open to the public and will be held in a barrier-free facility in accordance with the Americans with Disabilities Act. Any person with a disability who requires a disability-related modification or accommodation in order to participate in the public meeting may make a request for such modification or accommodation by contacting Michelle Leech at (916) 574-7912, at least five working days before the meeting.

Opportunities are provided for public comment on each agenda item. Board members who are not on the committee may also attend and comment.

Note: Pharmacists and pharmacy technicians who attend the full committee meeting can be awarded two hours of CE, in accordance with the board's CE policy. A maximum of four CE hours can be earned each year by attending the meetings of two different board committees.

Call to Order 1 p.m.

1. Consumer Fact Sheet Series with California School of Pharmacy Interns
2. Update Report of *The Script*
3. Development of New Consumer Brochures
4. Notice to Consumers Posters, as Required by 16 CCR Section 1707.2
5. Establishment of Public Hearing Schedule to Implement Senate Bill 472, Standardized, Patient-Centered Prescription Labels by 2011
6. Board of Pharmacy Web Site Redesign
7. Miscellaneous Consumer Issues/Articles in the Media
8. Update on the Board's Public Outreach Activities

Adjournment 3 p.m.

Meeting materials will be on the board's Web site by January 4, 2008

Agenda Item 1

Consumer Fact Sheet Series with California School of Pharmacy Interns

California State Board of Pharmacy
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www.pharmacy.ca.gov

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

Date: January 2, 2008

To: Members, Communication & Public Education Committee

Subject: Consumer Fact Sheet Series with California Schools of Pharmacy Pharmacist Interns

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BACKGROUND:

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.

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.

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.

The following pages contain the information on this project and template for the fact sheet.

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

Dear Dean _____:

Periodically, pharmacist interns or faculty advisors ask the California State Board of Pharmacy about opportunities for interns to gain experience working at the board. Generally the answer has been no. However, we now have an opportunity to offer pharmacy school interns about working on a project with the board.

The board is interested in offering pharmacist interns in your school of pharmacy the opportunity to work on a joint project with the board to produce public information fact sheets on items of public health interest. Once developed, the one-page fact sheets will be published and distributed by the board from its office and at community outreach events and made available from the board's Web site. We believe that this experience is appropriate for both basic and in some cases advanced internship experience.

The fact sheets are intended to provide quick and summary information about a given health issue. Each fact sheet will address a consumer issue and include questions to "Ask a pharmacist" about, so that consumers can make informed decisions about their medications and other health issues in the news. The fact sheets will benefit the public by educating them about the topic and encouraging discussions with pharmacists as health care providers. The students will gain experience by researching a health care topic and producing salient public information at a basic reading level, in a limited space.

A template for the fact sheets has been developed and follows this page. Each fact sheet should contain general information on the topic, and contain facts or perhaps in some cases common misunderstandings/myths about the topic. The fact sheets may include questions consumers can discuss with their pharmacists on making wise decisions in the subject area.

Copies of these fact sheets that have been developed with UCSF's interns and the Center for Consumer Self Care follow this page.

Additionally each fact sheet will require footnotes to document the origin of information referenced on the fact sheet (this information will be checked by the board).

The role of your school's faculty in this project will be minimal and involve advising interns about this project and providing them with information about how to contact the appropriate project leader at the board. The board may ask for subject matter assistance from faculty members as reviewers in some cases.

After an intern submits a fact sheet, the board will use internal and sometimes external reviewers to review the content, along with obtaining legal review. Completed fact sheets will be formatted and published by the board into the final fact sheet. The board will

acknowledge the student's contribution via a letter to the student and supervising faculty member at the school of pharmacy.

Additionally, once each year, the board will host a competition to acknowledge the best fact sheets developed over the prior year. The board will acknowledge the winners of this competition.

The board strongly supports the expansion of this project to all California schools of pharmacy. We believe that an intern's ability to research and distill key health care information about a topic, and present it in a consumer-friendly format, will benefit the interns in their future careers as well as the public who would benefit from the information.

Should you have questions, please do not hesitate to contact me at (916) 574-7911.

Thank you for your consideration and future participation.

Sincerely

vkh

Consumer
FACT SHEET TEMPLATE

Title:

Issue/Why Important/Facts/Myths:

Patients Need to Ask/Understand:

What Patients Should Do/Questions to Ask:

Contacts For More Information:

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

School of Pharmacy

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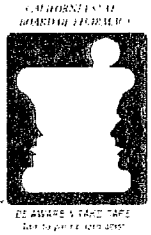
1625 N. Market Blvd., Suite N-219, Sacramento, CA 95834 (916) 574-7900
UCSF Center for Consumer Self Care
3333 California Street, San Francisco, CA 94143-0613



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.

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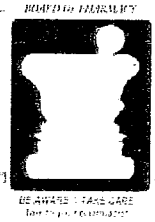

Diabetes

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.

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CALIFORNIA STATE BOARD OF PHARMACY
BE AWARE & TAKE CARE
Talk to your pharmacist

OSP 06 97190-3

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.

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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

Agenda Item 2

Update Report of *The Script*

California State Board of Pharmacy
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Phone (916) 574-7900
Fax (916) 574-8618
www.pharmacy.ca.gov

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

Date: **January 2, 2008**

To: **Members, Communication & Public Education Committee**

Subject: ***The Script***

The next issue of *The Script* is being finalized for publication and distribution later this month. 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 committee may wish to discuss items for future newsletters at this meeting. The next newsletter is planned for July.

Agenda Item 3

Development of New Consumer Brochures

California State Board of Pharmacy
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Fax (916) 574-8618
www.pharmacy.ca.gov

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

Date: January 3, 2008

To: Members, Communication and Public Education Committee

Subject: Update on Development of New Consumer Brochures

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1. Revisions to overview brochure, complaint brochure, and drug discount brochure

   Board staff Victor Perez and Karen Abbe revised the text and graphic layout of the following Board of Pharmacy (board) brochures:

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

   Suggested edits proposed during the last Communication and Public Education Committee meeting were incorporated.

   Committee members and Executive Officer Herold recommended that all board brochures have a generally consistent format and appearance. The revised brochures support that effort, including the use of the board's logo and slogan (Be Aware and Take Care: Talk to Your Pharmacist!).

   A copy of each revised brochure is provided in the meeting materials.

2. Text for Buying Drugs From Foreign Countries or on the Internet brochure

   New language has been drafted by Ms. Abbe to update "What You Should Know Before Buying Medication From Foreign Countries or on the Internet."

   The draft text of this brochure reflects substantial revisions reflecting current world market conditions, the risk of counterfeit drugs, and information from the FDA. Relevant information from the Department of Homeland Security is also included in the revised text. We will have a finalized brochure for the committee at its next meeting.

3. Pharmacist Licensure Information for 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.

Ms. Herold wrote an article relating to pharmacist licensing in California for applicants for a recent issue of the CSHP magazine. This article will be formatted into a fact sheet for applicants in the next few weeks.

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
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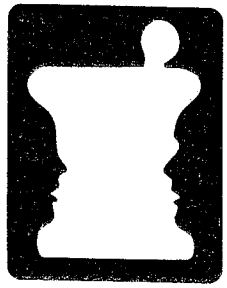
DEPARTMENT OF CONSUMER AFFAIRS

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.

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.

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

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 COMPLAINT?

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

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?

Agenda Item 4

Notice to Consumers Posters as required by 16 CCR Section 1707.2

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

Date: January 2, 2008

To: Members, Communication & Public Education Committee

Subject: Notice to Consumers

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 on the following pages. 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.

Staff is now working with two different artists on converting this wording into a readable, interesting and yet informative format. I hope to present several of these posters to the committee at the meeting for comment.

After the design is finalized, the posters will be printed and mailed to all California pharmacies. We hope to do this by July 2008. The estimated cost will be around $80,000.

§ 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!

Agenda Item 5

Establishment of Public Hearing Schedule to Implement Senate Bill 472, Standardized, Patient-Centered Prescription Labels by 2011

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

Date: January 2, 2008

To: Members, Communication & Public Education Committee

Subject: Senate Bill 472 Medication Label Subcommittee

Last fall, Governor Schwarzenegger signed SB 472 (Corbett, Chapter 470, Statutes of 2007) 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 we 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

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

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

The Medication Label Subcommittee is a subcommittee of the public education committee.

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.

A copy of SB 472 follows this page. Additionally, I am enclosing some material we have gathered on patient comprehension of prescription container information.

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.

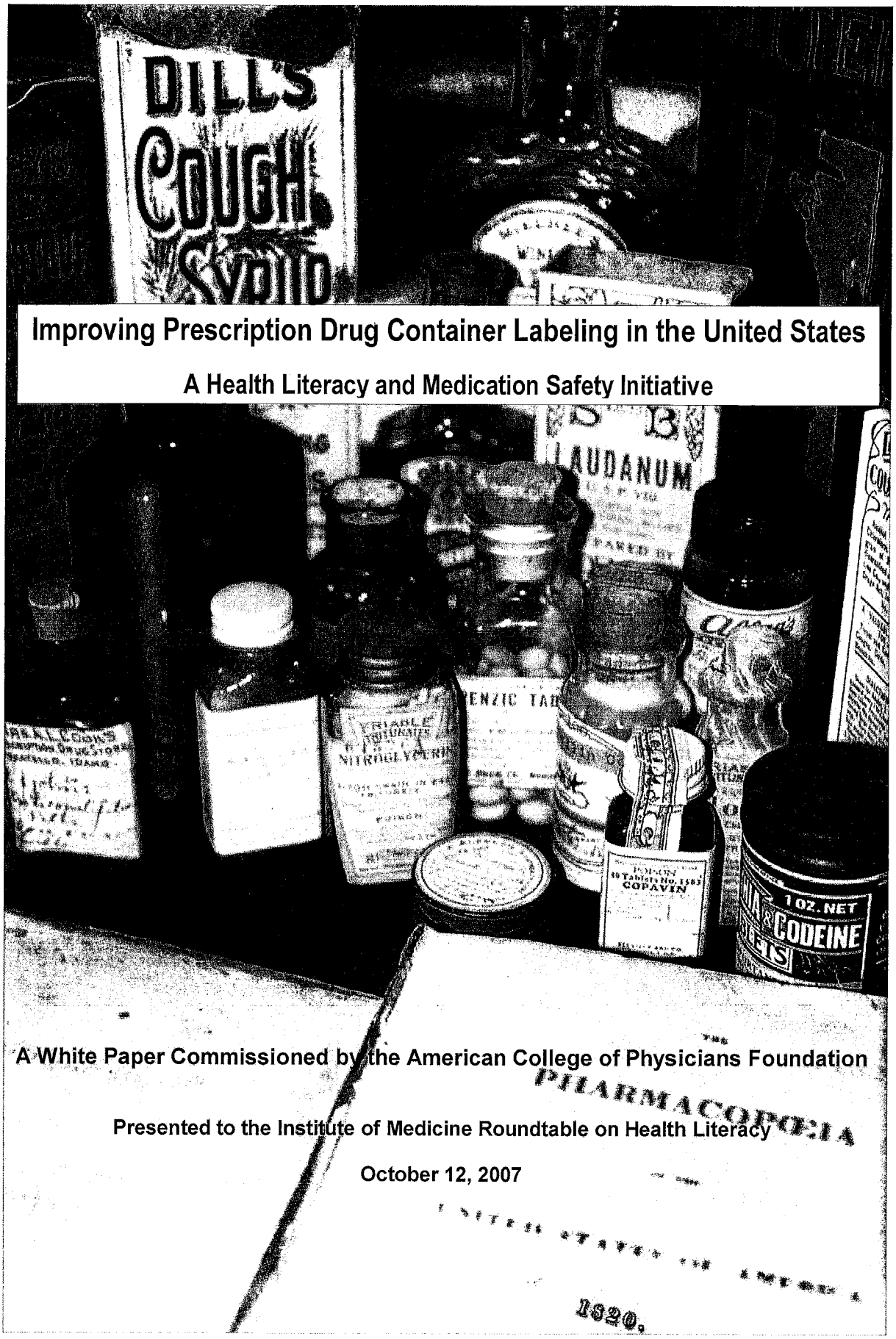
(7) Technology requirements necessary to implement the standards.

(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

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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

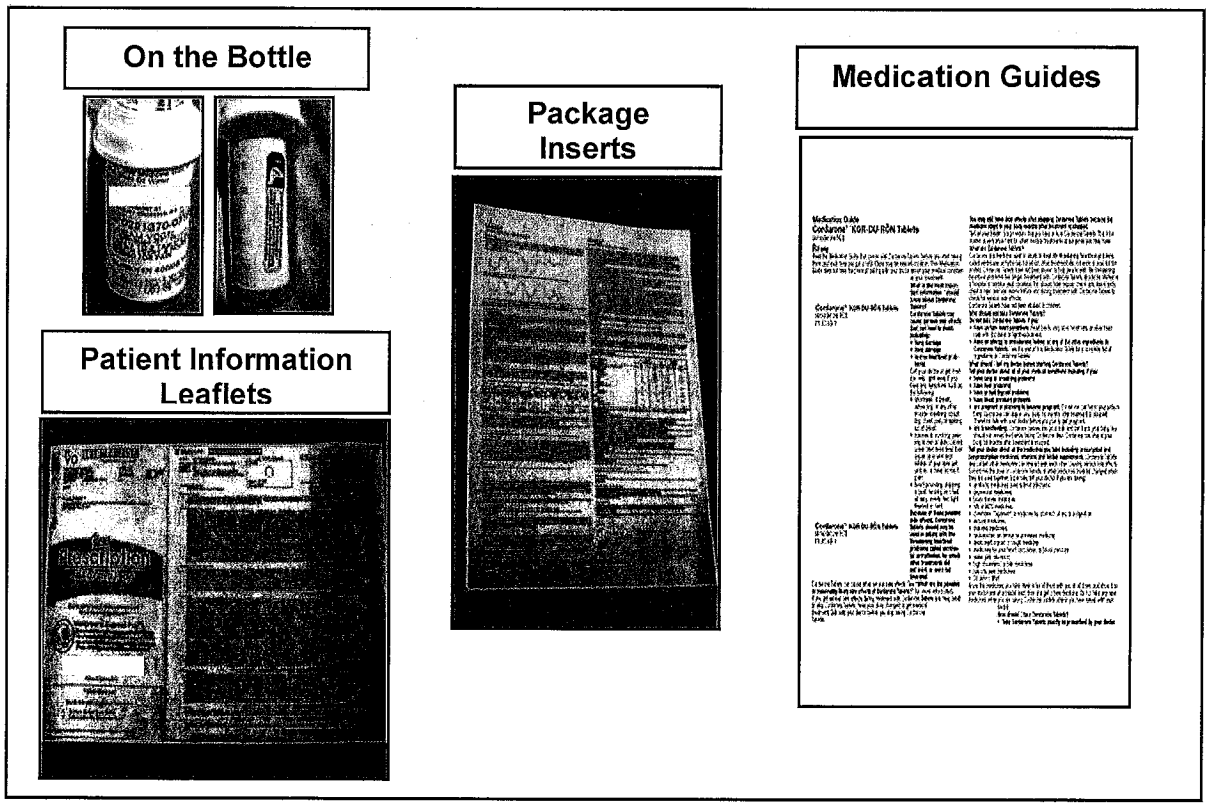
Patient safety remains one of the most important objectives for health care providers and organizations.[1-5] Medication errors, in particular, are the most common form of mistakes that lead to patient injury, hospitalization, and death.[6-19] According to the recent IOM report, Preventing Medication 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]

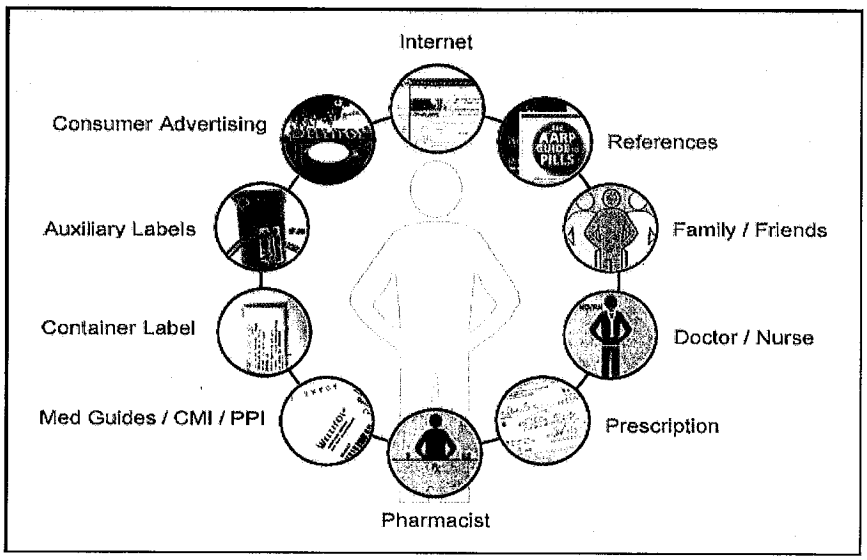
Yet reading fluency and the full range of literacy skills are likely to vary with an individual's familiarity with the content of the text.[26-28] Health materials and encounters often use difficult and unfamiliar medical terms.[29] Therefore, the estimates of limited health literacy using the NAAL general 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

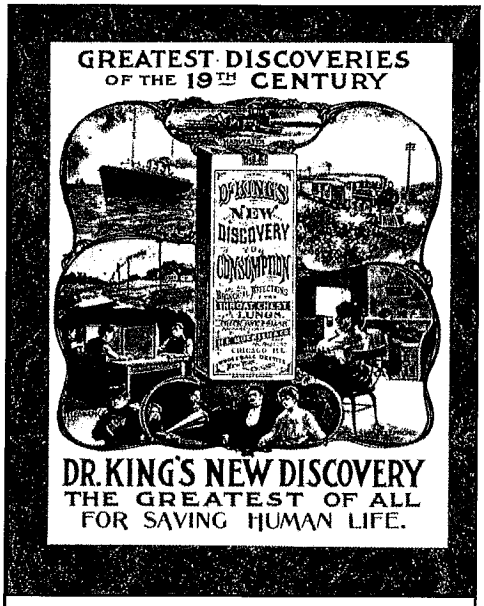
The looming problem of prescription drug container labeling is best appreciated after having a basic understanding of the relevant historical events leading up to the present circumstances. Since the formal establishment of the modern Food and Drug Administration (FDA) as a regulatory agency in 1906, 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.

