Agenda Item 1
Consumer Fact Sheets

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: June 22, 2007

To: Members, Communication & Public Education Committee

Subject: Update on the Consumer Fact Sheet Series with UCSF's Center for Consumer Self Care

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Four years ago, the board approved a proposal by the committee to integrate pharmacy students into public outreach activities. The project involved UCSF students developing one-page fact sheets on diverse health care topics for public education.

An important objective of the fact sheets was to develop new educational materials for issues that emerge in the health care area and for which there is no or little written consumer information available. This would aid the interns who develop the materials and gain the experience of developing consumer informational materials. It also benefits the board, because it gains an invigorated set of public informational materials that are topical and not generally available.

The UCSF Center for Consumer Self Care works directly with the students to develop the fact sheets, which are then reviewed by faculty members and then by the board. The board distributes these fact sheets at community health fairs and has them available online. The fact sheet format is intended to be attractive whether printed or photocopied. Bill Soller, PhD, of the UCSF Center for Consumer Self Care is overseeing this project.

To date, nine fact sheets have been approved by the committee, as follows:

- 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 Medication Down the Toilet!
- Thinking of Herbals?
- Diabetes – Engage Your Health Care Team

These nine fact sheets have been translated into Spanish, Vietnamese and Chinese.

At the September 2006 committee meeting, Dr. Soller provided four new draft fact sheets, as follows:

- An Aspirin a Day? ... Maybe, Check it Out!
- Uncommon Sense for the Common Cold
- Medication Errors, Mistakes Happen ... Protect Yourself
- Putting the Chill on Myths about Colds and Flu

The committee recommended changes to the draft fact sheets in September 2006, which were provided to Dr. Soller. In January 2007, the board's new consumer outreach analyst Karen Abbe noted several additional changes that needed to be made to the draft fact sheets, and also requested annotated references to specific data contained in the fact sheets.

At the April 2007 Communication & Public Education Committee meeting, Dr. Soller provided edited versions of the four draft fact sheets. The edited versions contained some of the suggested changes, as well as new language not previously included. No annotated versions were provided for the committee.

Dr. Soller also provided additional (new) draft fact sheets for the committee's review and consideration:

- Preventing falls
- Is the site reliable?
- Your rights as a patient and consumer of healthcare!

Dr. Soller also referenced the following draft fact sheets under development. To date, the board's staff has not seen these items:

- Consumer reporting of adverse drug events
- Driving when you are taking medicines
- Tips for Parents
- Allergies to medicines

Dr. Soller agreed to develop a draft fact sheet on the subject of pill-splitting for consideration at the June 2007 Communication & Public Education committee meeting. We have not yet been provided with a draft of this fact sheet.

Since the April meeting, we have sought corrections to these fact sheets, and hoped to have the corrected versions and the 12 proposed new ones available for comment. However, as of this date, the board does not have these materials. Additionally, the nine (approved) fact sheets currently posted on the board's Web site contain a previous UCSF Center for Consumer Self Care address. Select fact sheets posted to the UCSF Web site contain the board's previous address at 400 R Street and (both) UCSF's Parnassus Avenue and California Street addresses.

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. Rebound headaches and the danger of taking too many OTC pain relievers for headaches
3. Hormone replacement therapy -- what is the current thinking?
4. Pediatric issues
5. Poison control issues
6. Ask for drug product information and labels in your native language if you cannot read English
7. Cough and cold meds and addiction issues (specifically, dextromethorophan)
8. Disposal of unused medications
9. 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
10. 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
11. Ask your Pharmacist or Doctor
    - Have a question?
    - Ask your Pharmacist for Native Language Materials/Labeling
12. 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
13. What Can I do to Prevent Disease?
    - Regular Check Ups
    - Screening
    - What Medicare Offers
14. Childhood Illnesses and Conditions
    - Head Lice
    - Fever Reducers: Questions to Ask
    - Immunizations: Questions to Ask & Schedules
15. 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

16. 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 on *The Script*

California State Board of Pharmacy
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STATE AND CONSUMERS AFFAIRS AGENCY
DEPARTMENT OF CONSUMER AFFAIRS
ARNOLD SCHWARZENEGGER, GOVERNOR

Date: June 22, 2007

To: Members, Communication & Public Education Committee

Subject: *The Script*

The next issue of *The Script* is planned for publication and distribution in July 2007. The focus of this issue will be application of laws and questions, answers about pharmacy practice asked of the board, and new regulation requirements.

There is also an article on pill splitting aimed at pharmacists.

The issue has been designed by board staffer Victor Perez, and is currently at the State Printing Plant for production and mailing.

The Pharmacy Foundation of California recently mailed the January 2007 issue of *The Script* to all California licensed pharmacists. They have also agreed to print and mail the July issue to all California pharmacists.

Agenda Item 3
New Public Outreach Materials

California State Board of Pharmacy
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STATE AND CONSUMERS AFFAIRS AGENCY
DEPARTMENT OF CONSUMER AFFAIRS
ARNOLD SCHWARZENEGGER, GOVERNOR

Date: June 22, 2007

To: Members, Communication & Public Education Committee

Subject: Update on Development of New Consumer Brochures

Consumer Outreach Analyst Karen Abbe has initiated work on revising our public education materials, and developing new materials. Four documents are included in the meeting material packet for comment by the committee:

1. Board of Pharmacy Overview Brochure

   The Communication & Public Education Committee approved the revised text provided on April 3, 2007. The approved text was provided to the DCA Policy & Publications Development Office (PPD) on April 11, 2007. DCA edited the brochure title and text and prepared a graphic layout. This brochure follows.

2. Board of Pharmacy Complaint Brochure

   The Communication & Public Education Committee approved the revised text during the April meeting. The approved text was provided to the DCA Policy & Publications Development Office (PPD) on April 11, 2007. DCA edited the text and prepared a graphic layout. The prepared brochure is attached.

3. BOP Fact Sheet on Pill Splitting

   Absent a draft fact sheet from UCSF's Center for Consumer Self Care, Ms. Abbe drafted text on the subject of pill splitting. The text is geared towards consumers, and provides "dos" and "don'ts" on the practice of pill splitting. The proposed text is attached. We will continue to work on it after hearing the Committee's comments.

4. Prescription Drug Discount Program for Medicare Recipients

   Ms. Abbe revised the text included in the board's original brochure that was developed in response to SB 393 (Speier, Chapter 946, Statutes of 1999). This state program allows Medicare recipients to obtain medications at the MediCal price if the patients pay out of pocket for the medication. The revised text reflects the Medicare Part D Plan benefits that are now available to beneficiaries. The revised text is attached. The text is similar to that of a brochure recently revised by the Senate Rules Committee.

Two documents are currently under development:

1. Informational Fact Sheet for Applicants (geared to pharmacists currently licensed in other states) – applying for the CPJE or a California intern pharmacist license

   The board produces detailed instructions for applicants for the pharmacist examination, however, some applicants do not read this information or retain it. A fact sheet on the specific subject of pharmacists licensed in other states should aid these applicants in applying for the exam.

2. Informational Fact Sheet for Applicants (geared to foreign graduates) – how foreign graduates can qualify for a pharmacist license in California

WEB SITE

We hope to have the medication errors section of the Web site developed by the October Board Meeting, when the new Web site is rolled out. It will contain best practices, citation and fine statistics issued by the board, articles, and links to other Web sites. We intend it to be a resource center.

About the Board

The California State Board of Pharmacy (Board) is part of the Department of Consumer Affairs (DCA). The Board regulates the more than 100,000 pharmacists, pharmacies, and other individuals and businesses that store, ship, compound, dispense, or handle prescription drugs and medical devices in the State of California.

The Board consists of a total of 13 members—seven pharmacists and four public members—who are appointed by the Governor and the Legislature. Because the Board receives its operating funds through licensing fees, it is self-supporting—it receives no monies from the State's General Fund.

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) 574-7915 (8am–noon); (916) 574-7909 (12:30–4:30pm)

Call the Department of Consumer Affairs' Consumer Information Center toll-free at (800) 952-5210

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STATE OF CALIFORNIA
DEPARTMENT OF CONSUMER AFFAIRS

Quality Care for California

California State Board of Pharmacy
1625 N. Market Blvd., Suite N-219
Sacramento, CA 95834
(916) 574-7900

What We Do

Protecting the health and safety of Californians is the Board's mission. We do this by developing and enforcing regulations to protect the public from misuse and diversion of prescription drugs from pharmacies.

The Board licenses:

- Pharmacists;
- Pharmacist Interns;
- Pharmacy Technicians;
- Foreign-educated Pharmacists
- Pharmacies;
- Non-resident Pharmacies;
- Wholesale Drug Facilities;
- Veterinary Food Animal Drug Retailers;
- Out-of-State Distributors;
- Clinics;
- Hypodermic Needle and Syringe Distributors; and
- Designated Representatives (unlicensed persons who are involved in the wholesaling of medicine and medical devices).

To become a pharmacist in the State of California, individuals must graduate from an accredited university, pass two examinations, and complete required experience in both community and hospital pharmacies. Licensed pharmacists must receive continuing education in order to renew their licenses.

Check the License!

Before you decide on a pharmacist, or if you have concerns about an existing pharmacist, visit the Board's Web site at www.pharmacy.ca.gov for information on license status, official actions taken, and more.

The Web site also offers:

- Consumer Education Material
- Applications and Forms
- Complaint Resolution
- Publications and Newsletters
- Pharmacy Law and Regulations
- Licensing Requirements and Renewal Information
- A schedule of upcoming public Board and committee meetings

Visitors to the Web site can also sign up for e-mail updates and alerts.

Original from Chair

(ORIGINAL TEXT APPROVED BY COMMITTEE)

Healthy Californians Through Quality Pharmacist's Care

(name, logo, etc.)

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.

Did You Know?

The board licenses more than 90,000 individuals and firms including:

- Pharmacists
- Intern pharmacists
- Pharmacy technicians
- Foreign educated pharmacists
- Pharmacies
- Non-resident pharmacies
- Wholesaler drug facilities
- Veterinary food animal drug retailers
- Exemptees (non-pharmacists who may operate sites other than pharmacies)
- Out-of-state distributors
- Clinics
- Hypodermic needle and syringe distributors

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 those who comply with these standards to ensure practitioners and businesses possess necessary skills and follow essential components.

The board ensures that pharmacists provide patients with quality pharmacist care when dispensing prescribed medicine, providing information to protect patients to prevent drug misadventures, and taking responsibility for 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. 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

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 and critical forums vital to pharmacy services 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

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) 574-7915 (8:00 a.m. - 12:00 p.m.)

(916) 574-7909 (12:30 p.m. - 4:30 p.m.)

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 to www.pharmacy.ca.gov, click on "Information For Consumers", then scroll to "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

Protecting the health and safety of California's consumers is the mission of the California State Board of Pharmacy (Board), and investigating consumer complaints is one of the main tools the Board uses to provide that protection. Complaints regarding incidents such as prescription errors and suspected misconduct by pharmacists may be violations of pharmacy law and should be reported—whether a person was harmed or not—to the Board. Each complaint is evaluated to determine whether it involves a pharmacist, pharmacy, or firm regulated by the Board, and whether the action is in violation of California Pharmacy Law.

How Do I File a Complaint?

Complaint forms are available online on the Board's Web site at www.pharmacy.ca.gov, or from the Department of Consumer Affairs' Consumer Information Center at (800) 952-5210. The online form may be filled out and mailed to the Board at:

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

or it can be filed electronically on the Web site.

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

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Call the Department of Consumer Affairs' Consumer Information Center toll-free at (800) 952-5210.

07_049 06/07

STATE OF CALIFORNIA
DEPARTMENT OF CONSUMER AFFAIRS

Do You Have a Complaint?

We want to hear from you!

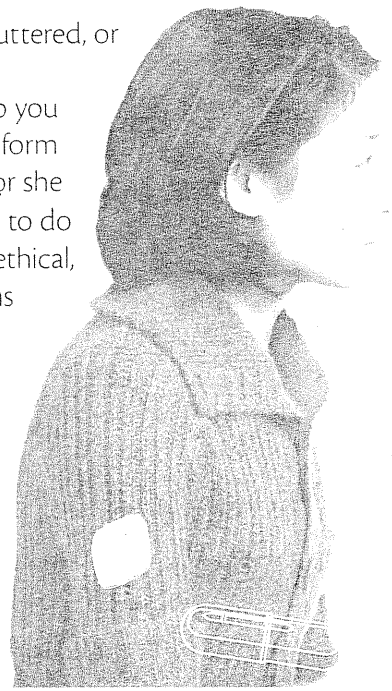
California State Board of Pharmacy
1625 N. Market Blvd., Suite N-219
Sacramento, CA 95834
(916) 574-7900

What is Considered Misconduct?

Here are a few examples of instances in which consumers should file a complaint:

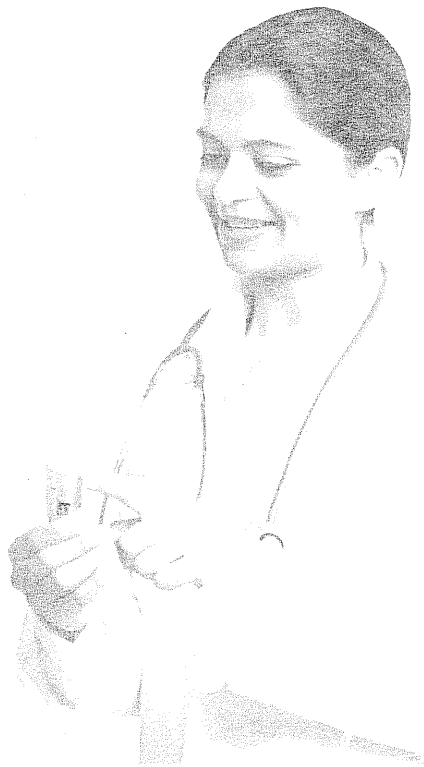
Pharmacist misconduct occurs when (but is not limited to):

- A pharmacist fails to give you a consult to explain how to take a new medicine, or explain a change in instructions, or informa you of the medicine's possible side effects
- A non-pharmacist counsels you regarding your prescription
- Your prescription is filled by a non-pharmacist
- A pharmacist fails to maintain patient confidentiality regarding your prescription
- A pharmacist may be under the influence of drugs or alcohol
- The pharmacy is dirty, cluttered, or looks unsanitary
- A pharmacist fails to help you obtain your prescription form another pharmacy if he or she is out of stock, or refuses to do so because of his or her ethical, moral, or religious reasons



Prescription errors occur when (but are not limited to):

- Incorrect information is entered on the label of the prescription container
- A prescription is dispensed with the wrong drug or dosage
- A prescription is refilled without proper authorization form the prescribing physician
- The pharmacist substitutes a generic drug for a brand-name drug without informing the patient
- A prescription is filled using drugs that are expired



What Happens to the Complaint?

If the complaint is within the Board's jurisdiction, it 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 the proper agency for processing. The Board completes most investigations within 120 days. Routine investigations by the Board can take up to 90 days, while more complex cases may take longer. Complaints may result in a disciplinary action being taken against a licensee. Depending on the severity of the violation, the action may be in the form of a reprimand, a citation and fine, or revocation of the license with the loss of the right to practice or operate a pharmacy.