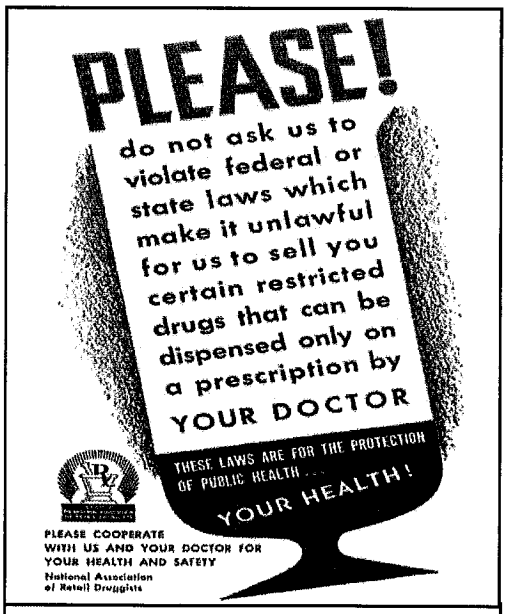
With growing concern over a new class of sulfa drugs among other new therapeutic agents, the Food, Drug, and Cosmetics Act of 1938 (FDCA) further grounded the FDA as an agent of public health, deeming many more new drugs too much of a hazard for self-medication and requiring a physician's prescription 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.

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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.*

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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

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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

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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)

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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?

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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

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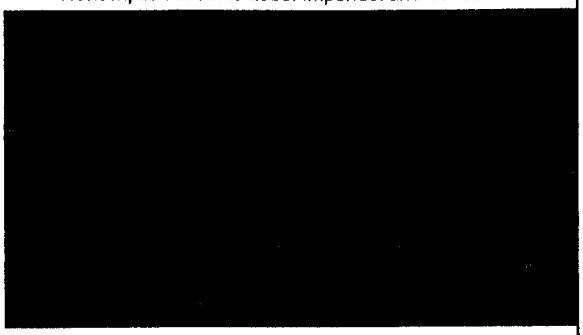
Transcription of Rx to Label Imperfect and Variable



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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**

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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

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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

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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

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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

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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

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Current Situation Unsatisfactory Need For Radical Change

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

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Patient's Day

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

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

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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		

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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		

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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		

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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		

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Proposal
Universal Medication Schedule UMS

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

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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

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Patient's Day
TID Med

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

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Patient's Day
TID Med & QID Med

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

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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

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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

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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

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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 ($p<0.001$)

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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) 432-1234

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

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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 Stale 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

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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

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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

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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"

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FDA Definition of Equivalence

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

  80%-125% of those of branded product

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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

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Uniform Medication Schedule

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

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Agenda Item 6

Board of Pharmacy Web Site Redesign

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

Date: **January 2, 2008**

To: **Members, Communication & Public Education Committee**

Subject: **New Board of Pharmacy Web Site**

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 have two staff, Kim de Long and Victor Perez worked on this project.

Currently, we are 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 our Web page and that of the Department of Consumer Affairs are provided in this tab section.

CA.GOV CALIFORNIA DEPARTMENT OF CONSUMER AFFAIRS

GOVERNOR SCHWARZENEGGER
Visit His Website

STATE OF CALIFORNIA
dca
DEPARTMENT OF CONSUMER AFFAIRS

REBUILD LIFE

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
HELP CALIFORNIA 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

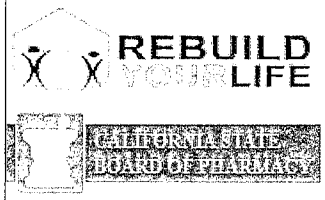
Visit the Flex Your Power Website

Save money, energy and the environment. Flex your POWER.org

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.



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

CONTACT US

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

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

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.

This web site contains PDF documents that require the most current version of Adobe Reader to view. To download click on the icon below.

Internet

Agenda Item 7

Miscellaneous Consumer Issues/Articles in the Media

California State Board of Pharmacy
1625 N. Market Blvd, Suite N219, 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

Date: January 2, 2008

To: Communication and Public Education Committee

Subject: Miscellaneous Consumer Issues and Articles in the News

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Attached are several articles of consumer interest. During this meeting, the committee can review and discuss these items in the event it wishes to propose action at the next committee meeting.

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.)

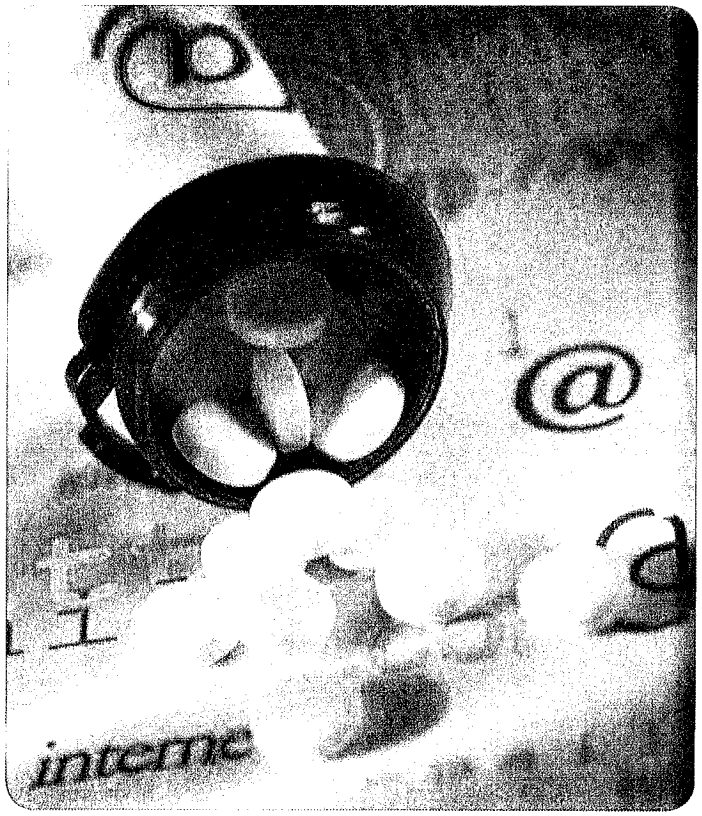
on cbp.gov:

- 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.

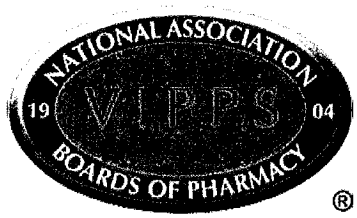
The Food and Drug Administration cannot warn people enough about the possible dangers of buying medications online. Some Web sites sell medicine, such as prescription and over-the-counter drugs, that may not be safe to use and could put people's health at risk. The current system of federal and state 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

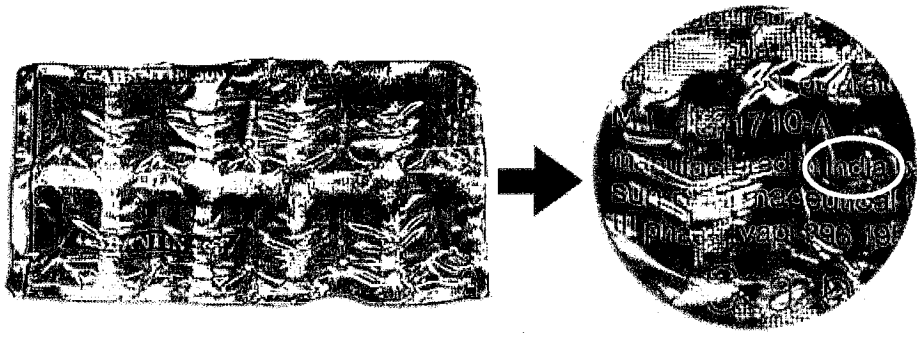
- Are too old, too strong or too weak.
- Aren't FDA-approved.
- Aren't made using safe standards.
- Aren't safe to use with other medicines or products.
- Aren't labeled, stored, or shipped correctly.

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

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

Public Ed

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.

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

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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

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PERSPECTIVE

Previous Volume 357:960-963 September 6, 2007 Number 10 Next

Sidelining Safety — The FDA's Inadequate Response to the IOM

Sheila Weiss Smith, Ph.D.

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Having been commissioned by the Food and Drug Administration (FDA) to evaluate the U.S. drug-safety system, the Institute of Medicine (IOM) published a report, *The Future of Drug Safety,* in September 2006 identifying weaknesses in the laws, regulations, resources, and practice of ensuring drug safety.[1] Some of the IOM's recommendations were directed toward Congress, which it believed should increase FDA funding and regulatory authority. Some outlined ways in which other federal agencies could work in partnership with the FDA for the public good. But most of the report outlined deficiencies that the FDA itself — or the Department of Health and Human Services (DHHS), to which it belongs — should correct.

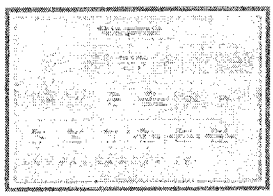
In general, the IOM implored the agency to "embrace a culture of safety" by increasing the priority accorded to the safety of patients. Such an emphasis could have ramifications for medical care that would be as broad and positive as those that the 1999 IOM report on medical error, *To Err Is Human,*[2] has had for the health care system. Sadly, the FDA's official response falls far short of what the American public expects and deserves.[3] Indeed, it highlights the very reason that the agency — with which I have had some firsthand experience — is in need of monumental change: its philosophy is no longer aligned with its regulatory mandate.

The basic criterion for approval of a new drug is that its benefits outweigh its associated risks — so benefits must be considered in light of the drug's toxicity and known safety problems. In its response to the IOM report, however, the FDA described its "fundamental dilemma" as weighing the "tradeoff between safety and access."[3] Under the 1992 Prescription Drug User Fee Act, resources were provided to accelerate access to new drugs, and the FDA shortened review times and began to approve certain drugs earlier in the clinical development process.[4] Safety was affected in several ways. First, some drugs were approved on the basis of surrogate end points and fewer safety data than had previously been required. Second, user-fee funds could not be used for postmarketing safety assessments; this restriction changed in 2002, but even now such use is permitted only in limited circumstances. Third, mechanisms intended to speed access to potentially lifesaving medicines were broadly interpreted. Drugs for the treatment of common chronic conditions such as diabetes (troglitazone), obesity (dexfenfluramine), and pain (rofecoxib) were

approved under expedited programs and later were withdrawn from the market for safety reasons.

The public expects the FDA to be the final arbiter of drug safety. Accelerated development programs and expedited reviews hasten the introduction of lifesaving drugs, but they should not be an option for treatments intended for chronic conditions; these drugs should have safety standards that tolerate minimal uncertainty. By pitting safety directly against "access and innovation," the agency betrays its mandate to ensure that U.S. drugs are both safe and effective.

Moreover, the very structure of the FDA marginalizes safety. All regulatory authority lies within the drug-evaluation divisions of the Office of New Drugs (OND) in the Center for Drug Evaluation and Research (see organizational chart); staff members in these divisions evaluate and approve drugs, negotiate labeling, and request risk-management programs and postmarketing studies. Despite the agency's theoretical emphasis on epidemiology, such expertise is often absent from these divisions. The FDA's safety experts work in a separate Office of Surveillance and Epidemiology (OSE) — which is not even a part of OND — and serve only as consultants to the review divisions, having no direct regulatory authority. Although they may be asked to provide background information as context for interpreting an application, they do not regularly participate in drug reviews.



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Current Structure of the Food and Drug Administration.

The Division of Neurology Products and the Division of Psychiatry Products are part of the Office of Drug Evaluation I.

Several IOM recommendations speak to the importance of including safety experts as integral players in the drug-review process. Yet instead of undertaking a fundamental restructuring to integrate the relevant offices, the FDA merely initiated two pilot projects that involve OSE personnel in drug reviews to determine the "logistics and value" of doing so. But something akin to a pilot had already been done. More than 10 years ago, Greg Burkhart moved from the Epidemiology Branch (now the OSE) to the Division of Neuropharmacological Drug Products (now the Divisions of Neurology Products and Psychiatry Products in one of the Offices of Drug Evaluation). His successor in the latter post, Judith Racoosin, who had trained as a postdoctoral fellow in the OSE, spoke to the IOM committee in January 2006 about her work as a safety team leader.[1] It is partially on the basis of her experience that the IOM report argues that a critical step in promoting a culture of safety is to change the role of the safety expert from occasional consultant to vital participant in the day-to-day work of regulatory decision making.

Of course, even with such participation in preapproval reviews, premarketing clinical trials would have limited ability to identify uncommon adverse events. A safety data set supporting a new drug application for treatment of a chronic disease typically includes fewer than 3000 patients, some of whom have had only a single exposure to the drug. Postmarketing surveillance for adverse events and ad hoc safety studies are therefore crucial, but although responsibility for these activities falls to the OSE, all regulatory authority remains with the division that approved the drug. In the postmarketing realm, the IOM committee recommended establishing joint regulatory authority, so that

either the OND or the OSE could take regulatory actions. The agency responded by creating two process-review teams, hiring external consultants to improve communications, and developing standard operating procedures that will, it says, "articulate the division of responsibility between OND and OSE" in presenting safety data to advisory committees. Although the FDA claimed that it is committed to ensuring that the "safety staff has a strong voice" in safety-related decision making, it did not confer any regulatory authority on the OSE.

The sidelining of safety experts extends to the FDA's external advisory committees, which are composed of physicians with expertise in a given therapeutic area, along with a biostatistician, a patient representative, and an industry representative. Safety experts serve on a separate Drug Safety and Risk Management Advisory Committee, which sometimes meets with other advisory committees, and individual safety experts are sometimes asked to consult on particular safety issues. In response to an IOM recommendation that scientists with expertise in pharmacoepidemiology or public health be included as regular members of all scientific advisory committees, the agency has proposed that it include such expertise "when safety issues are an important component of the issues before the Committee." But safety should always be on the agenda. Such expertise is critical for evaluating and interpreting often sparse safety data at the time of drug approval, for evaluating proposed postmarketing studies, and for assessing risk-management action plans. The FDA's response once again highlights the low priority it assigns to its responsibility for arbitrating drug safety.

Recognizing the pervasiveness of this marginalization at the agency, the IOM recommended that DHHS appoint an external management advisory board to help find ways of transforming the agency's culture. The FDA responded, instead, with a series of internal initiatives, pilot studies, and further evaluations that leave safety experts working largely in isolation, with limited resources and outdated technology.[5]

In my view, the FDA's response to the IOM report demonstrates a lack of understanding of the magnitude of the changes required to create a culture of safety. Apparently, the agency's leadership has yet to recognize that the adoption of such a culture would benefit all stakeholders — industry, the community of scientists, and most important, the American public.

Dr. Smith reports having served on a number of FDA advisory committees as an ad hoc member and having served as a consultant to the IOM panel. She reports receiving grant support from PhRMA and Sanofi-Aventis, serving as a consultant on lawsuits for Bayer and Spectrum and against Abbott Laboratories, and serving on Covance's scientific advisory board on isotretinoin risk management. No other potential conflict of interest relevant to this article was reported.

Source Information

Dr. Smith is an associate professor at the Center on Drugs and Public Policy, Department of Pharmaceutical Health Services Research, University of Maryland School of Pharmacy, and in the Department of Epidemiology and Preventive Medicine, University of Maryland School of Medicine — both in Baltimore.