Can I Follow-up on My Complaint?

Yes. Formal disciplinary actions are a matter of public record. If you write to the Board requesting information on the outcome of your complaint, the Board will respond in writing with the following information:

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

Original from Client

(ORIGINAL TEXT APPROVED BY COMMITTEE)

Do you have a complaint?

(name, logo, etc.)

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
- A non-pharmacist counsels you regarding your prescription
- A pharmacist is not present and your prescription is filled by a non-pharmacist
- A pharmacist fails to maintain the confidentiality of your prescription
- A pharmacist appears unable to function safely (due to alcohol or drug abuse)
- The pharmacy is dirty, cluttered, or looks unsanitary
- A pharmacist fails to assist 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 drug or device from another pharmacy, when the pharmacist refuses to fill the prescription for ethical, moral, or religious reasons

What are Prescription Errors?

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

- Incorrect information is entered on the label of the prescription container
- A prescription is dispensed with the wrong drug or wrong dosage
- A prescription is refilled without proper authorization from the prescribing physician
- A generic drug is substituted for a brand name drug, without informing the patient of the substitution

- A prescription is filled using drugs whose expiration date has passed

How to File a Complaint

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

Tablet splitting – is it safe?

Splitting a tablet in half can help if you find a larger pill hard to swallow, but the most common reason people split tablets is to save money. Dividing a higher dose tablet in half can result in fewer co-payments because some manufacturers price higher dose tablets at the same price as lower dose tablets.

That doesn't mean all medications can be split safely. The decision to split or not split should be made by weighing the benefits against the risks. Consider the possible drawbacks, and ask your prescribing physician and pharmacist whether splitting is right for you. A pharmacist's professional judgment and patient's best interest should prevail when deciding whether a pill split is in order. Here are some "do's and don'ts" of pill splitting.

DO

- Talk to your pharmacist and prescribing physician about whether your medication can be split safely and effectively
- Use a commercially available device specifically designed to split tablets; splitters are available from $3 to $15
- Remember that prolonged exposure to air and/or moisture can affect a split tablet, so splitting should occur only one tablet at a time
- Take one half of a split pill at one dosing, and the other half at the next dosing time

DON'T

- Don't split pills if it causes excessive fragmentation of the tablet or a non-therapeutic dose of the medication
- Don't split pills if you have manual dexterity problems, visual acuity problems, mental difficulties, or a cognitive impairment
- Don't split tablets if you're uncomfortable with the procedure
- Don't split enteric-coated tablets, film-coated tablets, or extended-release tablets because medication can be destroyed by premature exposure to stomach fluids
- Don't split all tablets from a prescription in one sitting because splitting in advance can cause long-term exposure to air and moisture and may degrade tablet texture and efficacy
- Don't split capsules, liquids, or topical medications
- Don't split small tablets or oddly-shaped tablets
- Don't split tablets with a kitchen knife or any other device that could result in an inaccurate split
- Don't split pills that have a narrow therapeutic index

(BOP logo, address, etc.)

Prescription Drug Discount Program for Medicare Recipients

(name, logo, etc.)

You may be able to save up to 40% on the cost of your prescriptions not available under Medicare Part D, the Medicare 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. 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 <u>not</u> 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 <u>not</u> 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?

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 every month. 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!

Agenda Item 4
Update on Committee Projects

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: June 22, 2007

To: Members, Communication & Public Education Committee

Subject: Update on Committee Projects

At the meeting, board staff will update the Committee on the following projects:

a. Activities of the California Health Communication Partnership
b. Pill Splitting
c. Public Forum on Medicare Part D Plans
d. SCR 49 Medication Errors Task Force Report
e. Board of Pharmacy Web Site Redesign

Agenda Item 5
Miscellaneous Consumer Issues and Articles in the News

California State Board of Pharmacy
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STATE AND CONSUMERS AFFAIRS AGENCY
DEPARTMENT OF CONSUMER AFFAIRS
ARNOLD SCHWARZENEGGER, GOVERNOR

Date: June 22, 2007

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.

THE WALL STREET JOURNAL. ONLINE

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May 20, 2007

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Health Costs

Drugs Bought From Abroad

By JILIAN MINCER
May 20, 2007

Consumers who pay a lot for brand-name drugs may save as much as 50% by purchasing from international sources. But that route has risks and isn't for everyone.

For one thing, "drug counterfeiting is a serious problem, and it is increasing," says Steven Findlay, managing editor of Consumer Reports Best Buy Drugs. In particular, he says people should avoid buying medications while visiting developing countries because between 20% and 50% of the drugs offered for sale are counterfeit.

Mr. Findlay recommends sticking with better-known Canadian Web sites. For instance, Consumer Reports recommends using sites that have been certified by the Canadian International Pharmacy Association (www.ciparx.ca[1]).

The Food and Drug Administration advises against foreign drug purchases because it can't guarantee the products, but the government generally hasn't prosecuted individuals for buying small amounts of prescription drugs for themselves or family members.

Senators Olympia J. Snowe (R., Maine) and Byron Dorgan (D., N.D.) had introduced legislation that would have permitted the importation of prescription drugs and included a number of safeguards. While that recently failed to make it into law, the legislation is expected to resurface.

Drew Nannis, a spokesman for AARP, says that organization supported the legislation because "we know our members are having a hard time dealing with the high cost of prescription drugs."

States Assist With Buying

Meanwhile, several states -- including Minnesota, Wisconsin and Illinois -- offer information or programs about importing drugs from Canada. For example, consumers can access the Minnesota consumer information by going to www.minnesotarxconnect.com[2]. The state has reviewed the Canadian pharmacies listed on the site.

The Illinois program can be found at www.i-saverx.net[3]. Residents of Illinois, Wisconsin, Kansas, Missouri and Vermont are eligible for I-SaveRx, through which they can purchase prescriptions from licensed, inspected pharmacies in Canada and the U.K.

Right for You?

Purchasing drugs across the border could be a good choice if you're not insured or if you have large out-of-pocket expenses for several brand-name drugs. Note, though, that you generally can't pay for drugs from abroad using a flexible spending account or health savings account.

Mr. Findlay of Consumer Reports says millions of older Americans, many of whom use several medications, may not need to shop abroad because they are now covered by Medicare drug plans.

However, some seniors are opting for the Canadian purchases after they fall into the "doughnut hole" gap in coverage. For 2007, that begins when the total cost of drugs used reaches $2,400 and it ends when someone has spent a total $3,850 out-of-pocket. Be aware that if a person purchases drugs from Canada, the amount is not applied to reaching the end of the hole.

In any event, don't shop abroad before thoroughly checking out homegrown prices. Drug prices typically are available through health plans and retailers. States including Florida, New York, Maryland and Washington have drug-price comparison Web sites.

Also ask your doctor about switching from brand-name drugs to less expensive generics.

"The average generic costs less in the United States than in Canada," says Don L. Bell, general counsel for the National Association of Chain Drug Stores. The U.S. generics also have been inspected by the FDA, unlike medications sold in other countries.

Consumer Reports found that many of the large discount chains, including Costco and Wal-Mart, offer significant savings on generic drugs.

Another way to save is by contacting the pharmaceutical-company assistance programs or the Partnership for Prescription Assistance at www.pparx.org[4].