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Public Ed

U.S. News & World Report

Wednesday, September 12, 2007

Comarow on Quality

Protecting Patients Popping Piles of Pills

September 11, 2007 05:50 PM ET | Comarow, Avery | Permanent Link

Millions of Americans suffer from polypharmacy, booms the TV. *Are you among them?* That'd stop you cold on the way to the kitchen during a commercial break, wouldn't it? Polypharmacy means taking a large number of medications, which indeed millions of Americans do. More than 20 million people take six or more prescription and nonprescription drugs; more than 12 million take *eight* or more.

It's not hard to see how it can happen. Combine a history of heart disease with a couple of everyday complaints like acid reflux and the occasional rebellion from the lower digestive tract and you're talking half-a-dozen meds, easy—a beta blocker, an ACE inhibitor, a cholesterol-lowering statin, and an aspirin for the heart; a proton-pump inhibitor for the heartburn; dietary psyllium fiber for the digestive difficulty. As the typical drug count increases with the pill-taker's age, so does the risk of drug interaction, as well as the possibility that you'll be the victim of newly discovered hazards in one or more of the medications, especially if they haven't been marketed that long.

Pharmaceutical manufacturers are supposed to run studies of a new drug's safety after the drug goes on the market, but getting doctors and patients to sign up for these studies has been difficult. Patients and physicians can directly report problems to the Food and Drug Administration's MedWatch program, but it, too, has had spotty success. An analysis published today in the *Archives of Internal Medicine* shows that the number of deaths and injuries reported to MedWatch almost tripled between 1998 and 2005, four times faster than the growth in the number of prescriptions written. The FDA says much of the increase is simply due to better reporting. The study authors disagree. Coauthor Curt Furberg, a professor of public health sciences at Wake Forest University School of Medicine and longtime critic of MedWatch, says that the sharp rise "shows [that] current efforts to ensure the safety of drugs are not adequate, and that physicians and patients are unaware of these risks."

How, then, can individual patients learn about drug interactions and other dangers?

Hugo Stephenson, an Australian physician who relocated to the United States many years ago, thinks he can help. Next month he plans to launch iGuard, a service that will assign a five-level "risk rating" to each drug entered by a patient into a personal medical profile, which is housed at the iGuard website after the patient registers. The risk will represent not only the hazards of individual drugs but also potential drug interactions, all keyed to the patient's medical history. Once registered in the iGuard system, patients will receive alerts when new findings emerge. There won't be any charge—Stephenson will strip out details that identify individual patients and sell the data to researchers—and the rather complicated way in which various risks are determined

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As of mid-September, the iGuard site is open for registration, but Stephenson agrees that it isn't ready for use. Currently, drugs are assigned risk levels, but the nature of the risk is not explained. Stephenson promises that when the site is officially up and running, it will feature explanations that patients can then bounce off their doctor. I hope iGuard can deliver. Nothing else has.

Tags: FDA | drugs | prescription drugs

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This release was updated on Nov. 1, 2007 to include changes to the fourth paragraph.

FDA News

FOR IMMEDIATE RELEASE
November 1, 2007

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FDA Says Consumers Continue to Buy Risky Drugs Online

Self-medication a concern; FDA-approved generics may be cheaper alternative

A yearlong U.S. Food and Drug Administration (FDA) investigation into drugs mailed to the United States from foreign countries suggests that consumers may be buying drugs online to avoid the need for a prescription from their physician. The FDA sampling of imported drugs also indicates that consumers continue to spend money unnecessarily on potentially risky drug products bought over the Internet.

The investigation found 88 percent of the 2,069 drug packages examined appeared to be prescription medicines available in the United States. Of the remaining products, some were dietary supplements, some were foreign products with labeling that was illegible or incomprehensible, and some were medications not available in the United States. More than half (53 percent) of the products sampled have FDA-approved generic versions, likely sold at lower costs, according to earlier studies that have shown generics in the United States to be generally cheaper than a comparable drug in Canada or Western Europe. In fact, approved generic versions of approximately half (47 percent) of the sampled products can be bought for $4 at several national chain pharmacies, a price often lower than the shipping costs for the same drugs purchased online.

"The data lead us to believe that many people are buying drugs online not to save money but to bypass the need for a prescription from their doctor since these Web sites typically do not require the purchaser to have a prescription," said Randall Lutter, Ph.D., FDA's deputy commissioner for policy. "In essence, they seem to be getting and using prescription drugs without a prescription, an intrinsically risky practice."

These data are based on surveys conducted from September 2006 to August 2007 in international mail facilities and courier facilities across the country. At each city surveyed, a selection of parcels suspected by U.S. Customs and Border Protection of containing pharmaceuticals were stopped. FDA then recorded data on the contents of these parcels, before handling them in accordance with its usual procedures.

In general, a Web site can appear legitimate, but in fact be a front for an illegal operation. FDA urges consumers to beware of unregulated Internet drug sellers, because many of their products might not contain the correct ingredients and could contain toxic substances. Several drugs found in this survey require special monitoring by physicians or other health care professionals for potential adverse events and to ensure their effectiveness. These include antibiotics, antidepressants, the blood thinner warfarin, and levothyroxine (a thyroid replacement hormone).

For more information:
FDA Finds Consumers Continue to Buy Potentially Risky Drugs Over the Internet
http://www.fda.gov/bbs/topics/NEWS/2007/NEW01663.html

Buying Medicines and Medical Products Online
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Public Ed

Health

Drugs That Go Untaken

Too often, lifesaving medicine is prescribed but not used

By Katherine Hobson
Posted September 29, 2007

Damian Galvan knew it was time to own up. The nurse overseeing his cancer treatment at M.D. Anderson Cancer Center in Houston had summoned him from his home in Brownsville, Texas, saying his latest lab results indicated his disease—chronic myelogenous leukemia—had returned. The lifesaving medications Galvan was on must not be working, he said. "I asked the nurse to close the door," Galvan, now 33, remembers. "I said, 'I have to be honest with you—it's not that the medications aren't working. I haven't been taking them for six months.'"

You'd think Galvan would be a rarity, that anyone with a life-threatening medical condition would diligently take his medicine. But according to an August report by the National Council on Patient Information and Education, only about half of patients take their medications as prescribed, and the longer someone is on a drug, the more likely he is to start skipping doses. The global cost of medication nonadherence (or non-compliance), as the doctors call it, is estimated at $177 billion a year, including indirect costs like lost productivity.

The human cost is high, too. A study in the September 10 issue of *Archives of Internal Medicine* found that heart disease patients who skipped their meds had more than twice the chance of a heart attack, stroke, or other cardiovascular event compared with those who took them faithfully. Another recent study found that breast cancer patients who were instructed to take tamoxifen were 16 percent more likely to die if they failed to fill at least 30 percent of their prescriptions for the drug than if they filled all prescriptions. Glaucoma patients can go blind without treatment, yet one study found that only 58 percent of those who had lost sight in one eye were taking their medications as directed. Even a few organ transplant recipients eschew drugs, says Robert Hobbs, a cardiologist at the Cleveland Clinic. In some cases, he says, "it's clear that when they stopped taking their medications, they died."

It's not a problem ripe for a quick fix. The reasons for nonadherence are diverse, which means the solutions must be, too. "Medicine is not set up to worry about what happens when people leave the doctor's office," says Alan Christensen, a psychologist at the University of Iowa who has researched adherence. The NCPIE report calls on the government, healthcare workers, and professional societies

to make adherence a top priority, recommending a national education campaign, professional training, more federal funding for research, and improvements in health literacy.

Why skip doses? One biggie: side effects. Tamoxifen, for example, can cause menopause-like symptoms, and aromatase inhibitors, a newer class of breast-cancer medicines, may provoke musculoskeletal problems. After surgery, a patient may be told to take either or both for years, to prevent a recurrence. But a new study found that 13 percent of women on aromatase inhibitors stopped because of problems like tendonitis, arthritis, and other aches and pains. "Many people don't take advantage of their treatment," says Marisa Weiss, an oncologist in Philadelphia and founder of breastcancer.org. If a drug's side effects are bugging you, she says, talk to your doctor, who may be able to prescribe a substitute, change the dosage, or give you a brief supervised break to see if symptoms disappear.

For some, expense is the sticking point. A recent study in *Health Affairs* found that retirees who had annual benefit limits on their health plans were more likely to stop taking their meds than those without caps on their benefits. If you can't afford your prescriptions, tell your doctor. He may switch you to a cheaper alternative, give you free samples of the drug, or help you enroll in a pharmaceutical company's assistance program, which can provide no- or low-cost drugs to patients who can't otherwise afford them.

Confusion. Many patients are simply confused about how to take their meds, says Ruth Parker, a health literacy researcher and expert contributor to the NCPIE report. Studies show that people misunderstand doctors' instructions and prescription labels, and their confusion can be compounded by old age and multiple medications. Parker wants to see standardization of labels; for now, keep an updated list of your drugs, including the dosage, and your understanding of when and how to take them. Carrying that list with you lets you review your prescriptions with your doctor or pharmacist, she says. And if you're a caregiver to someone who may forget to take medications, keep that list for yourself—and find a way to remind the person of her dosage schedule, maybe with phone calls, Post-Its, or the classic days-of-the-week pillbox.

That low-tech solution can work. A study in the October 1 issue of *Clinical Infectious Diseases* showed that passing out pillboxes to HIV patients at high risk of skipping their meds—a $5 investment per person—improved adherence by 4 percent and cut their risk of progressing to full-blown AIDS by 11 percent. Drug companies are also working to make it easier to take meds, by combining two drugs into one pill, or reformulating drugs so they can be taken less frequently.

Some patients may not understand why they're on a medication—and why they need to stay on it, even if they feel well. A study released this summer looked at veterans who'd been prescribed statins—at low or no cost—to prevent heart problems. Within six months, more than half stopped taking the drugs or weren't taking them correctly. The nonadherers were more likely to say they didn't see themselves at high risk of a heart attack, believed a low-fat diet they'd adopted made the drug unnecessary, or figured that once their cholesterol levels came down, they were "cured." "There's a communication problem," says Devin Mann, an author of the study and an internist at Mount Sinai School of Medicine in New York. "We all need to start out on the same page so patients know why they're on a drug and how long

they'll be on it."

Improving one's communication with doctors may be the cheapest and most far-reaching step the average person can take. But Christensen says doctors need to take responsibility, too. "It can even be something like asking the patient whether he'd prefer the once-daily or once-monthly form of a treatment," he says. "It's like when you're trying to get your 4-year-old to eat his vegetables. You don't say, 'Eat your vegetables,' you say, 'Would you rather have the peas or the carrots?' "

Patients' mistaken beliefs or misguided attitudes are increasingly problematic in the treatment of cancer, where it's becoming common for patients to take oral drugs for years. "People get tired of being reminded they have cancer," says Maurie Markman, vice president for clinical research at M.D. Anderson.

For Galvan, the decision not to take his drugs resulted from a combination of unpleasant physical effects—he hated giving himself a weekly injection as well as the rashes that followed—and a desire to escape the reality of a shocking diagnosis. "I felt this sense of urgency to be normal again," he says. "I went from only taking a Tylenol once in a while to having a big Ziploc gallon bag full of pills, another full of syringes, and another full of vials." It was the post-confessional heart-to-heart he had with his nurse and doctor that made a light bulb go on. "They told me, 'You're not the first person to do this, but if you don't take your medicine, you will die.'" Now healthy—and taking his medication as prescribed—he still returns to M.D. Anderson twice a year to make sure his cancer hasn't returned. But he's no longer being monitored more frequently to be sure he's complying. "They saw," he says, "that I'm a man of my word."

TALK WITH THE DOC

The best route to consistent and proper use of prescription drugs, experts say, involves making sure the doctor and you—or the loved one whose care you're overseeing—are on the same page. Some things you need to know whenever a doctor writes you a prescription or a pharmacist fills it:

- Why am I taking this medicine?
- How does it work in my body?
- What's the dosage schedule, and how do I take it?
- Will it safely mix with the other medicines I'm taking?
- What should I do if I accidentally skip a dose?
- What side effects might I experience? Which can I ignore, and which do I need to report?
- How will I know if the medicine is working?
- What should I do when I'm about to run out?

Source: American Society of Consultant Pharmacists

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Public Ed

October 31, 2007

Non-English Speakers Charge Bias in Prescription Labeling

By ANNE BARNARD

Pharmacies across the city routinely fail to help non-English speakers understand their prescriptions, raising the chances that customers could harm themselves by taking medicines incorrectly, immigrant advocacy groups charge in a discrimination complaint that they plan to file today with the New York attorney general's office.

The complaint names 16 pharmacies in Brooklyn, Queens and Long Island, most of them operated by chains. It argues that federal civil rights law and state health regulations require pharmacies to provide linguistic help to guarantee that people who speak little or no English receive equal access to health care. That assistance should include interpreters at pharmacies and written translations of medication instructions, the advocates say.

Nisha Agarwal, a lawyer for one of the groups filing the complaint, said the attorney general's office had already issued subpoenas to several pharmacies listed in an earlier version of the complaint filed in July. The new version names more pharmacies, and an accompanying report includes more examples of comprehension problems non-English speakers have had.

"The idea is that people should not be placed in danger by not understanding their medication regimen," said Andrew Friedman, an executive director of Make the Road New York, one of the groups filing the complaint, along with New York Lawyers for the Public Interest and the New York Immigration Coalition.

Jeffrey Lerner, a spokesman for the attorney general's office, said only, "We have an ongoing investigation."

The pharmacies named include six operated by Rite Aid, three CVS stores, three Duane Reade stores, a Walgreens and a Wal-Mart. CVS said it was cooperating with the attorney general. The other companies declined to comment on the pending legal matter, but said they were trying to provide good service for diverse populations.

Tiffani Bruce, a spokeswoman for Walgreens, said the chain provided medication labels in 14 languages and kept a nationwide database of its pharmacists who speak other languages, enabling a pharmacist to call a colleague who can talk to a customer.

CVS said it provided telephone interpreters in 150 languages, and Rite Aid said it tried to hire bilingual pharmacists and provided labels in 12 languages.

In a survey of pharmacists at 200 New York drugstores to be published next month in the Journal of Urban Health, 88 percent said they saw non-English-speaking customers daily, and 80 percent said they had the ability to translate labels, according to Linda Weiss, a senior research associate at the New York Academy of Medicine, who conducted the study. But only 34 percent said they translated labels daily, and 26 percent said they never did.

Many states require hospitals to provide translation and interpretation services in emergency rooms. Last year, New York State's Department of Health tightened regulations to require that all hospital departments provide interpreters to non-English speakers within 20 minutes.

Health advocates have increasingly used federal civil rights law to push hospitals, nursing homes and clinics to provide language services. Language barriers to health services constitute discrimination based on national origin, they argue, a violation of federal civil rights law, which applies to hospitals because they receive federal funds through Medicare and other programs.

The latest effort aims to expand similar requirements to pharmacies. The complaints also cite the New York Education Law, which requires that medications be labeled in a way that ordinary people can understand. That is meaningless if they are in a language the patient does not comprehend, Mr. Friedman said.

This month, California enacted a law requiring the state's pharmacy board to implement new requirements for clear prescription labeling by 2011, and to "consider" the needs of non-English speakers.

The advocacy groups provided The New York Times with a copy of the complaint and the accompanying report.

The report chronicles the stories of more than a dozen New Yorkers who said they struggled to understand their prescriptions at local pharmacies. Reyita Rivera, 47, for example, who speaks and reads only Spanish, said she could not understand the printed instructions that came with her antidepressant medication, and ended up taking too much. She said she had to be admitted to a Queens hospital after the medication caused a racing heartbeat.

"That experience scared me a lot. I felt very bad — I thought I was just going crazy," Mrs. Rivera, a Dominican immigrant, said in an interview, speaking through an interpreter.

She said she could not communicate with the staff at her pharmacy in Ridgewood, Queens, and received no printed explanation of the medication in Spanish.

José Cadavid, 63, of Woodside, Queens, said he usually could not get his pharmacists to explain his medication in Spanish. "Whenever I go to the pharmacy I see a lot of people struggling to communicate," said Mr. Cadavid, who immigrated from Colombia. "There's no one helping them. It affects a lot of people."

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Your kid has a cold -- what now?

- Story Highlights
- Parents seek answers after FDA advises against cold medications for young kids
- Doctors recommend alternative therapies such as massage and essential oils
- One expert says big doses of vitamin C can help

By Elizabeth Cohen
CNN

Empowered Patient, a regular feature from CNN Medical News correspondent Elizabeth Cohen, helps put you in the driver's seat when it comes to health care.

ATLANTA, Georgia (CNN) -- On the popular parenting Web site urbanbaby.com, a writer asks whether it's OK to give an 18-month-old "a tiny bit of Robitussin" for her "cold/cough and fever."

"No flames please," the parent requests.

But flames she got.

"Idiot," one user writes.

"The answer is *of course not*," another writes. "Come on ... these cough syrups are totally ineffective in ameliorating the common cold and are harmful to your child."

Over-the-counter cough and cold medications for a child under 6 goes against the advice of the Food and Drug Administration -- and apparently that of many fellow parents on the Internet. These medications have been blamed for more than 100 deaths and at least thousands of trips to the emergency room.

But what else can a parent do?

"I use these types of meds at night so we can all get some sleep," writes another parent on urbanbaby.com. "It's the only thing that helps with her cough at night," another says.

Or as one parent puts it succinctly on the Craigslist parenting forum: "It sucks not knowing what to do."

Here are a few alternatives that physicians give their patients when little ones are miserable with a cough or cold.

Music and a massage

"Gentle massage with an essential oil such as lavender may help to promote sleep," says Dr. Michelle Bailey, a pediatrician and associate director of education at Duke Integrative Medicine, which blends traditional medical treatments with alternative therapies.

She says minimizing stress, since it weakens the immune system, is important, too. "There is a connection between the mind and the body, so relaxing the mind may have a positive relaxation effect on the body during times of illness," she says. "Relaxation tapes or CDs may help reduce stress."

Tea and a bath

"I like to recommend ginger tea with honey," says Dr. Paula Gardiner of Harvard Medical School's Osher Institute. (For babies under 1, hold the honey -- it could make them sick). She also tells patients a warm bath with eucalyptus oil helps open stuffed-up nasal passages. Bailey says menthol in the bath works, too.

Vitamin C and vapor rub

Vitamin C also is worth trying, says Dr. Kathi Kemper, a professor of pediatrics at Wake Forest University School of Medicine in North Carolina and a specialist in integrative medicine. But she says there isn't enough in orange juice. "Doses need to be several hundred milligrams, depending on the age of the child," she says. "My 10-year-old gets two grams daily when he starts to get a cold."

She also recommends a vapor rub for stuffy noses -- except for infants under 1 month. (She says applying it under the nose can cause apnea in such infants.)

These suggestions, the doctors say, are in addition to the basics that any pediatrician would recommend: warm liquids, a humidifier, a saline nose spray and a nasal bulb syringe to suck out what's stuffing up your little one.

But even with all these tricks, there's nothing that will magically make your child's cough or cold go away -- or magically get them to sleep.

All AboutPediatrics

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http://www.latimes.com/features/health/la-he-coupons3dec03,1,2732046.story?track=rss
From the Los Angeles Times

Heading to the drugstore? Clip a coupon -- but read the fine print

Many consumers don't know that deals are available on prescription medication. But generics are often still cheaper.

By Francesca Lunzer Kritz
Special to The Times

December 3, 2007

The next time your pharmacist hands over a prescription and the bill, consider handing something back -- a coupon.

More than 200 drug coupons available online or from doctors or pharmacists have face values that could save individual consumers tens to hundreds of dollars each year.

But few patients seem to know about them. Only about 1% of the 286 billion grocery coupons distributed last year were redeemed, according to market research firm CMS Inc., but the percentage is even lower, for now, for prescription drug coupons.

Drug companies often do little marketing for the discounts, says David Harrell, chief executive of Optimizerx.com, a website launched early this year that posts links to drug coupons for consumers. The money-saving offers include not just coupons, but free trials, rebates and loyalty cards that save money on future prescriptions.

Increased marketing of the offers is likely to build awareness. Even for consumers who aren't generally coupon clippers, these offers might be worth a second look.

They might also warrant a second thought -- the savings may not actually add up.

More companies have begun to create enticements for particular brand-name drugs, partly in response to a growing number of lower-cost generic versions, says Carl Cohen, president of marketing solutions for Cegedim Dendrite, a market research firm that looks at efforts by drug companies to promote drugs to consumers. For example, Lipitor, the top-selling cholesterol-lowering drug, whose competitor, Zocor, lost its patent last summer, now has a variety of company-sponsored price cuts on its site, Lipitor.com. And of the five top-selling prescription drugs in 2006, ranked by trade publication MedADNews, three offer discount coupons.

Meanwhile, prescription coupon sites such as Optimizerx .com and Internetdrugcoupons .com, launched in July, are making it easier to find the offers. A third site, Reduceprescription costs.com, has coupon links and other tips for saving money on drugs. And some general coupon sites, such as fatwallet.com, have been adding drug coupon links as well.

By and large, the three main drug coupon sites have similar offers, though a recent check found coupons for osteoporosis drug Actonel on the first two, but not the third. And of those sites, Optimizerx is the only one to bombard users with ads. A click on a Lipitor offer, for example, also launched ads for eHealth insurance, pet medicines, drugs from Canada and a natural way to lower your cholesterol.

Where to find them

Looking for offers? Pharmacies often have tear sheets on a bulletin board near the pharmacy or the main door. Doctors' offices may have additional information, though those deals are sometimes available only through a physician. And a drug's website usually posts such information prominently. For example, Advair, an asthma drug, offers a free prescription on its site via a message to "click here for savings."

Some offers require a bit more searching to find, such as for Diovan, a blood pressure drug. People who visit that site need to know to click on the "BP [blood pressure] Success Zone Program" link, and then search further under "program benefits." The Internet coupon sites typically do the searching for you. Click "Diovan" on Internetdrugcoupons.com, and the site explains how to get the discount offer.

Although the average grocery coupon has a face value of $1.02, according to CMS, drug offers can run far higher. Recent ones have included up to a $20 rebate on a one-month prescription of the overactive-bladder drug Detrol LA, a voucher for a seven-day supply of the sleeping pill Ambien (retail price, $35 at drugstore.com) and a free one-month supply of three breast cancer drugs.

That doesn't mean consumers should jump at every money-saving offer.

People being treated for a specific condition may not actually receive better care if they switch from their current medication to a new one simply because of a $10-off coupon. And, especially if the coupon is for one time only, the new drug could cost more in the long run.

Reading the fine print is crucial, says Matthew Tilley, head of marketing at CMS. Drug coupons cannot be used by people insured by most federal and state insurance plans such as Medicare and Medicaid (Medi-Cal in California), because the federal and state governments consider coupons a kickback to consumers. However, programs that involve no money back, such as free trials, are often allowed.

Some coupons are simply handed in with a prescription for an immediate price reduction; others, such as the offer for Detrol LA, are rebates that need to be mailed to the company along with the original receipt from the pharmacy. Wording on the coupon will explain whether it can be used for a co-pay. If so, and if the coupon's face value is higher than that of the co-pay, consumers will get only the value of the co-pay.

Consumer-friendly?

Recent chatter on coupon blogs suggests consumers like drug coupons, with many posters saying they had found a coupon for a drug they, a child, parent or even a grandparent takes. But not everyone considers the coupons consumer-friendly. The Food and Drug Administration is planning a study of consumer perceptions of drug coupons to see if, when partnered with a drug ad, the allure of the discount keeps consumers from adequately paying attention to side effects and other risks.

Last year, the FDA posted a federal register notice asking for public comments on the proposed study. The agency has since pulled the notice, spokesman Sandy Walsh said, in order to refine the parameters of the study, but in the meantime, comments voicing opposition to coupons came into the agency. The Prescription Access Litigation Project, for example, a group devoted to lowering the cost of prescription drugs, filed comments representing 23 consumer groups calling for an outright ban on prescription drug coupons. Among the complaints: that coupons interfere with a doctor/patient relationship by leading consumers to ask their doctor for a drug for which they've seen or received a coupon, and that they deceive consumers into using high-priced brand names over generics.

"A $10 coupon is nothing compared [to] the long-term savings from using a cheaper generic drug, particularly for long-term maintenance drugs," says Alex Sugarman-Brozan, the group's director.

Still, for certain consumers, the coupons can pay off.

"Coupons are a meaningful money-saver for people whose doctor has determined that [this] is the drug they should be on," says Dr. William H. Shrank, a pharmacoepidemiologist at Harvard Medical School. "But patients should be aware that, even if they are insured, they may be charged a large amount once the coupon is used, as insurers often require high-tier co-payments for these branded drugs."

Patients interested in a coupon should determine whether a generic is available -- and then ask their physician if the generic is appropriate. Because brand-name drugs can be two to four times more expensive than generics, the brand-name drug is often more costly even if a coupon is available, says Steven Findlay, a healthcare analyst with Consumers Union.

A look at several sites turned up few drugs with coupon offers for which there was a generic equivalent, and in those cases, the coupon didn't bring the brand name down to the generic's lower price.

Synthroid, for example, a brand-name drug from Abbott Laboratories that treats thyroid hormone insufficiency, costs $13.99 per month at drugstore .com, versus $8.99 for the generic. But the coupon Abbott is now promoting only takes $3 off of each prescription, making the generic cheaper by $24 per year.

Although generic drug manufacturers rarely, if ever, offer coupons, specific insurers may. Blue Cross of California has a program called Generic Advantage, for example, which will often cover the cost of the co-pay each month if consumers choose a generic version of a drug.

And although the coupon deals may save money, consumers will almost always have to give up some privacy. Drug companies usually require personal information including name, age, address, phone number and e-mail address in exchange for the offer.

Some sites let consumers opt out of receiving additional information, but doing so can preclude getting future discount offers.

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FDA Considers Easing Curbs on Drug Makers

Research on Off-Label Use Could Be Sent to Doctors

By Christopher Lee
Washington Post Staff Writer
Saturday, December 1, 2007; A04

The Food and Drug Administration is considering allowing pharmaceutical makers to provide doctors with medical journal studies of unapproved uses for drugs, a move critics say would undermine long-standing restrictions on marketing medicines for "off-label" purposes.

Under a draft "guidance" prepared by the FDA, drug and medical device manufacturers could distribute unabridged reprints of peer-reviewed research from reputable medical journals as long as the articles were not written, edited or otherwise "significantly influenced" by the manufacturers or people with financial ties to them. No other promotional materials could be attached to the reprints, which would have to be labeled as describing uses for the products that have not been approved by the FDA.

The proposal would be a break with the FDA's prohibition on the marketing of drugs and medical devices for unapproved purposes, which dates to 1938. It is legal for doctors to prescribe approved drugs for off-label uses, however, and the practice is common for some types of drugs.

In 1997, Congress created a temporary exception allowing companies to distribute reprints so long as they submitted them to the FDA for advance review and had formally asked the FDA to approve the new use. That exception expired in 2006. In recent years, the marketing restrictions have been the subject of legal challenges on free speech grounds.

Rep. Henry A. Waxman (D-Calif.), chairman of the House Committee on Oversight and Government Reform, said creating a new path to promote off-label uses could improperly influence doctors' prescribing habits. In a letter yesterday, Waxman urged FDA Commissioner Andrew C. von Eschenbach to suspend drafting of the new guidance and cooperate with a committee inquiry into the issue.

The draft guidance "would open the door to abusive marketing practices that will jeopardize safety, undermine public health, and lead to an increase in unapproved uses of powerful drugs," Waxman wrote.

Companies would be less likely to conduct definitive scientific studies and seek formal FDA approval for alternative uses of drugs and devices if they could promote and profit from off-label uses anyway, Waxman contended. He said the proposal could grant undue influence to incomplete or distorted studies, some of them industry-funded. And he pointed to several high-profile cases in which drugs such as Vioxx and Celebrex were trumpeted in flawed journal articles that either underreported dangers or overstated benefits.

"While there may need to be a balance between First Amendment and protection of the public health," Waxman wrote, "the answer is not to open the door to unrestricted dissemination of potentially questionable information about drug safety and effectiveness."

FDA spokeswoman Rita Chappelle said the agency does not comment on letters from Congress.

Ken Johnson, senior vice president of the Pharmaceutical Research and Manufacturers of America, said it is "premature" to comment specifically on the FDA draft, but that providing the articles to doctors could help them make better prescribing decisions.

"These off-label uses or treatment regimens may be important and may even constitute a medically recognized standard of care," the guidance says.

Some people depend on off-label uses of drugs, said Diane Dorman, vice president for public policy at the National Organization for Rare Disorders.

"There are nearly 30 million people in the United States affected by almost 7,000 known rare diseases," Dorman said. "Consequently, most of those disease states are treated off-label because there is no therapy specific for their disease. So getting that information to physicians, I would consider to be very, very important for the patient."

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Improving patient compliance with low-cost wireless technologies
(10/11/2006)

Patient non-compliance represents significant lost revenue to pharmaceutical makers. Industry experts estimate that 50% of all prescriptions filled are never consumed, 20% of all new drug prescriptions are never filled the first time, and 30-40% of initial prescriptions are never refilled.

According to Datamonitor, patient non-adherence costs the pharmaceutical industry in excess of $30 billion a year. In the US statin market alone, non-adherence in a single year adds up to an estimated $3.9 billion in lost revenues for the industry.

Improving patient compliance, even slightly, can have significant impacts on revenues for drug makers, expenses for third party payers and outcomes for patients. For a $1 billion product, a 5% increase in patient adherence can reap $30-40 million in revenue.

According to Jane Martin, a respiratory therapist and founder of pulmonary patient support programs in Michigan, the most successful patient compliance interventions come down to "patient education made so simple and convincingly logical, that there is little reason for a patient not follow the prescribed instructions."

In Martin's case, she identified the areas of development, chemistry, engineering, user-friendly product design, and distribution as all being vital components in the success of inhaled pulmonary medications for her COPD patients. But she encourages the pharmaceutical industry to work on methods of integrating technology with the human element to improve the level of adherence.

"You have to impact the patient's behavior as well as educate them about the relative benefits of the medication" suggests Robert Nauman, Principal at BioPharma Advisors. "Patients need consistent information reinforcement to change their behavior. Relevant content is the key to the adoption of positive behaviors."

As outlined in previous eyeforpharma articles (www.eyeforpharma.com/search.asp?news=45652), the following behaviors have been identified as some of the top reasons for patient non-adherence:
- simply forgetting (65%);
- concerns about the drugs themselves (45%);
- and feeling the drug is unnecessary (43%).

Phil Cohen of Mobile Reach Media believes wireless technologies offer just the kind of simplicity Martin and Nauman advocate, while providing a quick and effective solution to the three leading reasons for non-compliance.

Cell phones are a user friendly, yet multi-faceted technology that allow those concerned with patient adherence to identify non-compliant patients, determine the key issues hindering their adherence, and respond in an effective, timely and simple manner.

Cohen says that although wireless technologies, like SMS, have been around for a few years now, wireless carriers have made the technology nearly impossible to execute effectively for the purpose of improving adherence. But that's all changing, he says, "as carriers want more volume of transactions on their networks, prices are falling and richer media driven content is being made available to subscribers."

Cohen believes the timing and fit are ripe for wireless technologies to help pharmaceutical companies, healthcare providers, insurers, and governments initiate programs that improve patient compliance.

Applying wireless technologies to improve patient adherence
According to a recent World Health Organization report on patient compliance, studies consistently find significant cost-savings and increases in the effectiveness of health interventions that are attributable to low-cost interventions for improving adherence. In many cases investments in improving adherence are fully repaid with savings in health care utilization and, in other instances, the improvement in health outcomes fully justifies the investment.

Pharmas investing in patient compliance initiatives stand to benefit to the tune of tens of millions of dollars per project, while those who are not, risk leaving hundreds of millions of dollars on the table across their portfolios.

Solving adherence problems really shouldn't require 'rocket science.' Issues hindering adherence are usually not technical matters, but are related to cognitive behavior A solution begins with effectively identifying and understanding the 'trouble spots' from the

patient's perspective in order to be able to selectively apply a relevant solution.

For patients that simply forget to take their medication - the leading reason for non-compliance - an effective wireless solution can be used to detect non-adherence and to intercede with an increase in relevant information. Treatment regimen reminders and relevant content delivered in a timely manner (i.e. when their dose is getting late and may be missed) provide a significant improvement over education alone. That additional information helps patients questioning the efficacy of their treatments at a time when they may begin to 'drop off' their medication. A timed communication protocol, in which patients are encouraged to look for both the subtle and overreaching signs of their progress helps reinforce the need to stay on the medication as prescribed by their physician.

Patients also may become non-adherent in response to concerns about drug side effects (45%). Cohen suggests a simple, interactive wireless communication can be used to both detect and instantly respond to side effects. Such communication, he says, will either generate a level of comfort among patients that some side effects are 'normal' or initiate a response by appropriate medical staff for instances of adverse side effects, driving increased awareness of the issue in both cases.