Write to Jilian Mincer at jilian.mincer@dowjones.com[5]

URL for this article:
http://online.wsj.com/article/SB117952761439908103.html

Hyperlinks in this Article:
(1) http://www.ciparx.ca
(2) http://www.minnesotarxconnect.com
(3) http://www.i-saverx.net
(4) http://www.pparx.org
(5) mailto:jilian.mincer@dowjones.com

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May 22, 2007

QUICK FIX

Avoid Pharmacy Mixup

By JENNIFER CORBETT DOOREN
May 22, 2007; Page D2

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The Problem: Possible errors at the pharmacy due to sound-alike medication names.

The Solution: Before leaving the doctor's office, make sure you know the exact name of the medication, the prescribed strength and why it's being prescribed. You should also know how often the medication should be taken and ideally have the doctor describe what the pill looks like.

If a doctor phones in the prescription, ask the doctor or nurse for the same information and write it down so you'll have the information at the pharmacy when you pick up the prescription.

Once the prescription is filled, let the pharmacist explain what the medication is for and how it should be used to make sure that description matches the one given by your doctor.

Also, the Institute of Medicine recommends reading the printed information about the drug that is typically given out with prescriptions or asking for such material if it isn't included.

Write to Jennifer Corbett Dooren at jennifer.corbett-dooren@dowjones.com[1]

URL for this article:
http://online.wsj.com/article/SB117980468283410504.html

Hyperlinks in this Article:
(1) mailto:jennifer.corbett-dooren@dowjones.com

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For online drugs, buyer beware

By January W. Payne
THE WASHINGTON POST

June 5, 2007

Buying prescription medications online may save money – but the Food and Drug Administration has released a warning cautioning that "24 apparently related Web sites" may be distributing counterfeit prescription drugs.

Marv Shepherd, director of the pharmacoeconomics center at the University of Texas at Austin, said there may be thousands of Web sites selling counterfeit medications, many outside the United States, where regulation is typically less strict.

Three consumers recently purchased counterfeit Xenical (used for weight loss) on two sites – Brandpills.com and Pillspharm.com, according to the FDA. None of the medications contained orlistat, the active ingredient in Xenical, and one contained sibutramine, the active ingredient in Meridia, another weight-loss drug, the FDA reports.

The two Web sites involved are associated with Pharmacycall365.com – which listed the two sites, as well as 22 others, under its "Our Web sites" heading. (To see a list of the 24 sites, go to **www.fda.gov** and "pharmacy365.")

The FDA offers the following tips for online retailers:

- Stick with U.S.-based sites.
- Buy only from licensed pharmacies.
- Ensure the site requires a prescription.
- Make sure the site offers the ability to speak with a person who can answer questions.
- Look for sites that display a Verified Internet Pharmacy Practice Sites seal of approval from the National Association of Boards of Pharmacy.

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May 22, 2007

HEALTH JOURNAL
By TARA PARKER-POPE

Take Your Medicine: Strategies For Sticking to a Drug Regimen

May 22, 2007; Page D1

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Last summer, my doctor wrote me a prescription for a twice-daily medication. While swallowing a pill two times a day sounds simple enough, I rarely remember. I have scribbled reminders on my bathroom mirror and even pasted a "Take Your Pill" sign on my computer. Try as I might, I can't seem to get into the habit.

ONLINE TODAY

[1] • Join Tara Parker-Pope and other readers in a discussion[2] on strategies for remembering to take medication.

As it turns out, I'm not alone. One of the most vexing problems in health care today is the fact that as many as 50% of patients don't take their medicine on a regular basis or at all. The reasons are complex. Patients with high blood pressure, high cholesterol or osteoporosis often forget to take their drugs because they don't have obvious symptoms to remind them. Other patients stop taking pills when they start to feel better -- as is common with antibiotics.

"There are a lot of reasons why people are not taking their medications as prescribed," says Sunil Kripalani, assistant professor of medicine at Emory University in Atlanta. "For some, it's an issue of simply remembering."

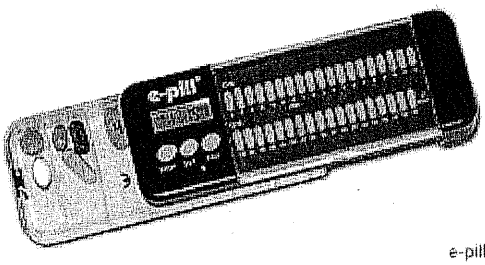
Dr. Kripalani recently reviewed dozens of studies on medication compliance to determine what, if anything, can improve the chances of a patient's taking his or her pills on a regular basis. The review, published in the Archives of Internal Medicine in March, found that tactics such as follow-up phone calls from pharmacists, drug coupons on refills, simplified dosing and packaging, and even electronic pill dispensers can all help.

Getting patients to take their medicine has a big impact on the health-care industry. When patients take their pills, drug companies earn more, insurance companies lower costs and patients are healthier. A study in Asheville, N.C., paid pharmacists to counsel patients and make sure they were taking their medication. City workers were offered financial incentives to take part in the program. After one year, the workers' average blood-sugar levels had dropped 6%, the city was saving an average of $500 per patient in health-care costs, and the workers took an average of 6.5 fewer sick days than similar workers not in the program.

Alan Brookhart, an instructor of medicine at Harvard Medical School, says patients can be erratic in their medication habits, often allowing long lapses between refills. A study of statin use recently published in the Archives of Internal Medicine showed that frequent follow-up with a doctor can improve adherence. "A physician visit appears to trigger a reinitiation of therapy," says Dr. Brookhart.

Drug companies, which stand to gain millions if more patients refill prescriptions, have gotten into the act, offering easier dosing regimens and reminder programs. Roche Laboratories offers Boniva, a once-a-month osteoporosis drug, which it says is easier to take than weekly bone drugs like **Merck & Co.**'s Fosamax. The MyBoniva program on the Web offers a free first prescription and monthly reminders. **Novartis,** maker of

Diovan and Lotrel blood-pressure drugs, offers a free trial, money-off coupons on refills, and a free blood-pressure monitor at its BP Success Zone Web site.



e-pill

Packaging changes can also help. While most antibiotics come in pill bottles, **Pfizer** has packaged its Zithromax brand as a Z-pack -- which uses foil packaging and labeling for each day of the five-day treatment.

Patients should check to see if a drug company offers a reminder program or discounts on refills. In addition, a doctor may be able to simplify the prescription, substituting a simpler dose or offering an extended-release pill. Doctors and pharmacists can also look at your entire pill schedule and help you simplify it.

Drugstores and Web sites such as epill.com[3] offer inexpensive pill boxes and high-tech electronic versions with alarms. Researchers at Emory University are developing an individualized picture-card system (www.picturerxcard.com[4]) that includes pictures of pills to help patients keep track of complicated pill schedules. Experts say it's also a good idea to link your pill taking with an activity you do every day -- like brushing your teeth or shaving.

• Email healthjournal@wsj.com[5].

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A Private Foundation Working Toward a High Performance Health System

Improving the Medicare Part D Program for the Most Vulnerable Beneficiaries

May 24, 2007 | Volume 60

Authors: Laura Summer, M.P.H., Patricia Nemore, J.D., and Jeanne Finberg, J.D.
Editor(s): Betsy Dosset

Overview

Prescription drug coverage became available under Medicare for the first time in 2006 under Medicare Part D—the most significant change in government health care programs in 40 years. While it offers the potential for improved access to needed medications for millions of Americans, Part D has had both successes and challenges. With the program now in its second year, researchers have the opportunity to learn from experiences and strengthen the program, particularly as it affects the frailest, sickest, and most vulnerable beneficiaries. Although 13.2 million beneficiaries are eligible for a low-income subsidy to helps pay for premiums and medication copayments, 3.3 million of this group are not enrolled in Part D and not receiving the subsidy. This report discusses some of the challenges vulnerable Medicare beneficiaries face in using Part D and makes specific recommendations, like using simpler, more standard procedures and ensuring that needed counseling support is provided.