The third key impediment to compliance – feeling like the prescribed medicine is unnecessary – also can be addressed with wireless intervention. Self-efficacy ratings collected in real-time with the aid of wireless compliance technologies may more accurately document a patient's true attitudes about the effectiveness and perceived side effects of the prescribed drug than recollections collected on a paper questionnaire at a later time are able to capture. In addition, incremental reporting offers opportunities for educational interventions that reassure patients that the effects they are feeling (or not) are "normal" or desirable with a given drug and to reinforce the importance of adhering to the prescribed drug and dosing protocol.

Wireless technology makes sense as an educational tool because its messages are, by definition, short and to the point. In a world where we are constantly bombarded with messages from various media, wireless messaging can often 'hit the spot' in a quick and effective manner. Furthermore, the wireless device today, is a medium that often gets priority treatment; cell phone calls rarely go unanswered, and short messages, are almost always retrieved right away, because it can be done without significant interruption to other activities.

Overcoming inertia with the voice of a health 'leader'

"If industry experts say that 50% of all prescriptions are never consumed and 20% of all new drug prescriptions are never filled the first time, there is clearly a need for tools that will help patients overcome the initial inertia of beginning their treatments and understanding the relevant benefits of that action," says Cohen. "There is an obvious need to keep the patient's initial enthusiasm from the visit with their physician alive until they have actually filled the prescription and initialized an established routine of behavior that will bring about positive change."

Even though one's personal healthcare should be the most primal concern, there is evidence all around us that we behave to the contrary. One need only look at the number of smokers in the world or the level of consumption of unhealthy foods for anecdotal evidence that people are not taking action.

Sometimes all people need is a reminder from the 'right authority' with some rationale as to why it is important to them to take the medication as prescribed.

According to the UK Medicines Partnership project, people are more likely to adhere if they believe that their doctor, nurse, physician assistant or pharmacist cares whether or not they stick with the plan. Studies show that people who receive explanations from a concerned doctor are more satisfied with the help they receive and like the doctor more. And the more they like the doctor, the better they follow a treatment plan.

In the case of prescription non-compliance, the physician as a health 'leader' and influencer can be largely represented by an automated, wireless service with a simple message reminding patients what they must do to get healthy.

Nauman cites a pilot project done several years ago were a vaccine company was losing 85% of its patients before their second dose. Through cellular technology, physicians were given a microsite to register patients and enroll them in a reminder program. The results showed that 70% of the patients who were on the program came back for their second dose as a result of the reminder program.

Being able to reach patients at critical times, no matter where they are, and involving other parties to intervene directly with the patient in real-time when there is an identified risk of non-adherence may yield increased effectiveness and adherence.

Through the looking glass

A successful patient compliance program might begin, for example, with patients being encouraged (at the time a prescription is initially written) to participate in a proven adherence method to increase their chances of success, suggests Cohen. By getting communication started right away and by alerting a wireless adherence service provider quickly, the patient can be guided by educational messaging even before they start their medication.

Once a wireless adherence service is activated on a patient's mobile device, if non-adherence is detected, an automated reminder to comply can be delivered. If the reminder is not heeded, Cohen says, a friend, family member or even a willing physician can be automatically notified in real-time and may intervene with the patient. This is particularly true of parents with teenagers or young

adults who may be on medication while at school.

If a patient's family, friends or other key influencers are playing the primary role in maintaining adherence, the physician may only receive periodic, aggregated patient activity notices as a secondary line of defense in adherence monitoring, Cohen points out. This gives doctors complete discretion, he says, as to whether their involvement is required, how much time they might want to invest and if office staff should intervene to investigate what is causing non-adherence with individual patients.

After a while, Cohen says, patients may stop using the adherence system altogether when good habits are established or may simply find it is not 'right' for them. Others may choose to change the key intervener for their service to friends and family. But the bottom line, he says, is patients should be allowed to opt out if they choose to do so to preserve patient satisfaction.

Most patients, however, will cognitively recognize the value and appreciate the intervention, Cohen says. Despite the significant impact wireless programs can have on improving patient compliance, however, an overall adherence solution should incorporate other adherence tools and efforts, each targeting specific patients, but combining to be greater than the sum of the parts.

Whose responsibility?
It can be argued that those who stand to gain the most financially should be the ones to invest the time and effort into ensuring patient adherence, Cohen says. But he warns patients are less likely to feel comfortable that it is in their best interests to remain compliant if they are being urged to do so by those with an obvious financial incentive to see them do so indefinitely.

Physicians, pharmacists and family members hold the most sway over encouraging adherence, because they have, presumably, already earned the trust of the patient. The challenge is to create a reliable system that allows these influencers to be involved in increasing health benefits to patients, while encroaching only minimally on their limited available time to do so.

"Programs need to be devised and coordinated at the level of the drug manufacturers and retailers, which manage and encourage physician involvement in this vital role," Cohen says. "But doctors must be duly compensated for increased time spent on adherence efforts with patients and for results achieved."

At least in the beginning, Cohen suggests, the pharmaceutical industry should foot the bill for compliance programs, since they have the most to lose financially from patient non-adherence. But ultimately, he says, early successes and lobbying power can be used to convince retailers, insurers and governments to contribute, as all will gain from better patient compliance.

In fact, a recent study sponsored by GlaxoSmithKline found that in the state of Ohio, one in five patients do not take their medications as recommended, adding $700 million a year to healthcare costs statewide.

The bottom line for pharma: Compliance pays
Wireless solutions will likely be effective among only a sub-population of all patients in any given group. With 65-70% penetration of cell phones in the greater population, not everyone can participate. And among those that do participate, some attrition can be expected during the initial period of a program.

However, if a solution is cost effective and does a good job of increasing adherence among those who do participate, the net effect can be significant.

For example, Cohen says, maybe only 15% of a given patient population would be willing to participate in a wireless adherence program. And perhaps only 75% of those already have a phone, leaving 11% able to participate. If patient attrition from the program reached as high as 50% for various reasons during the first months of the program, only 6.5% from the initial 15% that showed interest in the program would remain.

But if the adherence rate among the remaining 6.5% could be increased from the average 40% rate commonly achieved to 85% with the program, net adherence rates among the entire group of patients ever written a prescription for the drug in question could be boosted by 2.5%.

If the drug in question costs $80/month, for example, a pharma company's product generating 2 million prescriptions annually could reap increased annual revenues of $48 million. In addition, patients' health would be improved and insurers would avoid additional expenses due to hospitalizations, surgeries or other protracted healthcare interventions. In the above scenario, if a typical wireless adherence service costs $5 per patient per month, a return on investment from 300-600% can be achieved. That compares quite favorably with typical average returns on direct to consumer advertising (200%), traditional in-office details by sales representatives (172%) and e-detailing (248%).

Moving forward
According to the IFPMA's director general Harvey Bale, the industry's role should go beyond the traditional one of bringing the medicines to the market. Industry, he says, also has a necessary role in helping to inform patients about their products. This should be in such a way, Bale suggests, that broader and increased knowledge and understanding can support the patient's relation to, and dialogue with, the prescribing doctor and the other health professionals involved, such as nurses and pharmacists, in following the prescribed treatment to achieve the best outcome for both the patient and the health care system.

In many scenarios, wireless technologies can efficiently and cost-effectively improve patient adherence, but Cohen says the industry faces a few challenges moving forward. Pharmas, in conjunction with technology providers, must:

- Understand where improvements can be made within the confines of governmental regulations
- Choose technology that can enable the desired levels of adherence improvement in a flexible and cost effective manner
- Prove increased adherence, leading to exceptional ROI
- Validate ease of use among patients
- Understand that different situations call for different wireless technologies and deploy the easiest technologies and maintain ease of use among patients

The most logical place to begin as a proof of concept, Cohen suggests, is with high value drugs (blockbuster or semi-blockbuster products) taken at low dosage frequencies (e.g. 1-4 times per month) and carrying a fairly high price (i.e. $60+/month). But significant returns on investment in wireless adherence programs promise to make the technology a "must have" for many products in pharma's portfolios.

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VIEWPOINT

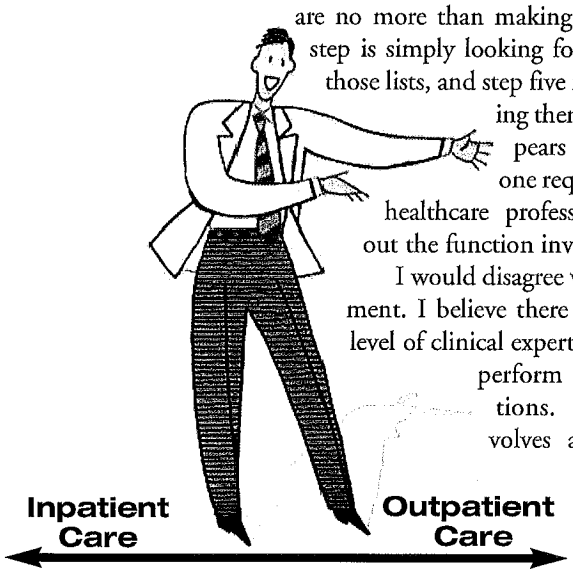
Bruce Canaday, Pharm.D.

Public Ed

Whose job is medication reconciliation, anyway?

Who should take ownership of medication reconciliation? The Joint Commission tells us that medication reconciliation is a process made up of five steps: develop a list of current medications, develop a list of medications to be prescribed, compare the medications on the two lists, make clinical decisions based on the comparison, and communicate the new list to appropriate caregivers and the patient.

An argument could be made that the first two steps are no more than making lists, the third step is simply looking for differences in those lists, and step five is communicating them. Step four appears to be the only one requiring a trained healthcare professional to carry out the function involved.



I would disagree with this assessment. I believe there is a significant level of clinical expertise necessary to perform all five functions. Step one involves asking patients what medications they are on, transferring medication lists between community and institutional pharmacies, and contacting prescribers to develop a list of drugs patients are taking. Step two, or choosing the "right" medications to prescribe for a patient, should be part of a very well thought out, patient-specific therapeutic plan requiring, at a minimum, knowledge of the patient's conditions, the desired outcomes, and a clear understanding of the risks, benefits, and proper use of each medication under consideration.

Similarly, step three should be a comparative clinical evaluation of the medications on the two lists based on the above criteria, leading directly to step four. Step four, the "clinical decisions" piece, requires the highest level of expertise to ensure that the "right" medications are used to optimize patient outcomes. The final step, communicating the new list to appropriate caregivers and the patient, while no less critical, should be handled by the best communicator available.

So who is best qualified to fulfill these five steps? Successful execution of these five steps mandates a knowledge base that is, I believe, unique to the pharmacist. Certainly other professions can and do bring something to the table. I'm not saying that pharmacists are the only option. However, the person "responsible" for execution and the outcome should be a pharmacist since pharmacists are the best trained in medication management. To quote the old Carly Simon song, "Nobody does it better!"

But accepting that "medrec" is our responsibility is only half the battle. What does responsibility mean? If we are to accept responsibility, we cannot do so by remote control. I have seen too many pharmacists claim responsibility for medrec when all they've done is sit on a committee that designed a process of developing a medication listing on the front end. Meanwhile they've deferred the work of medrec to nurses, aides, and others.

Why are so many pharmacists content to sit on the sidelines and watch? Why are we not stepping up to use our professional expertise to deal with the issue of poor communication of medical information at transition points that is responsible for so many medication errors and adverse drug events?

Ultimately, the most common argument against having pharmacists do this is lack of resources—code for "money." While we have to be fiscally prudent, our ultimate responsibility must be to provide the best possible patient care. At the end of the day, resource allocation is not about how much money there is—there is a lot of money in health care—it is about how the money is allocated; it is about priorities. Shame on hospital administrators for not recognizing that having pharmacists actively engaged in this process should be a priority. And shame on us for not being able to convince our bosses, our colleagues, and our patients that our skills are worth paying for because we can reduce medication errors and adverse effects due to medications.

Personally, I think the "best care possible" standard is met by asking, "Would that be what I want for my mother?" In this case, the person I want making decisions about medication use for my loved ones—taking responsibility for medication reconciliation—will have "pharmacist" on his or her name tag.

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Illustration: Dynamic Graphics, Inc.

Of Interest to Pharmacists

Public Ed

Medication reconciliation policies incomplete at many hospitals

Michael Barbella

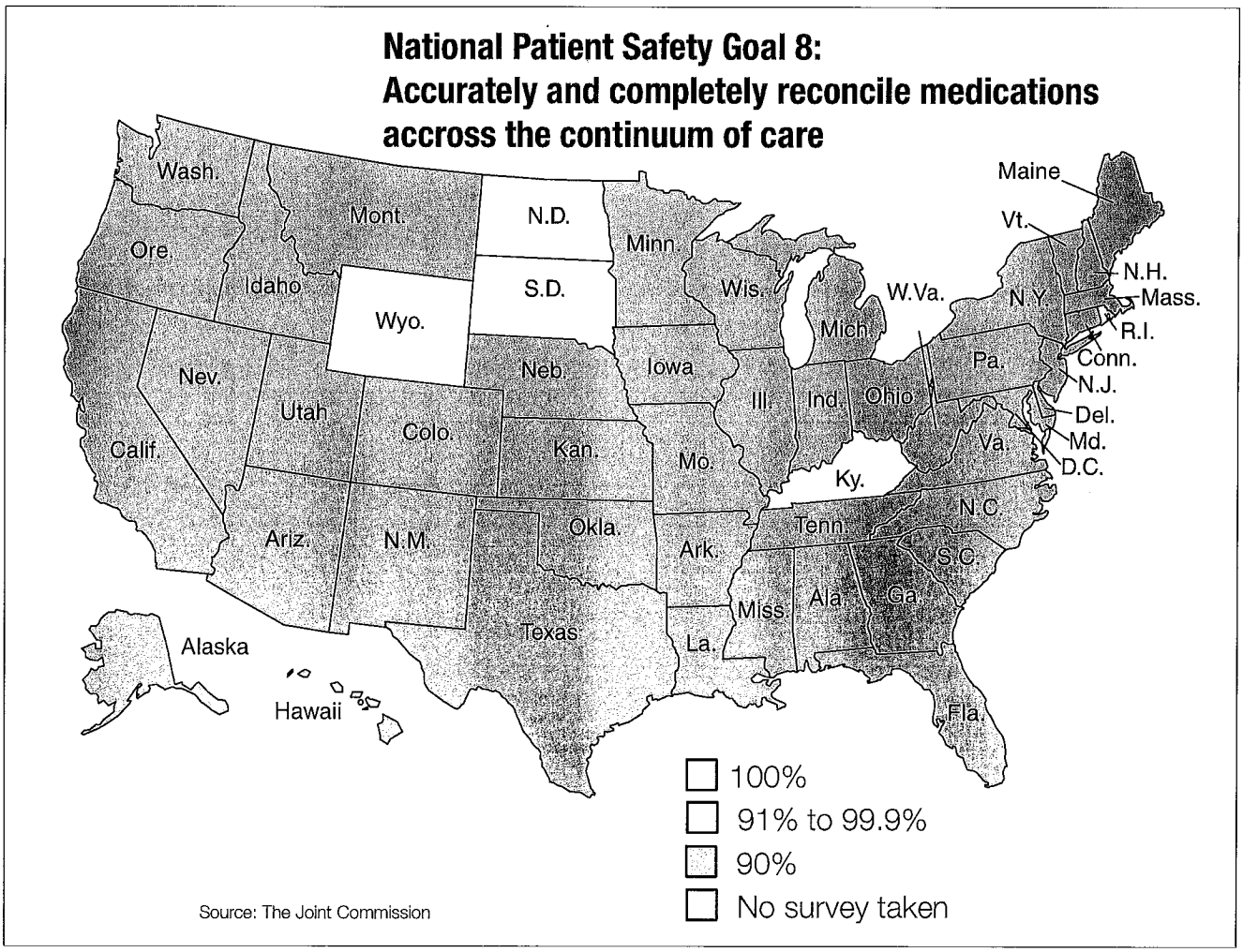
Overall, most hospital pharmacists think their institutions do a good job of reconciling patients' medications. But two out of 10 know of incidents in which inadequate policies have led to patient harm, an exclusive *Drug Topics* survey concluded.

In many cases, respondents said their hospital's policies failed to catch a duplication of medication or missing doses, the survey found. In other instances, medications were omitted or there was no follow-up. And several respondents blamed their hospital's shoddy medication reconciliation policy on inadequate staffing.

Medication reconciliation "was done late in the evening when staffing was less than earlier in the day," one pharmacist wrote. "Patients being admitted during shift changes resulted in late med reconciliation, or it not being done at all." Another health-system R.Ph simply stated, "Took too long to reconcile home meds."

Drug Topics conducted the nationwide survey of hospital pharmacists from Sept. 27 through Oct. 10. The survey was sent to 12,105 subscribers of the magazine; 640 pharmacists responded.

Seven percent of those who responded said the Joint Commission found fault with the way their hos-



Medication reconciliation process at hospitals suffered relapse in 2006

The nation's hospitals did a poor job last year of reconciling patients' medications. And the problem seems to have gotten worse.