Executive Summary

In 2006, prescription drug coverage became available under Medicare for the first time. Called Medicare Part D, the program is the most significant change in government health care programs in 40 years, offering the potential for improved access to needed medications for millions of Americans.

The new program has had success, but has also faced daunting challenges. Researchers now have a chance, early in Part D's second year, to learn from the experience to date and to strengthen the program, particularly as it affects the frailest, sickest, and most vulnerable beneficiaries, including nursing home residents.

The complexity of the program poses particular challenges for "dual eligibles"—Medicare beneficiaries who also qualify for Medicaid benefits. These beneficiaries, most of whom previously had received drug coverage through Medicaid, were switched to Medicare coverage under Part D and auto-assigned to eligible plans beginning January 1, 2006.

Although dual eligibles had the option to switch to a different plan for their drug coverage if they preferred, they were not necessarily in a good position to effectively do so. In addition to having the lowest incomes, this group disproportionately includes beneficiaries with multiple chronic conditions that result in high prescription drug usage: dual eligibles average 10 more prescriptions per month than other beneficiaries. They are the least-educated group of Medicare beneficiaries and are the most likely to be limited in English proficiency. In addition, a disproportionately high percentage of dual eligibles have cognitive impairments.

Although 13.2 million beneficiaries are eligible for a low-income subsidy that helps pay the premiums for Part D and the copayments for medications, 3.3 million of this group are not receiving the subsidy and are not enrolled in Part D. Administrators must find better ways to reach out to those beneficiaries, simplify the enrollment process, and assist beneficiaries in navigating that process. Better communication and closer monitoring of the program's operations would help enhance its

quality and increase its value to beneficiaries.

The implementation of the Part D program was a huge undertaking accomplished very quickly. Unlike other benefits available under traditional Medicare, Part D is administered through almost 1,900 stand-alone prescription drug plans (PDPs). The number of PDP options ranges from 45 to 66, depending on where the beneficiary lives. Part D coverage is also available through more than 1,000 private Medicare Advantage Part D plans (MA-PDs) that provide Part A (hospital insurance) and Part B (supplementary medical insurance), as well as Part D prescription drug benefits.

Plans differ from each other in design; in costs of premiums, deductibles, and coinsurance or copayments; in formulary composition; and in the process for obtaining coverage for drugs not included in the formulary. In addition, Part D plans have broad discretion, within certain statutorily prescribed parameters, to decide which drugs to include in their formularies; the strengths and dosage forms of covered drugs to include; and the types of "utilization management processes" used to control drug costs and usages.

To complicate the process even more, a number of entities are involved in the administration of the Part D program: The Centers for Medicare and Medicaid Services (CMS) administers the Medicare program and has overall responsibility for Part D; the Social Security Administration and state Medicaid offices have primary responsibility for approving applicants for the low-income subsidy; Part D plans provide the benefits; physicians prescribe medications based on plan design; and pharmacies fill the prescriptions.

Under utilization management, plans may establish different copayments for different drugs: "tiered pricing" distinguishes among preferred drugs, non-preferred drugs, generic drugs, and specialty drugs. Plans may also limit the number of pills or dosage amounts; require that beneficiaries request prior authorization for covered prescription drugs; or require that they try particular medications included in the plan's formulary before those prescribed by the physician ("step therapy").

Some evidence suggests that utilization management techniques have caused delays or otherwise restricted access to prescription medications, including mental health drugs. These techniques have the potential to cause disastrous outcomes in patients—particularly the most vulnerable.

This report discusses some of the challenges vulnerable Medicare beneficiaries face in using Part D and makes specific recommendations to strengthen the program in certain areas (box). Legislative authority is needed to accomplish some of these changes, such as eliminating or amending the resource test, changing the rules for individuals needing long-term care services, and ensuring that funds for counseling are appropriately available. Legislative changes would also be useful to ensure that current drug regimens are considered when auto-enrollment occurs. In the interim, a different regulatory interpretation of certain legal provisions could help. Most of the other changes that are needed could be accomplished administratively.

Recommendations to Strengthen Part D Program Areas

The Low-Income Subsidy

- Eliminate or amend the resource test
- Provide enrollment encouragement and assistance
- Monitor redeeming and redetermination

Transition from Medicaid to Medicare

- Use available information in making plan assignments
- Simplify the transition process by extending the supply of non-formulary drugs
- Expand the "point-of-service" system

The Use of Formularies and Utilization Management Tools

- Improve the coverage determination process
- Use simpler, more standard procedures

Part D and Long-Term Services and Supports

- Ease the process to get appropriate drugs to nursing home residents
- Extend protections for nursing home residents to individuals in the community

Program Quality

- Strengthen electronic communication
- Provide program information in new ways
- Ensure support for counseling

These beneficiaries are the least able to understand how to pursue an exception request or other coverage determination. Some changes to current practices could help beneficiaries and those who assist them resolve problems related to the coverage of specific drugs. Concerted efforts to inform beneficiaries about the coverage determination process, for example, would be helpful, as would standardization of the procedures and criteria used in the exceptions and appeals process.

Experience in 2006 suggests additional steps that could be taken to ensure that the Part D program operates more effectively. More monitoring on the part of CMS is needed, and the government should take steps to strengthen electronic communication systems, provide program information in new ways, and ensure that beneficiary counselors are available, particularly for the frailest, sickest, and most vulnerable.

Citation

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Herb enthusiasts often don't follow indications

- Report: Nearly half of adults who use herbal supplements don't do so correctly
- Only 3.8 percent of people using ginseng followed evidence-based indications
- Doctors, pharmacists urged to share evidence-based info on supplements

NEW YORK (Reuters) -- Roughly half of adults who use herbal supplements do not use them in accordance with "evidence-based" indications, U.S. researchers report.

The findings, which appear in the Mayo Clinic Proceedings for May, stem from more than 30,000 adults who were surveyed regarding their use of herbs.

The six herbs studied and their evidence-based indications were: echinacea for upper respiratory tract infection, garlic for high cholesterol, ginseng for mental performance/diabetes, St. John's wort for depression, soy for high cholesterol/hot flashes, and kava-kava for anxiety.

Overall, 55 percent of subjects used herbs for their appropriate evidence-based indications, results showed. However, for most of the herbs, evidence-based usage rates hovered around 32 percent.

The exceptions were ginseng, with an evidence-based usage rate of just 3.8 percent, and echinacea, by far the most popular herb, with a rate of 68 percent.

Women were more likely than men to use herbs according to their evidence-based indication, as were college-educated individuals. Conversely, people younger than age 60 and black persons were more apt to herbs for things outside their evidence-based indications.

In a written statement, study chief Dr. Aditya Bardia, from the Mayo Clinic in Rochester, Minnesota, urges doctors, pharmacists, and other health professionals to "proactively educate consumers and advocate for public health policies that would disseminate evidence-based information regarding the appropriate use of herbs."

"Further research is needed to confirm the study findings and evaluate mechanisms that enhance evidence-based use of herbal supplements," the authors conclude.

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FDA consumer site offers information

By January W. Payne
WASHINGTON POST

June 5, 2007

Consumers have a new online source into the world of government-regulated food, drugs and medical devices. A Web page (**www.fda.gov/consumer**) developed by the Food and Drug Administration puts a variety of consumer health information – previously scattered throughout the agency's site – onto one user-friendly page with direct links to referenced topics.

Among the new page's offerings are primers on preventing food poisoning while barbecuing, coping with memory loss and reading nutrition labels. It also links to reliable sources of health information, such as the National Institutes of Health's popular MedlinePlus.gov, and includes a "Test Your Knowledge" section that quizzes people on medical matters.