A new report from the Joint Commission concluded that only two-thirds of American hospitals reconciled medications, down from 99.9% in 2005. There was a similar drop in reconciling medications across the continuum of care, including at discharge: 72.5% of the nation's hospitals consistently did so last year, a drop of 27.2% from 2005, according to the report, *Improving America's Hospitals: The Joint Commission's Annual Report on Quality and Safety 2007.*

"This is a test of hospital competency in redesigning care processes," said Joint Commission president Dennis O'Leary. "It's seemingly simple to get the list of medications from where the patient was to where the patient is going. But in fact it is a terrible challenge."

Medication reconciliation proved to be one of the biggest challenges for hospitals last year, the report stated. The commission identified nine issues that were most difficult for hospitals to meet, and medication reconciliation was the second-most problematic, recording a 54% compliance rate. Only one issue proved to be more difficult for hospitals to meet than medication reconciliation: improving the effectiveness of communication among caregivers. That issue had a 42% compliance rate, the report found.

Other difficult issues for hospitals last year included the proper and safe storage of medications, ensuring that medication orders are written clearly and transcribed accurately, proper pain assessment, improving medication safety, managing safety risks, and keeping a "complete and accurate" medical record of all patients served.

pitals handled medication reconciliation, the process by which healthcare practitioners obtain and document a complete list of a patient's current medications upon admission to a hospital or healthcare facility. A complete list of the patient's medications should ideally be given to the next healthcare provider upon discharge or transfer to another facility.

The Joint Commission has included medication reconciliation on its list of National Patient Safety Goals for the past several years. The process also is endorsed by the Institute for Healthcare Improvement.

When asked if the Joint Commission found fault with their hospital's medication reconciliation policy, and, if yes, how, many pharmacists responded with a simple "not being done." Others said additional steps were needed in outpatient areas, while some said their program was not far enough along.

"Our policy didn't include reconciling home meds upon admission with home meds to be taken after discharge," one pharmacist explained. "It does now, but remains the problem area."

Another R.Ph. griped that there is "inconsistent following of the (medication reconciliation) policy" at his institution. "Some providers are very good, some not."

Still others said the Joint Commission faulted their policies because they were not uniformly followed throughout the hospital, or because physicians were not active enough in the process.

Seventy percent of respondents said their hospitals allow patients to bring in their own medications. Among those pharmacists, 53% noted they have run into problems identifying patients' medications.

When asked for suggestions to improve the patient handoff process at their hospitals, respondents proposed a better communication process, more accurate drug information, and increased involvement from pharmacists.

"Better communication [is required] with the patient to verify that he understands the medication changes that have been made," wrote one pharmacist. Other respondents challenged doctors, nurses, and pharmacists to be more communicative with one another, while some felt there should be more interaction during shift changes and at patient transfers. One pharmacist even placed the responsibility of improving the process on the patient, calling for "a better understanding for patients as to what they are expected to provide to caregivers." DT

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Adverse Drug Events Spike

Reported fatal adverse drug events increased 2.7-fold from 1998 through 2005 to more than 15,000, and serious, non-fatal drug events jumped to nearly 90,000, researchers have found. The reason for the increases "is not completely known," said the Food and Drug Administration (FDA).

"Reported serious events increased four times faster than the total number of outpatient prescriptions during the period," said researchers writing in the Sept. 10 issue of *Archives of Internal Medicine*. "In a subset of drugs with 500 or more cases reported in any year, drugs related to safety withdrawals accounted for 26 percent of reported events in that group in 1999, declining to less than 1 percent in 2005."

Authors Thomas J. Moore, AB, and Michael R. Cohen, RPh, MS, ScD, of the Institute for Safe Medication Practices; and Curt D. Furberg, MD, PhD, of the Wake Forest University School of Medicine, analyzed 467,809 voluntary reports submitted directly to the FDA or through drug manufacturers to the Adverse Event Reporting System.

They found that fatal adverse events nearly tripled from 5,519 in 1998 to 15,107 in 2005 and serious, non-fatal events increased 2.6-fold—from 34,966 to 89,842.

"The increase was influenced by relatively few drugs: 298 of the 1,489 drugs identified (20 percent) accounted for 407,394 of the 467,809 events (87 percent), the authors said.

The FDA said in a statement that it was aware of the growing number of reported problems and takes them seriously, but the reason for the increase "is not completely known."

"While some of this has to do with the increasing number of prescriptions, there are clearly other factors responsible for this increase, such as the increase in public attention to drug safety, and use of the Internet to make it easier for the public to submit [reports]," Gerald Dal Pan of the FDA's surveillance and epidemiology office said in the statement.

Top 5 Drugs Linked to Fatalities or Serious Adverse Events 1998-2005

DRUG	FATALITIES
Oxycodone	5,548
Fentanyl	3,545
Clozapine	3,277
Morphine	1,616
Acetaminophen	1,393

DRUG	SERIOUS, NON-FATAL
Estrogens	11,514
Insulin	9,597
Infliximab	8,754
Interferon beta	8,320
Paroxetine	8,095

Source: Archives of Internal Medicine

Medicare Surety Bond Proposal Challenged

NCPA is strongly objecting to a proposal that would require independent pharmacies to purchase $65,000 surety bonds to continue providing durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) to Medicare patients. The Centers for Medicare & Medicaid Services (CMS), which is proposing the requirement, estimates that such bonds would cost $2,000 each.

NCPA is pointing out to CMS and lawmakers on Capitol Hill that practicing pharmacists already are licensed and regulated by the states, so a surety bond is an unnecessary and burdensome requirement.

Zoledronic Acid Decreases Rate of Repeat Hip Fractures and Mortality

An annual infusion of zoledronic acid within 90 days after repair of a low-trauma hip fracture was associated with a reduction in the rate of new clinical fractures and improved survival. This conclusion was published in a study in *The New England Journal of Medicine* (published online before print, September 17, 2007).

Researchers found a 35% reduction in new clinical fractures and a 28% reduction in death from any cause compared with placebo. An editorial accompanying the study said, "No other controlled clinical trial has previously shown efficacy of any osteoporosis medication for reducing the recurrence of fracture in patients who already had broken a hip."

In a randomized, double-blind, placebo-controlled trial, 1,065 patients were assigned to receive yearly intravenous zoledronic acid (at a dose of 5 mg), and 1,062 patients were assigned to receive placebo. The infusions were first administered within 90 days after surgical repair of a hip fracture. All patients (mean age, 74.5 years) received supplemental vitamin D and calcium. The median follow-up was 1.9 years. The primary end point was a new clinical fracture.

Only 42% had osteoporosis that was diagnosed on the basis of measurement of bone mineral density by dual-energy x-ray absorptiometry (DXA) at the time of the fracture, which may reflect the insensitivity and inadequacy of DXA as a screening tool for identifying patients at risk for hip fracture, the authors report.

The rates of any new clinical fracture were 8.6% in the zoledronic acid group and 13.9% in the placebo group, a 35% risk reduction with zoledronic acid ($P = 0.001$); the respective rates of a new clinical vertebral fracture were 1.7% and 3.8% ($P = 0.02$), and the respective rates of new nonvertebral fractures were 7.6% and 10.7% ($P = 0.03$). In the safety analysis, 101 of 1,054 patients in the zoledronic acid group (9.6%) and 141 of 1,057 patients in the placebo group (13.3%) died, a reduction of 28% in deaths from any cause in the zoledronic acid group ($P = 0.01$). The most frequent adverse events in patients receiving zoledronic acid were pyrexia, myalgia, and bone and musculoskeletal pain. The rates of renal and cardiovascular adverse events, including atrial fibrillation and stroke, were similar in the two groups.

Researchers noted that patients in this trial could not tolerate or would not take an oral bisphosphonate, and a previous risedronate trial was not successful in reducing hip fracture in patients older than age 80.

The editorial also notes that the results "appear both powerful and compelling. The reduction in fracture incidence and death was striking and clearly establishes the need for pharmacologic intervention in patients who fracture a hip."

Adverse Drug Events Reported to FDA Increased

The number of serious adverse drug events (ADEs) reported to the Food and Drug Administration (FDA) more than doubled between 1998 and 2005, as did associated deaths, according to a report in the *Archives of Internal Medicine* (Arch Intern Med 2007; 167:1752-9).

FDA defined a serious ADE as one that resulted in death, a birth defect, disability, or hospitalization; was life-threatening; or required intervention to prevent harm. These events are voluntarily reported to FDA through its Adverse Event Reporting System (AERS), also known as "MedWatch." The reports come to FDA directly or through drug manufacturers, which are required to forward them to the agency, the study said.

Researchers from the Institute for Safe Medication Practices analyzed serious ADEs reported to FDA through AERS. The annual number of reports from 1998 through 2005 increased 2.6-fold during that period, from 34,966 to 89,842; a total of 467,809 serious ADEs were reported during that time. The number of fatal ADEs increased from 5,519 to 15,107 in the same time frame, a 2.7-fold increase.

"The overall relative increase was four times faster than the growth in total U. S. outpatient prescriptions, which grew in the same period from 2.7 billion to 3.8 billion," the authors said.

A total of 1,489 drugs were associated with ADEs, but a subset of 51 drugs, each of which having 500 or more reports in any year, accounted for 203,957, or 43.6% of the total ADEs reported in the study.

"Contrary to our expectations, drugs related to safety withdrawals were a modest share of all reported events

and declined in importance over time," the authors write. In the subset of 51 drugs with 500 or more reports in a year, the percentage of reported events associated with drugs related to safety withdrawals declined from 26% in 1999 to less than 1% in 2005.

In addition, "Among the most frequently reported drugs associated with fatal events, we observed a disproportionate contribution of pain medications and drugs that modify the immune system," researchers noted.

"The results highlight the importance of this public health problem and illustrate the need for improved systems to manage the risks of prescription drugs," the authors said.

Use of Alternative Plus Conventional Medications May Put Elderly at Risk

Concurrent use of complementary/alternative medicines (CAM) and conventional medications is common in the Medicare population, yet little is known about potential interactions, according to a study published in the *Annals of Pharmacotherapy* (Ann Pharmacother 2007;41:1617-24). The study is considered to be the first population-based analysis of the prevalence of concurrent CAM products.

The elderly are of special concern, the authors note, because polypharmacy is well documented, sensitivity to some medications is greater, and the organs that process many drugs become less functional as people age. "These factors raise the likelihood that potentially toxic drug combinations will occur," the article says. In addition, about half of herbal product users do not discuss their use with a health care professional, creating a theoretically significant risk for adverse CMA product-drug interactions.

The authors performed a retrospective analysis on data from the Cardiovascular Health Study for four years: 1994, 1995, 1997, and 1999. Of 5,052 participants, the median age was 75, 60.2% were female, 16.6% were African-American, and 83.4% were white. The percent using CAM products during the four time periods was 6.3%, 6.7%, 12.8%, and 15.1%. The percent using both CAM products and conventional drugs was 6.0%, 6.2%, 11.7%, and 14.4%. Of these, 294 (5.8%) individuals took combinations considered to have a significant risk for an adverse interaction. Combinations with risk were observed on 393 separate interviews.

Garlic, ginkgo, and ginseng are the top three CAM products used in this population. Most of these interactions (379) involved a risk of bleeding as a result of the use of ginkgo, garlic, or ginseng together with aspirin, warfarin, ticlopidine, or pentoxifylline. An additional 786 observations of combinations were considered to have some potential risk for an adverse interaction.

The authors noted that although participants presented all CAM products and conventional medications taken the previous two weeks to a study team member, other desirable information was limited. Researchers did not know the doses taken, the prevalence of use during the evaluation period, or whether the CAM and conventional medications were taken simultaneously each day.

The authors encourage further research to define the risks of combining these medications and the risk on the elderly population.

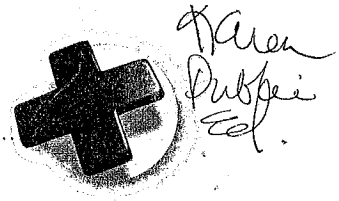
Being Overweight Does Not Cause Memory Problems

While obesity has been shown to contribute to high blood pressure, heart disease, and diabetes, being overweight in old age does not lead to memory problems, according to a study published in *Neurology* (published online before print September 19, 2007).

The study, conducted from 1993 to 2003, involved 3,885 community-dwelling people living in Chicago older than age 65. Of the participants, almost 25% were obese, with a body-mass index (BMI) more than 30, and 37% were overweight, with a BMI between 25 and 29.9. There was an average follow-up of 6.4 years.

Four cognitive tests were given at the beginning of the study and every three years over the six-year period. The study found no significant changes in memory or cognitive function throughout the study for overweight or obese participants. In fact, participants who were underweight had more cognitive decline over time.

"We do not know yet why being overweight or obese does not increase the risk for cognitive decline



Same Name Not Always Same Drug in Other Countries

The Institute for Safe Medication Practices has received a number of reports involving brand name medications that may contain different active ingredients in another country. In one report, a patient was prescribed Dilacor XR (diltiazem extended release) 120 mg daily for hypertension. While traveling to Serbia, he ran out of medication. A Serbian pharmacist filled the prescription, but he actually dispensed digoxin 0.25 mg because, in Serbia, Dilacor is a brand name for digoxin. The patient did not notice the change in tablet strength, so he continued to take the medication for three days upon return to the United States. However, he took extra doses each day (2–3 tablets) because he felt his blood pressure medication was not working. By the third day, the patient experienced signs of digoxin toxicity including nausea, vomiting, headaches, and chest pain worsened by exertion. He went to an emergency department and was admitted for monitoring and treatment with Digibind (digoxin immune FAB).

In another case, a hospitalized patient developed gastrointestinal (GI) bleeding and the medical team was trying to determine the cause. A pharmacy student on the team was asked to find out what "Cartia" was, since the patient had apparently been taking that medication prior to admission. The student found that several Web sites, as well as Micromedex, described Cartia as a 100 mg enteric-coated tablet of aspirin. When the student reported this information to the team, a decision was made to discontinue the drug as aspirin can cause GI bleeding. Fortunately, a medication error was averted when it was discovered that the patient was actually taking Cartia XT (diltiazem in the United States), which is bioequivalent to Cardizem CD, to treat hypertension and angina. Cartia is a trademark for enteric-coated aspirin in New Zealand and Australia. However, this product can be purchased over the Internet in the United States, and both products could be considered "heart" medications, increasing the risk of error. If a patient taking Cartia XT searches the Web and finds that "Cartia" is available without a prescription and inexpensive (one site advertised 28 tablets for $1.94 in U.S. dollars), a medication error could occur. Confusion could also exist among physicians trained outside the United States or patients who travel between the United States and New Zealand or Australia.

Finally, the trademark Entex LA is used for two different products in the United States and Canada. In the United States, Andrx Pharmaceuticals markets a capsule formulation of Entex LA that contains phenylephrine hydrochloride (30 mg extended-release) and guaifenesin (400 mg immediate-release). In Canada, Purdue Pharma Canada supplies Entex LA as a tablet that contains pseudoephedrine (120 mg) and guaifenesin (600 mg). Compounding the confusion, the indicated adult dose for each product is one tablet every 12 hours.

ISMP recommendations being cautious of drug information only obtained from the Internet. Always question patients on the reason they are taking their medications so as not to rely solely on drug references. Remind patients when they travel to carry an adequate supply of medications and a list by generic and brand name. Those needing a temporary supply while overseas should confirm that the correct drug has been dispensed. ap

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This article has been provided by the Institute for Safe Medication Practices (ISMP). The reports described in this column were received through the USP-ISMP Medication Errors Reporting Program (MERP). Errors, near misses, or hazardous conditions may be reported on the ISMP (www.ismp.org) or U.S. Pharmacopeia (www.usp.org) Web sites. ISMP can be reached at 215-947-7797 or ismpinfo@ismp.org.

Kaiser Daily Health Policy Report

Monday, November 05, 2007

Prescription Drugs

Fewer U.S. Residents Purchase Prescription Drugs From Canada, In Part Because of Medicare Drug Benefit

Online drug sales in 2006 from Canadian pharmacies to U.S. consumers dropped about 50%, from $420 million Canadian dollars in 2005 to $211 million Canadian dollars last year, according to data from IMS Health, the *Philadelphia Inquirer* reports. Drug sales across the border to U.S. patients -- once "a hot trend" -- have been suppressed by several factors, including threats from U.S. pharmaceutical companies to stop supplying drugs to Canadian firms, rising drug costs in Canada, a weaker U.S. dollar compared with the Canadian dollar and the 2006 introduction of the Medicare prescription drug benefit, the *Inquirer* reports.