But while the site appears friendlier than the main FDA site (**www.fda.gov**), it doesn't delve into sophisticated matters that some consumers may be seeking, said Arthur Levin, director of the Center for Medical Consumers, an advocacy group. What's missing, Levin said, is easy access to more-complex information such as drug approval letters and FDA advisory committee transcripts. To find those, consumers still need to drill down into the FDA's main Web site.

People may also sign up for a new free, monthly e-newsletter at **www.fda.gov/consumer/consumerenews.html**.

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Study: Over 10 percent of U.S. adults abuse drugs

- Over 10 percent of U.S. adults abuse or become addicted to drugs, study says
- Men more likely than women to abuse drugs, 13.8 percent to 7.1 percent
- Pot most commonly abused drug, followed by cocaine, amphetamines
- First detailed look at U.S. adult drug abuse since early 1990s

WASHINGTON (Reuters) -- More than 10 percent of U.S. adults abuse or become addicted to drugs such as marijuana, cocaine and amphetamines at some point in their lives, but few get treatment, according to a study published Monday.

The U.S. National Institutes of Health researchers called their work the first detailed accounting of drug abuse among U.S. adults since the early 1990s but did not compare the latest numbers with drug abuse prevalence in the past.

The researchers based their findings on interviews with 43,093 people in 2001 and 2002. They estimated 10.3 percent of U.S. adults abused drugs during their lifetimes, including 2.6 percent who become addicted.

The researchers said 2 percent reported symptoms of abuse or addiction in the previous year. They defined abuse as an intense desire to use drugs to the exclusion of other activities and addiction as physical dependence on a drug.

Men were much more likely than women to abuse drugs, the study found, with 13.8 percent of men and 7.1 percent of women doing so at some point. Drug problems also were more common among younger people, most frequently appearing around age 20.

Whites were more likely than blacks or Hispanics to report they had drug problems at some point, the study, published in the Archives of General Psychiatry, found. There was a higher-than-expected rate among American Indians.

"Drug addiction and abuse are common problems among adults in the United States," Dr. Wilson Compton of the NIH's National Institute on Drug Abuse, who led the study, said in a telephone interview.

"There's this myth that they (drugs) are mostly a problem of minorities and that would just not be true," Compton said.

Only 8.1 percent of drug abusers and 37.9 percent of those who became addicted said they got treatment, the study found.

"We are concerned because treatment rates are this low despite the availability of effective interventions," NIDA Director Dr. Nora Volkow said in a statement. "We must encourage the public to view addiction as a brain disease that needs to be treated like any other chronic disease."

Marijuana most common

The study found that marijuana was the most commonly abused drug -- 8.5 percent said they had abused it -- followed by cocaine (2.8 percent) and amphetamines (2 percent).

The study also looked at abuse of other drugs such as heroin, opioids, hallucinogens, PCP, inhalants, tranquilizers and sedatives. It did not track alcohol or tobacco use.

There was a strong relationship between drug problems and mental illness, particularly people with depression, bipolar disorders and anxiety disorders, Compton added.

Compton said people who come forward for treatment of a serious mental illness should be screened for drug abuse, and drug abusers should be screened for mental illness.

Compton said the costs to society of drug abuse include more crime, illness and family discord, and less work productivity.

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A year after Plan B change, access still hit-or-miss

By TONY PUGH -- McClatchy Washington Bureau
Published 3:49 pm PDT Friday, May 11, 2007

When the Food and Drug Administration allowed the so-called "morning-after pill" to be sold over the counter last year, reproductive rights advocates felt they'd cleared a major hurdle in eliminating delays that diminish the drug's effectiveness.

But nearly a year after the emergency contraceptive Plan B became easier to purchase, obtaining it without a prescription remains a hit-or-miss proposition for some women.

Inconsistent or confusing state laws and store policies, along with some pharmacists who won't dispense it for religious reasons, are complicating and sometimes blocking access to the drug.

FDA restrictions on how the drug is sold without a prescription are contributing to the problem, experts said. The agency requires Plan B to be stored behind the pharmacy counter rather than on store shelves, and buyers must be at least 18 years old and must prove it with government identification.

These restrictions permit pharmacy employees to block access to the drug, whether mistakenly or because of their personal objections. As a result, some noncitizens are being asked to produce government photo IDs, when photos aren't required, and some men are told that only women can buy the drug.

"We knew the (FDA) restrictions would cause a whole host of problems, some of which we hadn't even foreseen, so it's not a surprise that women are still encountering refusals," said Gretchen Borchelt, an attorney with the National Women's Law Center in Washington.

In some cases, pharmacists with personal objections aren't stocking the medication, won't fill or refill prescriptions and won't tell customers how to get the drug elsewhere. In small towns with few options, that can cause delays that greatly diminish the drug's effectiveness.

"We know we're seeing it more, but there's no way to really know whether it's increasing or if the women are reporting the incidents more," said Jackie Payne, the government relations director for the Planned Parenthood Federation of America.

Each year, roughly 3 million unintended pregnancies occur in the United States. About half are due to lack of contraception and the other half to contraception failure or misuse, according to the Guttmacher Institute. Some 25,000 to 32,000 unwanted pregnancies each year are the result of rape. About 42 percent of unintended pregnancies end in abortion.

Plan B, the only emergency contraceptive sold in the United States, is basically a higher dose of the hormones contained in conventional birth control pills. Plan B blocks the release of an egg from the ovaries or prevents a fertilized egg from being implanted in the uterus.

When taken within 72 hours of intercourse, the drug blocks conception with 89 percent reliability. It doesn't induce abortion and doesn't terminate pregnancy.

However, some see its use as a moral question.

Recognizing that, the American Pharmacists Association recommends that any pharmacist who refuses to dispense a drug because of moral objections allow a co-worker to do so, or refer customers to drugstores that will fill their orders.

"We don't have a problem with that. We consider it a religious liberty issue," said Francis Manion, senior counsel at The American Center for Law and Justice, a conservative legal organization that represents pharmacists who were suspended or fired after allegedly violating store policies on Plan B.

In an e-mail response, Carol Cox, a spokeswoman for Barr Laboratories, which makes Plan B, said the company expected "pharmacists who refused to dispense any FDA approved medicine to make the appropriate arrangements to ensure that approved FDA pharmaceutical products are available to patients at the point of purchase."

Many national pharmacy chains - such as Walgreens, Rite Aid, CVS and Wal-Mart - have such policies. These chains and five others have earned a "thumbs up" grade from Planned Parenthood for policies that ensure the availability of Plan B in their stores, on demand and without discrimination or delay.

But experts say those policies aren't always clear, nor are they always followed.

Earlier this year, Carrie Baker, a 42-year-old mother of two, couldn't get Plan B from her Kroger supermarket in Rome, Ga. She said the pharmacist said that she wouldn't stock the drug or order it because she didn't believe in abortion - though Plan B doesn't induce abortion.

"It was very frustrating," said Baker, the director of the women's studies program at Berry College. "I'm a loyal customer spending $100 a week at that store for over 10 years and here they treat me like a sinner, not respecting me enough to make my own decisions about my family and my life."

In response, Kroger reiterated its policy to carry the drug in all stores and to allow, but not require, co-workers to complete the transaction when a pharmacist objects.

"We are trying to be respectful of the religious and moral beliefs of our employees and the legal, privacy and consumer rights of our customers," Kroger spokesman Meghan Glynn said in an e-mail response.

Arizona, Georgia, Mississippi and South Dakota have laws or rules that allow pharmacists not to fill prescriptions if they have moral, religious or personal objections. This year, nine other states introduced similar legislation: Indiana, Missouri, New Jersey, North Carolina, Rhode Island, South Carolina, Texas, Vermont and West Virginia.

Six states restrict pharmacists from refusing to dispense lawful medications: California, Illinois, Maine, Massachusetts, Nevada and Washington. Five others - Delaware, New York, North Carolina, Oregon and Texas - allow pharmacists not to dispense a medication but require them to refer customers to pharmacies that will.

In December, a Rite Aid pharmacist in Seattle refused to sell Plan B without a prescription to 26-year-old Grace Stering, though the store had it in stock. Stering said the pharmacist told her he thought it was wrong to sell it.

"He literally said that to me. I was astonished," Stering said. "I was appalled by the way he treated me as a person. I mean you could literally sense the judgment."

After she asked him where she could purchase it, the pharmacist suggested a nearby pharmacy, where Stering later bought it. But she wasn't finished with Rite Aid.

When she got home, she got on the Internet, where she found and contacted the National Women's Law

Center. "That's when I realized how angry I was. I was typing and crying at the same time," she said.

The law center contacted Rite Aid officials, and several company representatives apologized, Stering said. The company reprimanded the pharmacist and retrained the employees on company policy, which calls for another employee to provide the product if a pharmacist refuses.

"I was really happy with the outcome," Stering said.

Not all problems with Plan B involve women. Galen Leigh Sherwin, the acting director of the Reproductive Rights Project of the New York Civil Liberties Union, said her organization got a complaint from a medical school instructor who wanted to use Plan B for a class demonstration.

A pharmacist told him he couldn't purchase it because he was a man. There's no sex restriction on over-the-counter sales as long as the buyer is at least 18.

"It's mostly things like that, where pharmacists just don't know the rules yet," Sherwin said. "They don't understand the age requirements and they don't understand the documentation requirements."

Hispanic health advocates say that some undocumented Hispanic woman are being denied the drug over-the-counter after wrongly being required to produce government IDs with photos.

"That's actually a really big concern for us," said Jessica Gonzalez-Rojas, the director of policy and advocacy at the National Latina Institute for Reproductive Health in New York City. "We want to make sure our community can access this drug, but there's some question about what constitutes a government ID. Can they use a Medicaid card? Can they use a government-issued ID from their home country? It doesn't specify."

To see Planned Parenthood's list of retail pharmacies and their policies on providing birth control, including Plan B, go to www.saveroe.com/campaigns/fillmypillsnow/scored

For a look at state policies on emergency contraceptives, go to the Guttmacher Institute Web site at www.guttmacher.org/statecenter/spibs/spib_EC.pdf

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U.S.News & WORLD REPORT

Monday, May 14, 2007

Health

Help for Parents of Teens Abusing Cough Medicines

By Matthew Shulman
Posted 5/11/07

Many parents may not realize it, but an increasingly popular drug that teenagers are using to get high may be sitting in the medicine cabinet: cough medicines. Both in liquid and gel-cap forms, they're highly accessible and cheap and come with little social stigma attached. But, like other over-the-counter drugs, they can be dangerous when abused. For information on what to look for and how to react to cough medicine abuse, parents can tap a new resource: FiveMoms.com.

The educational campaign, launched in May by the Consumer Healthcare Products Association (which represents the manufacturers of OTC drugs such as cough medicine), features five women, including a ediatric nurse practitioner, a deputy sheriff, and an accountant, whose lives have been affected by cough medicine abuse. FiveMoms.com includes blogs by each of the moms, a social networking forum for concerned parents, and information on how to spot if your teen is using.

"It's a preventable problem," says CHPA spokesperson Virginia Cox. "Parents need to educate themselves and have conversations with their kids."

Legal OTC cough medicines like Robitussin and Coricidin, which are safe and effective if taken in the appropriate and prescribed dosage--usually 15 to 30 mg--can cause serious cognitive problems, including psychosis and paranoid delusions, when taken in high-enough quantities. Most abusers take the medicine, whose active ingredient is the chemical dextromethorphan, for its anesthetic effects--and the resulting trancelike and dissociative state. The Partnership for a Drug Free America says 1 in 10 teenagers, or more than 2 million people, have abused dextromethorphan, some taking as much as 25 to 50 times the usual dosage of cough medicine.

Christy Crandell, one of the five moms, has a son currently serving a 13-year prison term for committing armed robbery while high on both cough medicine and marijuana. Crandell cautions parents to be aware of how their kids and teens are using the Internet, as thousands of websites promote the abuse of cough medicine and offer detailed information on the ways to use the drug.

It's important to find a clinician, specialist, or addiction facility that is knowledgeable about dextromethorphan abuse and can manage its care, says Shannon Miller, an associate professor of

psychiatry at the University of Cincinnati and an expert in medicine addiction. That's especially true because there are no Food and Drug Administration-approved drugs to treat cough medicine abuse and no specific treatment programs or therapies.

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FDA News

FOR IMMEDIATE RELEASE
P07-76
May 1, 2007

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888-INFO-FDA

FDA Warns Consumers about Counterfeit Drugs from Multiple Internet Sellers

The Food and Drug Administration (FDA) is cautioning U.S. consumers about dangers associated with buying prescription drugs over the Internet. This alert is being issued based on information the agency received showing that 24 apparently related Web sites may be involved in the distribution of counterfeit prescription drugs.

On three occasions during recent months, FDA received information that counterfeit versions of Xenical 120 mg capsules, a drug manufactured by Hoffmann-La Roche Inc. (Roche), were obtained by three consumers from two different Web sites. Xenical is an FDA-approved drug used to help obese individuals who meet certain weight and height requirements lose weight and maintain weight loss.

None of the capsules ordered off the Web sites contained orlistat, the active ingredient in authentic Xenical. In fact, laboratory analysis conducted by Roche and submitted to the FDA confirmed that one capsule contained sibutramine, which is the active ingredient in Meridia, an FDA-approved prescription drug manufactured by Abbott Laboratories.

While this product is also used to help people lose weight and maintain that loss, it should not be used in certain patient populations and therefore is not a substitute for other weight loss products. In addition the drug interactions profile is different between Xenical and sibutramine, as is the dosing frequency; sibutramine is administered once daily while Xenical is dosed three times a day.

Other samples of drug product obtained from two of the Internet orders were composed of only talc and starch. According to Roche, these two samples displayed a valid Roche lot number of B2306 and were labeled with an expiration date of April 2007. The correct expiration date for this lot number is actually March 2005. Pictures of the counterfeit Xenical capsules provided by Roche can be viewed at http://www.fda.gov/bbs/topics/news/photos/xenical.html.

Roche identified the two Web sites involved in this incident as brandpills.com and pillspharm.com. Further investigation by FDA disclosed that these Web sites are two of 24 Web sites that appear on the pharmacycall365.com home page under the "Our Websites" heading. Four of these Web sites previously have been identified by FDA's Office of Criminal Investigations as being associated with the distribution of counterfeit Tamiflu and counterfeit Cialis.

At this point, it appears that these Web sites are operated from outside of the United States. Consumers should be wary, if there is no way to contact the Web site pharmacy by phone, if prices are dramatically lower than the competition, or if no prescription from your doctor is required. As a result, FDA strongly cautions consumers about purchasing drugs from any of these Web sites which may be involved in the distribution of counterfeit drugs and reiterates previous public warnings about buying prescription drugs online. Consumers are urged to review the FDA Web page at www.fda.gov/buyonline/ for additional information prior to making purchases of prescription drugs over the Internet.

The 24 Web sites appear on pharmacycall365.com.