Legislation (S 1082) introduced this year by Sens. Olympia Snowe (R-Maine) and Byron Dorgan (D-N.D.) would reduce restrictions on imports and enhance safety by calling for all exporters and importers to register with federal authorities. The Pharmaceutical Research and Manufacturers of America opposes prescription drug imports, citing the possibilities that counterfeiting could rise and existing safety regulations could be compromised. FDA has "conducted periodic sweeps against drugs delivered through the mail," but "its leaders admit they lack the staff to do a thorough job," the *Inquirer* reports.

Ilisa Bernstein, FDA's director of pharmacy affairs, said the agency does not know for certain whether online sales are increasing or decreasing. She said, "We really don't have the resources to quantify the number of products coming in," adding that FDA uses a "risk-based approach" to select the drugs that pose a high level of danger and need closer safety scrutiny. Bernstein said, "What's scary is, a lot of these online sellers will sell you drugs without a prescription."

Randall Lutter, FDA's deputy commissioner for policy, in a statement said, "The data lead us to believe that many people are buying drugs online not to save money but to bypass the need for a prescription from their doctor, since these Web sites typically do not require the purchaser to have a prescription" (Stark, *Philadelphia Inquirer*, 11/5).

The New York Times
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November 3, 2007

Maker of Lipitor Digs In to Fight Generic Rival

By STEPHANIE SAUL and ALEX BERENSON

It is shaping up to be the biggest shift yet to a generic drug, potentially saving the nation $2 billion a year or more in prescription costs.

And scientists and doctors say that for most of the 16 million people in America who take drugs to reduce cholesterol, the low-priced alternative will work as well as the name-brand medicine — Lipitor, which is made by Pfizer and is the nation's most widely prescribed drug.

While Lipitor itself is not available as a generic, a very similar drug made by Merck, Zocor, lost its patent protection last year. The generic version of Zocor, simvastatin, is now much cheaper than Lipitor, leading insurers to press doctors and patients to switch.

But Pfizer is not letting its flagship drug go down without a fight.

The company has mounted a campaign that includes advertisements, lobbying efforts and a paid speaking tour by a former secretary of the federal Department of Health and Human Services. Pfizer is also promoting a study — whose findings many experts are questioning — that concluded that British patients who switched to simvastatin had more heart attacks and deaths than those who remained on Lipitor.

The Lipitor battle has become a test of the pharmaceutical industry's ability to defend name brands, even as insurers, patients and doctors seek to whittle the nation's $270 billion annual prescription drug bill by using generic alternatives whenever possible.

Lipitor and other cholesterol-lowering drugs, sometimes called statins, are the largest drug class, with spending of $22 billion last year in the United States alone. And they have been researched more thoroughly than any other group of drugs, making head-to-head comparisons easier.

Many doctors have come to see simvastatin as a viable substitute for Lipitor. Studies show that at commonly prescribed doses Lipitor and simvastatin are equally effective at reducing LDL cholesterol, the so-called bad cholesterol.

A big difference is that Lipitor costs $2.50 to $3 a day, while simvastatin sells for 75 cents to $1 a day at most retail pharmacies, and as little as 10 cents a day at discount pharmacies like Costco's.

Each month, doctors with patients on Lipitor are switching tens of thousands of them to simvastatin. And

simvastatin is also taking a growing share of the market for new patients who need a cholesterol drug. "Simvastatin is much less expensive to society over all and to patients," said Dr. Thomas H. Lee Jr., a prominent cardiologist. "If you put patients on generics," he said, "the chances that they're taking their medications six months later are higher than on a brand name drug. I think that a few hundred dollars a year does matter."

But Pfizer argues that Lipitor is the most effective statin and that patients who are having good results with it are not well-served by moving to another drug.

"The only reason one would want to switch from one drug to another is for the benefit of the patient's health," said Dr. Michael Berelowitz, senior vice president for worldwide medical affairs for Pfizer.

In September Pfizer began sounding safety alarms by citing an analysis of the medical histories of 2,500 people in Britain who switched to simvastatin from Lipitor, compared with 9,000 who did not make the change. The study concluded that patients who switched were more likely to have a heart attack or stroke than those who remained on Lipitor.

The results were presented on a poster at a European cardiology conference. And Dr. Berelowitz said the study had been accepted by the British Journal of Cardiology and would soon be published.

But independent researchers say that limitations in the study, which was conducted by Pfizer's own researchers, gives it little predictive power about what will happen to patients who take simvastatin instead of Lipitor. And they say the study is far less important than large clinical trials that have shown simvastatin's effectiveness at reducing cholesterol.

"It will run counter to everything that's been published to date if it's true," Dr. Lee said of the Pfizer study. He is president of the network of about 5,000 doctors in Partners HealthCare, the health system formed by Massachusetts General Hospital and Brigham and Women's Hospital in Boston.

Dr. Mark Fendrick, a professor of internal medicine at the University of Michigan and a specialist in health care economics, notes that for patients with extremely high cholesterol, Lipitor may be a better choice. An 80-milligram daily dose of Lipitor, the top dose, can reduce cholesterol by up to 60 percent, compared with about 50 percent for an 80-milligram dose of simvastatin, also the top dose.

But most patients with moderately high cholesterol take 10 or 20 milligrams of Lipitor a day, and can get comparable benefit from 40 or 80 milligrams of simvastatin, Dr. Fendrick said.

Dr. Robert O. Bonow, the chief of cardiology at Northwestern Memorial Hospital in Chicago and a past president of the American Heart Association, said patients' cholesterol levels should be monitored after the change, to make sure the simvastatin is having the desired effect.

"Switching itself is not a problem," Dr. Bonow said. "It's not that one drug has more risk or less risk."

Lipitor's share of the cholesterol-lowering drug market in this country has ebbed to 30 percent, down from 40 percent 18 months ago, when simvastatin was available only as name-brand Zocor — at prices that were higher than Lipitor's.

No generic version of Lipitor is in the offing because the Lipitor patent remains valid until at least March 2010. But the advent of generic Zocor has dented sales enough to hurt Pfizer's stock, which is trading near its lowest level in a decade.

In a recent conference call with Wall Street analysts, Pfizer vowed to step up its efforts to protect Lipitor. So far this year, the company has been spending more than 50 percent more on advertising the drug than it did in 2006, when its Lipitor ad spending for the year totaled $142.7 million.

Lately, Pfizer has been running a print and broadcast advertising campaign that features Dr. Robert Jarvik, the inventor of the artificial heart, endorsing Lipitor.

"There's a common misconception that all cholesterol-lowering medications are the same," Dr. Jarvik says in a radio ad. "They're not. There is no generic version of Lipitor."

Despite Pfizer's efforts, analysts and physicians say they see little chance of the company's stemming the generic tide. After two decades of prescribing cholesterol-lowering drugs, doctors are comfortable with both Lipitor and simvastatin, said Dr. Jon LeCroy, who is an industry analyst at Natixis Bleichroeder and a physician.

Insurers and pharmacy benefits companies are spurring patients to switch mainly by raising their out-of-pocket co-payments if they choose Lipitor, while lowering them for generic drugs. On Oct. 1, for example, Blue Cross and Blue Shield of Illinois raised the average co-payment for Lipitor by $10 to $20 a month, said Bridget Houlihan, a Blue Cross spokeswoman.

This year, Blue Care Network, a health maintenance organization affiliated with Blue Cross and Blue Shield of Michigan, offered to pay $100 to physicians for each patient who filled a prescription for a generic statin.

Pfizer is sponsoring a speaking tour by Dr. Louis W. Sullivan, a former secretary of Health and Human Services, who without citing Lipitor specifically is arguing against insurers' efforts to influence medical decisions.

The company has also been fighting the generics trend in the political arena. In a Sept. 10 letter to state lawmakers in Ohio, a Pfizer lobbyist cited the potential risks of switching to cheaper medicines.

That letter, from Linda Martens, Pfizer's assistant director of government relations in Ohio, noted the company's British study, saying it showed a 30 percent increase in cardiac risks "in patients who were switched from the leading cholesterol-lowering medicine, Lipitor, to another statin drug, simvastatin."

Independent researchers, however, say that the British study is of little value in comparing the two drugs, because it was not based on a clinical trial in which the two drugs were given to two randomly assigned groups of patients.

Instead, the Pfizer researchers simply compared the case histories of patients who had been switched with those who had not, regardless of the reasons they were taken off Lipitor. The results of the study are contradicted by a 9,000-patient clinical trial published in 2005, which found no statistically significant difference between Lipitor and Zocor.

Even a Pfizer doctor involved in the British study, Dr. Berkeley Phillips, said in an interview with the online publication WebMD that it did not prove that Lipitor worked better than simvastatin. "We can't say from this study that switching is bad or that one statin is better than another," Dr. Phillips said. "You would need a randomized clinical trial to say that."

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October 23, 2007

Sleep Drugs Found Only Mildly Effective, but Wildly Popular

By STEPHANIE SAUL

Your dreams miss you.

Or so says a television commercial for Rozerem, the sleeping pill. In the commercial, the dreams involve Abraham Lincoln, a beaver and a deep-sea diver.

Not the stuff most dreams are made of. But if the unusual pitch makes you want to try Rozerem, consider that it costs about $3.50 a pill; gets you to sleep 7 to 16 minutes faster than a placebo, or fake pill; and increases total sleep time 11 to 19 minutes, according to an analysis last year.

If those numbers send you out to buy another brand, consider this, as well: Sleeping pills in general do not greatly improve sleep for the average person.

American consumers spend $4.5 billion a year for sleep medications. Their popularity may lie in a mystery that confounds researchers. Many people who take them think they work far better than laboratory measurements show they do.

An analysis of sleeping pill studies found that when people were monitored in the lab, newer drugs like Ambien, Lunesta and Sonata worked better than fake pills. But the results were not overwhelming, said the analysis, which was published this year and financed by the National Institutes of Health.

The analysis said that viewed as a group, the pills reduced the average time to go to sleep 12.8 minutes compared with fake pills, and increased total sleep time 11.4 minutes. The drug makers point to individual studies with better results.

Subjects who took older drugs like Halcion and Restoril fell asleep 10 minutes faster and slept 32 minutes longer than the placebo group. Paradoxically, when subjects were asked how well they slept, they reported better results, 52 extra minutes of sleep with the older drugs and 32 minutes with the newer drugs.

"People seem to be getting a lot of relief from sleeping pills, but does getting 25 minutes of sleep really give you all that relief?" asked Dr. Wallace B. Mendelson, the former director of a sleep disorders unit at the University of Chicago. "A bigger aspect of this is that they change a person's perception of their state of consciousness."

Dr. Mendelson is semiretired and is a consultant for pharmaceutical companies.

Dr. Karl Doghramji, a sleep expert at Thomas Jefferson University in Philadelphia, agreed. "Sleeping pills do not increase sleep time dramatically, nor do they decrease wake time dramatically," he said. "Despite those facts, we do find patients who, when they take them, have a high level of satisfaction." Dr. Doghramji has disclosed in the past that he is a consultant to pharmaceutical companies.

Most sleeping pills work on the same brain receptors as drugs to treat anxiety. By reducing anxiety, the pills may make people worry less about not going to sleep. So they feel better.

Another theory about the discrepancy between measured sleep and perceived sleep involves

a condition called anterograde amnesia. While under the influence of most sleep medications, people have trouble forming memories. When they wake up, they may simply forget they had trouble sleeping.

"If you forget how long you lay in bed tossing and turning, in some ways that's just as good as sleeping," said Dr. Gary S. Richardson, a sleep disorders specialist at Henry Ford Hospital in Detroit who is a consultant and speaker for pharmaceutical companies and has conducted industry-sponsored research.

Sleep, after all, causes a natural state similar to amnesia, one reason toddlers often forget their violent nightmares by the next morning. If you stay in bed, as most people taking sleeping pills do, amnesia is not a bad thing.

Even some people who sleepwalked while taking Ambien, which was implicated in cases of odd, sometimes dangerous behavior while sleeping, believed they were having a good night's sleep. Rosemary Eckley, a graphic artist in New London, Wis., said she thought she was sleeping well on Ambien but woke to find her wrist broken, apparently in a fall while sleepwalking, she wrote in an e-mail exchange.

Reports of sleep-eating and sleep-driving on Ambien are reminiscent of problems nearly 20 years ago with Halcion. Some people who took that drug to sleep on airplanes developed a condition known as traveler's amnesia. They landed at their destinations, then got lost or forgot where they were, prompting the authorities in several countries to withdraw Halcion from the market.

Reports show that Ambien and similar drugs, advertised as safer than benzodiazepines like Halcion, can cause similar problems. The reports prompted the Food and Drug Administration to ask manufacturers to develop warning guides for distribution with virtually all sleep drugs. Despite such problems, most specialists say sleeping pills are generally safe. Dr. Mark W. Mahowald, director of the Minnesota Regional Sleep Disorders Center, which is involved in documenting cases of sleep-eating under the influence of Ambien, said serious side effects were rare and should not discourage the use of the pills.

The class of drugs known as nonbenzodiazepines, sometimes called "Z" drugs, includes Ambien, Lunesta and Sonata. Ambien and its generic equivalent, zolpidem, are the most widely used, together accounting for 40 percent of the market.

Newer drugs like Lunesta and Ambien CR, a controlled-release formula, cost about $4 a pill. Zolpidem recently sold for $2 a pill on walgreens.com.

Of the three drugs in the class, Sonata, which also retails for about $3.50 a pill, remains in the body the shortest time and, therefore, is normally used by people who have trouble falling asleep but no problem staying asleep. The advocacy organization Public Citizen's Health Research Group says its benefits are so minimal it should not be used.

King Pharmaceuticals, the maker of Sonata, did not respond to several messages seeking comment.

A study by an Oregon State University group that reviews the safety and effectiveness of drugs found that Lunesta offered little benefit over generic Ambien or older benzodiazepines, but cost more. Jonae Barnes, a spokeswoman for Lunesta's maker, Sepracor, said the company strongly disagreed and added that the Oregon group did not adequately consider waking time after falling asleep, an area in which Lunesta performed better.

Users also sometimes report that Lunesta leaves a bad taste in their mouths, according to studies of the drug.

Dr. Mahowald said the older drugs, including Halcion, also known as triazolam, offered better value than the newer ones.

"We tend to use the old benzodiazepines," he said of his practice. "They appear to be as effective as some of the newer ones, and they're infinitely less expensive." Dr. Mahowald said that his center participated in industry-sponsored clinical research, but that he did not personally work as a consultant or adviser to pharmaceutical companies.

Such drugs, which include flurazepam, brand name Dalmane, and temazepam, Restoril, sell in generic versions for 30 to 50 cents each.

Another inexpensive alternative, and one of the most widely used sleep medications in this country, is the antidepressant trazodone. It works well in many patients, but some people say it leaves them groggy the next day, according to Dr. Daniel Carlat, a psychiatrist in Newburyport, Mass., who publishes The Carlat Psychiatry Report and declines industry financing. In men, trazodone has been linked to rare cases of priapism, prolonged and

painful erections.

Some patients who fear using sleeping pills turn to over-the-counter remedies like Tylenol PM and Advil PM. Those contain the painkillers acetaminophen and ibuprofen combined with an antihistamine, diphenhydramine, the ingredient in the allergy medication Benadryl.

Antihistamines are known to make people sleepy, but there is little evidence that they improve sleep. They can also cause next-day sedation that impairs driving, as well as racing heartbeat and constipation. The Medical Letter, which reviews drugs, recommends against using antihistamines for sleep. Some doctors say users of Tylenol PM may be taking acetaminophen they do not need. Acetaminophen overdoses can cause liver failure.

Rozerem, with its unusual advertising campaign, has at least one benefit over other medications. Because it works by a different mechanism from the others, it is not a controlled substance and apparently does not affect the ability to form memories. It may be the sleeping pill of choice for elderly people who have trouble falling asleep, but suffer memory problems.

Still, researchers and drug companies have yet to find a holy grail. "The problem is, there is no ideal hypnotic," said Dr. Manisha Witmans, a sleep medicine specialist at the University of Alberta's Evidence-Based Practice Center. "The magic pill for sleep has not been invented yet."

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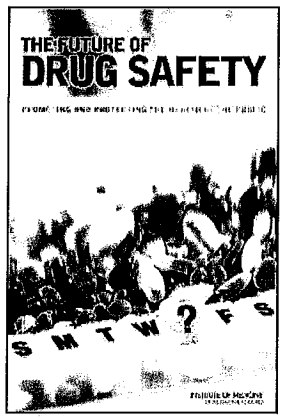
Public Ed

INSTITUTE OF MEDICINE

REPORT BRIEF • SEPTEMBER 2006

THE FUTURE OF DRUG SAFETY: ACTION STEPS FOR CONGRESS



The Institute of Medicine's Committee on the Assessment of the U.S. Drug Safety System intends that the 25 recommendations in its report will bring the strengths of the preapproval process (data, regulatory authority, organizational function and capabilities, and resources) to the postapproval phase in order to fulfill a lifecycle approach to the study, regulation, and communication about the risks and benefits of drugs.

CLARIFY FDA'S REGULATORY AUTHORITY

The Food and Drug Administration's authorities must be clarified and strengthened to empower the agency to take rapid and decisive actions when necessary and appropriate. FDA lacks the clear, unambiguous authority needed to enforce sponsor compliance with regulatory requirements and instead relies on the prospect of productive negotiations with industry.

5.1 The committee recommends that Congress ensure that FDA has the ability to require such postmarketing risk assessment and risk management programs as are needed to monitor and ensure safe use of drug products. These conditions may be imposed both before and after approval of a new drug, new indication, or new dosage, as well as after identification of new contraindications or patterns of adverse events. The limitations imposed should match the specific safety concerns and benefits presented by the drug product. The risk assessment and risk management program may include:

a) Distribution conditioned on compliance with agency-initiated changes in drug labels.
b) Distribution conditioned on specific warnings to be incorporated into all promotional materials (including broadcast DTC advertising).
c) Distribution conditioned on a moratorium on direct to consumer advertising.
d) Distribution restricted to certain facilities, pharmacists, or physicians with special training or experience.
e) Distribution conditioned on the performance of specified medical procedures.
f) Distribution conditioned on the performance of specified additional clinical trials or other studies.
g) Distribution conditioned on the maintenance of an active adverse event surveillance system.

5.2 The committee recommends that Congress provide oversight and enact any needed legislation to ensure compliance by both FDA and drug sponsors with the provisions listed above. FDA needs increased enforcement authority and better enforcement tools directed at drug sponsors, which should include fines, injunctions, and withdrawal of drug approval.

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REQUIRE SYMBOL TO ALERT CONSUMERS TO NEW PRODUCTS AND DENOTE HEIGHTENED REGULATORY ATTENTION

Marking the label and all promotional material for newly approved drugs or indications with a special symbol will help increase awareness of the nature of newly approved therapies (for example, the incompleteness of information on safety).

5.3 The committee recommends that Congress amend the Federal Food, Drug and Cosmetic Act to require that product labels carry a special symbol such as the black triangle used in the UK or an equivalent symbol for new drugs, new combinations of active substances, and new systems of delivery of existing drugs. FDA should restrict direct-to-consumer advertising during the period of time the special symbol is in effect. The symbol should remain on the drug label and related materials for 2 years unless FDA chooses to shorten or extend the period on a case by case basis.

ESTABLISH PERFORMANCE GOALS FOR SAFETY

The Prescription Drug User Fee Act mechanism that accounts for over half of the Center for Drug Evaluation and Research's funding and the reporting requirements associated with the user-fee program are excessively oriented toward supporting speed of approval and insufficiently attentive to safety.

3.5 To restore appropriate balance between the FDA's dual goals of speeding access to innovative drugs and ensuring drug safety over the product's lifecycle, the committee recommends that Congress should introduce specific safety-related performance goals in the Prescription Drug User Fee Act IV in 2007.

HOLD INDUSTRY AND RESEARCHERS ACCOUNTABLE FOR MAKING DRUG SAFETY STUDY RESULTS PUBLIC

The committee believes strongly in the importance of increasing the availability of information to the public and to researchers about risks and benefits, whether specific study results or CDER staff analyses of concerns. The National Library of Medicine hosts a website for registration of clinical trials, but with few exceptions, this is voluntary and does not include a summary of results.

4.11 To ensure that trial registration is mandatory, systematic, standardized, and complete, and that the registration site is able to accommodate the reporting of trial results, the committee recommends that Congress require industry sponsors to register in a timely manner at clinicaltrials.gov, at a minimum, all Phase 2 through 4 clinical trials, wherever they may have been conducted, if data from the trials are intended to be submitted to the FDA as part of a new drug application, supplemental new drug application, or to fulfill a post market commitment. The committee further recommends that this requirement include the posting of a structured field summary of the efficacy and safety results of the studies.

APPROPRIATE ADEQUATE RESOURCES FOR DRUG SAFETY

An agency whose crucial mission is to protect and advance the public's health should have adequate resources to do its job. Also, the effect on CDER's work of CDER's overdependence on PDUFA funding with restrictions on how FDA can use the money from user fees hurts FDA's credibility and may affect the agency's effectiveness.

7.1 To support improvements in drug safety and efficacy activities over a product's lifecycle,

the committee recommends that the Administration should request and Congress should approve substantially increased resources in both funds and personnel for FDA. The committee favors appropriations from general revenues, rather than user fees, to support the full spectrum of new drug safety responsibilities proposed in this report.

STABILIZE THE LEADERSHIP OF FDA

Instability in the Office of the Commissioner has been a serious problem for FDA and CDER in particular. A large, complex, science-based regulatory agency cannot perform optimally in the absence of stable, capable leadership, and clear, consistent direction.

3.1 The committee recommends that the Federal Food, Drug, and Cosmetic Act be amended to require that the FDA Commissioner currently appointed by the President with the advice and consent of the Senate also be appointed for a 6-year term of office. The Commissioner should be an individual with appropriate expertise to head a science-based agency, demonstrated capacity to lead and inspire, and a proven commitment to public health, scientific integrity, transparency, and communication. The President may remove the Commissioner from office only for reasons of inefficiency, neglect of duty, or malfeasance in office.

IMPROVE FDA'S COMMUNICATION TO THE PUBLIC

The public would benefit from more information about how drugs are studied before FDA approval, how drugs' risks and benefits are assessed, and what FDA review entails. Patients also need timely information about emerging safety concerns or about a drug's effectiveness in order to make better decisions in collaboration with their health care providers. FDA does not have an adequate mechanism for seeking and receiving specific scientific and patient/consumer advice on communication matters.

6.1 The committee recommends that Congress enact legislation establishing a new FDA advisory committee on communication with patients and consumers. The committee would be composed of members who represent consumer and patient perspectives and organizations. The advisory committee would advise CDER and other centers on communication issues related to efficacy, safety, and use during the lifecycle of drugs and other medical products, and it would support the centers in their mission to "help the public get the accurate, science-based information they need to use medicines and foods to improve their health."

OTHER RECOMMENDATIONS OF PARTICULAR INTEREST TO CONGRESS

3.4 The committee recommends that CDER appoint an Office of Surveillance and Epidemiology staff member to each New Drug Application review team and assign joint authority to Office of New Drugs and OSE for postapproval regulatory actions related to safety.

4.10 The committee recommends FDA establish a requirement that a substantial majority of the members of each advisory committee be free of significant financial involvement with companies whose interests may be affected by the committee's deliberations.

5.4 The committee recommends that FDA evaluate all new data on new molecular entities no later than 5 years after approval. Sponsors will submit a report of accumulated data relevant to drug safety and efficacy, including any additional data published in a peer reviewed journal, and will report on the status of any applicable conditions imposed on the distribution of the drug called for at or after the time of approval.

FOR MORE INFORMATION...

Copies of *The Future of Drug Safety: Promoting and Protecting the Health of the Public* are available from the National Academies Press, 500 Fifth Street, N.W., Lockbox 285, Washington, DC 20055; (800) 624-6242 or (202) 334-3313 (in the Washington Metropolitan area); Internet, http://www.nap.edu. The full text of this report is available at http://www.nap.edu.

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Public Ed

Public Health Advisory

Nonprescription Cough and Cold Medicine Use in Children

August 15, 2007

Federal Register Meeting Notice

FDA announced today that, in October, the Nonprescription Drugs Advisory Committee will discuss the safety and effectiveness of cough and cold drug product use in children. Questions have been raised about the safety of these products and whether the benefits justify any potential risks from the use of these products in children, especially in children under 2 years of age. In preparation for the meeting, FDA is reviewing safety and efficacy data for the ingredients of these products.

Some reports of serious adverse events associated with the use of these products appear to be the result of giving too much of these medicines to children. An over-the-counter cough and cold medicine can be harmful if more than the recommended amount is used, if it is given too often, or if more than one cough and cold medicine containing the same active ingredient are being used. To avoid giving a child too much medicine, parents must carefully follow the directions for use of the product in the "Drug Facts" box on the package label.

What should parents know about using cough and cold products in children?

- Do ***not*** use cough and cold products in children under 2 years of age UNLESS given specific directions to do so by a healthcare provider.
- Do not give children medicine that is packaged and made for adults. Use only products marked for use in babies, infants or children (sometimes called "pediatric" use).
- Cough and cold medicines come in many different strengths. If you are unsure about the right product for your child, ask a healthcare provider.
- If other medicines (over-the-counter or prescription) are being given to a child, the child's healthcare provider should review and approve their combined use.
- Read all of the information in the "Drug Facts" box on the package label so that you know the ***active ingredients*** and the ***warnings***.
- Follow the ***directions*** in the "Drug Facts" box. Do not give a child medicine more often or in greater amounts than is stated on the package.
- Too much medicine may lead to serious and life-threatening side effects, particularly in

children aged 2 years and younger.

- For liquid products, parents should use the measuring device (dropper, dosing cup or dosing spoon) that is packaged with each different medicine formulation and that is marked to deliver the recommended dose. A kitchen teaspoon or tablespoon is not an appropriate measuring device for giving medicines to children.

- If a measuring device is not included with the product, parents should purchase one at the pharmacy. Make sure that the dropper, dosing cup or dosing spoon has markings on it that match the dosing that is in the ***directions*** in the "Drug Facts" box on the package label, or is recommended by the child's health care provider.

- If you DO NOT UNDERSTAND the instructions on the product, or how to use the dosing device (dropper, dosing cup or dosing spoon), DO NOT USE the medicine. Consult your healthcare provider if you have questions or are confused.

- Cough and cold medicines only treat the symptoms of the common cold such as runny nose, congestion, fever, aches, and irritability. They do not cure the common cold. Children get better with time.

- If a child's condition worsens or does not improve, stop using the product and immediately take the child to a health care provider for evaluation.

Back to Top Back to Public Health Advisories

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Date created: August 15, 2007

FDA Urges Caution on Giving Cough and Cold Medicines to Children

FDA Patient Safety News: Show #68, October 2007

FDA is urging parents to be careful when giving cough and cold medications to children, especially those younger than two. Serious and even fatal adverse events can occur if a child is given too much medicine, or it is given too often, or if the child is given more than one medicine that contains the same active ingredient.

Here are some recommendations for parents from the FDA:

• Do not give cough and cold products to children under 2 years old unless specifically directed to do so by a healthcare provider.

• Do not give children medicine that's made for adults. Only use products marked for babies, infants or children, which are sometimes labeled as "pediatric". Caregivers should be sure to read the "Drug Facts" box on the label to understand how to use the product and know the active ingredients and warnings.

• Do not give your child other prescription or non-prescription medicines at the same time as cough and cold medicines without first checking with your child's healthcare provider.

• Do not use kitchen utensils like a teaspoon or tablespoon to measure out liquid medicines. Instead, use the dropper, dosing cup or dosing spoon that comes with the medicine. If a measuring device is not included, buy one at a pharmacy and be sure it has markings that match the dosing recommendations on the drug label or given by your child's healthcare provider.

FDA will hold a public meeting in October to discuss the safety and effectiveness of cough and cold products for children.

Additional Information:

FDA MedWatch Safety Alert. Nonprescription Cough and Cold Medicine Use in Children. August 16, 2007.
http://www.fda.gov/medwatch/safety/2007/safety07.htm#Cough

FDA MedWatch Safety Alert. Cough and Cold Medications in Children Less Than Two Years of Age. January 12, 2007.
http://www.fda.gov/medwatch/safety/2007/safety07.htm#coughcold

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FDA Patient Safety News is available at www.fda.gov/psn

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Study Shows Steep Rise In Adverse Drug Reactions

By JENNIFER CORBETT DOOREN
September 10, 2007 5:28 p.m.

WASHINGTON -- The number of serious drug side effects and deaths reported to the U.S. Food and Drug Administration more than doubled over an eight-year period, according to an analysis of adverse-drug events reported to the agency.

As part of the agency's so-called MedWatch reporting system, drug companies, health-care professionals and the public can file reports when they think a drug is connected to a side-effect or fatality. Drug companies are required to file such reports while they are voluntary for health-care professionals.

A study, published in Monday's Archives of Internal Medicine, looked at reports that are considered serious from 1998 to 2005. The study was conducted by researchers at the Institute for Safe Medication Practices in Huntingdon Valley, Pa., and Wake-Forest University School of Medicine in Winston-Salem, N.C.

Such reports also included reports of deaths in which people believe a particular drug might have contributed to, or caused, the death. Adverse-event reports have to be investigated by the FDA as the reports themselves don't necessarily mean a particular drug or drugs caused a problem.

A serious adverse drug event, defined by the FDA, means an event that resulted in death, a birth defect, disability, hospitalization, was life-threatening or required medical intervention to prevent harm.

From 1998 to 2005, there were 467,809 serious adverse events reported. The annual number of reports rose from 34,966 in 1998 to 89,842 in 2005 while the number of fatal adverse drug events increased from 5,519 to 15,107 in the same time frame.

The study noted that, overall, the relative increase in serious reports was four times faster than the growth in total U.S. outpatient prescriptions, which grew in the same period from 2.7 billion to 3.8 billion.

One of the study's authors, Thomas J. Moore, senior scientist, drug safety and policy at the Institute for Safe Medication Practices, said one of the surprises in the study was that drugs withdrawn from the market, such as **Merck** & Co.'s Vioxx, were a "modest" share of the serious event reports.

The study found the two top drugs listed in fatal reports were powerful painkillers oxycodone and fentanyl and were attributed to about 9,000 deaths. Other drugs in a list of top 15 drugs cited in death reports included anti-psychotics and acetaminophen, the active ingredient in over-the-counter pain drugs like Tylenol as well as prescription drugs.

Moore also said newer so-called biotech drugs that modify the immune system to diseases like multiple sclerosis, rheumatoid arthritis and Crohn's disease were associated with about 10,000 serious adverse reports, and accounted for about 15% of the rise in overall adverse event reports over the eight-year study period. Most of the drugs carry black-box warnings discussing serious side effects and the possibility of death.

The top two drugs with the most reports of non-fatal serious side effects were estrogen-containing products, used in birth-control pills and hormone-replacement therapy, and insulin, a drug used to treat diabetes, the study said.

"These data show a marked increase in reported deaths and serious injuries associated with drug therapy over the study period," the study's authors wrote. "The results highlight the importance of this public-health problem and illustrate the need for improved systems to manage the risks of prescription drugs."

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Agenda Item 8

Update on the Board's Public Outreach Activities

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

Date: **January 2, 2008**

To: **Communication and Public Education Committee**

Subject: **Update on the Board's Public Outreach Activities**

Public and licensee outreach activities performed since the September report to the committee include:

- Supervising Inspector Ming provided information about pharmacy law to the Indian Pharmacist Association on September 15.
- Supervising Inspector Nurse spoke about California's pedigree requirements at LogiPharma's annual conference in Philadelphia on September 17.
- Analyst Sue Durst staffed an information booth on September 17 at the Senior Fraud Fest event at the South San Francisco Conference Center.
- The board hosted an information booth at a health fair at the Siskiyou County Fairgrounds on September 22.
- Executive Officer Herold and AG Liaison Room will spoke at the Healthcare Distribution Management Association's two-day conference, California Pedigree: Preparing for Implementation on September 27.
- Executive Officer Herold and Supervising Inspector Nurse spoke at EPCglobal's annual US Exposition on California's pedigree requirements in Chicago on October 3.
- President Powers spoke to the Renaissance Society (a group of seniors) on October 5 about purchasing drugs online and other consumer issues involving pharmacy.
- Public Outreach Coordinator Abbe and Analyst Durst staffed a booth at the 22nd Annual Marin County Senior Information Fair on October 10.
- Executive Officer Herold and Supervising Inspector Nurse spoke about California's electronic pedigree requirements along with EPCglobal at CSHP's Seminar on October 20 in Palm Springs.
- The board staffed an information booth at the CSHP's Seminar on October 19 and 20.
- Executive Officer Herold provided information about the board's emergency response activities at CPhA's Synergy Conference on November 10.
- Supervising Inspector Ratcliff provided information about pharmacy law in a CE presentation to the Sacramento Valley Society of Health-System Pharmacists on December 12.

Future:

- Board Member Goldenberg will provide a presentation on the board's citation and fine program to pharmacists attending a USC continuing education program on January 26, 2008 in Ojai.
- Board Member Goldenberg will present information about the Board's emergency response plans at Kaiser Permanente CE Presentation on February 2.
- Board Member Schell will provide information on the board's compounding requirements at CPhA's annual meeting in February 2008.
- Executive Officer Herold, President Powers and Board Member Schell will present information about medication errors at CPhA's annual meeting.
- Supervising Inspector Nurse will provide information about e-pedigree law via video conference to a Secure Pharmacy conference in Philadelphia on February 26.
- Inspector Ming will provide information about pharmacy law to UCSF students on March 11.