AllPills.net
Pharmacy-4U.net

DirectMedsMall.com
Brandpills.com
Emediline.com
RX-ed.com
RXePharm.com
Pharmacea.org
PillsPharm.com
MensHealthDrugs.net
BigXplus.net
MediClub.md
InterTab.de
Pillenpharm.com
Bigger-X.com
PillsLand.com
EZMEDZ.com
UnitedMedicals.com
Best-Medz.com
USAPillsrx.net
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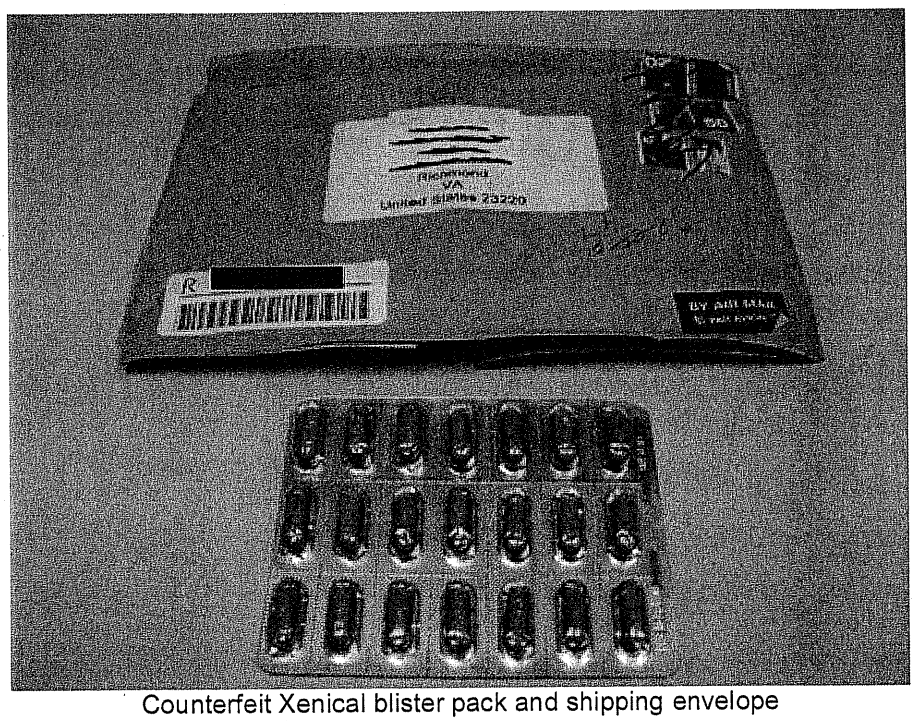
FDA Website Management Staff

FDA Warns Consumers About Counterfeit Drugs From Multiple Internet Sellers

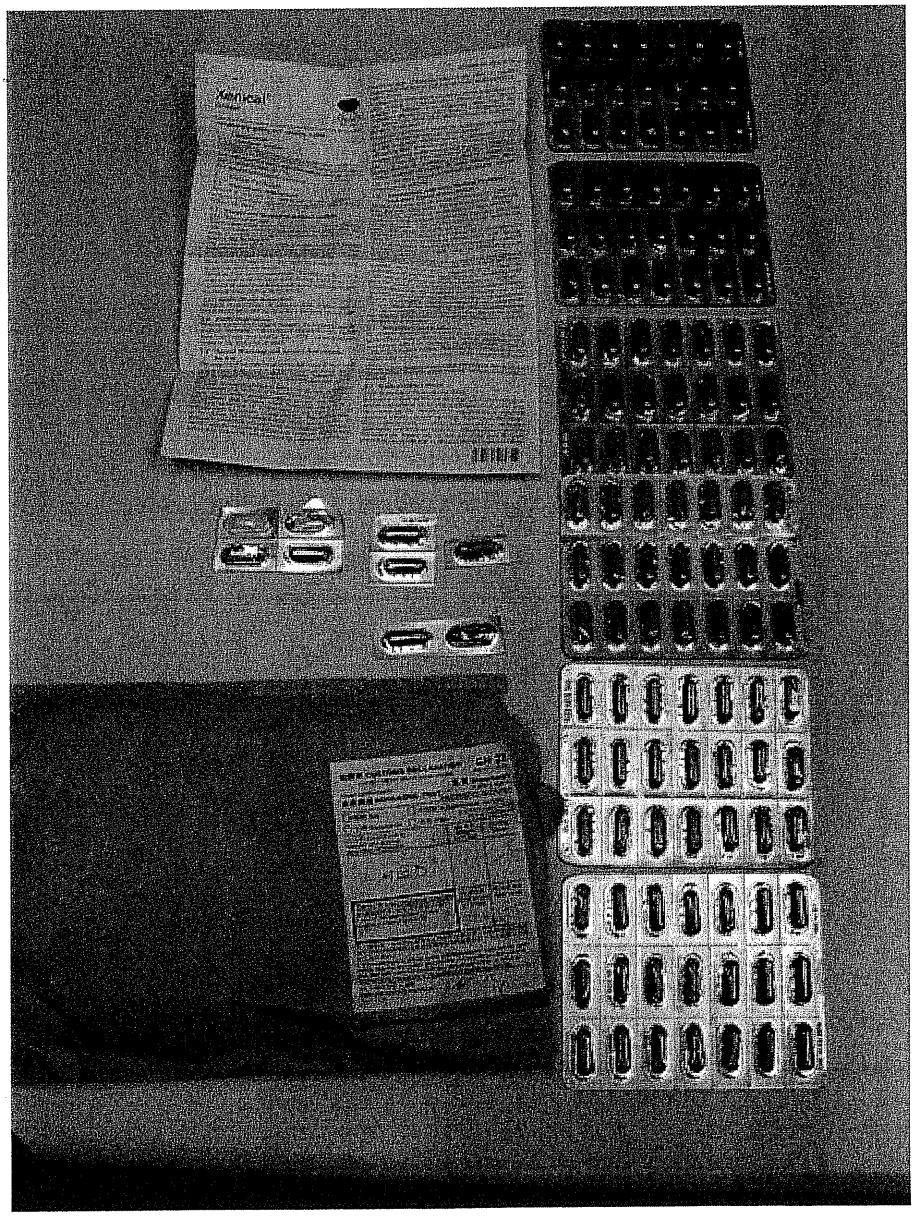
Photos of Counterfeit Xenical Capsules

Counterfeit Xenical capsules

Back of blister pack, noting lot number and expiration date



Counterfeit Xenical blister pack and shipping envelope



Counterfeit Xenical blister packs, shipping envelope, and patient information sheet

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FDA Website Management Staff

This story is taken from Health & Science News at sacbee.com.

Teen girls abuse prescription drugs more

-- The Associated Press
Published 3:23 pm PDT Monday, April 30, 2007

WASHINGTON (AP) Females are bucking the traditional drug abuse trends when it comes to prescription drugs such as antidepressants and tranquilizers.

Normally, usage rates for illicit drugs such as marijuana and cocaine are much higher for men than women. But for prescription drugs, the reverse is the case for teenage girls, said the White House Office of National Drug Control Policy.

Nearly one in 10 teenage girls reported using a prescription drug to get high at least once in the past year, officials said Monday. For teenage boys, the ratio was close to 1 out of 13.

Federal officials theorized that the trend reversal may be due to unique pressures faced by girls. Men typically abuse drugs and alcohol for the sensation, while surveys indicate women do so to increase their confidence, reduce tension or to lose weight.

"Too many Americans, and increasingly, too many young women simply do not know the addictive potential of these medicines," said John Walters, director of National Drug Control Policy.

The usage trends for prescription drugs were pulled from the 2005 National Survey on Drug Use and Health.

Officials said females are involved in 55 percent of the cases of emergency room visits involving prescription drugs. That percentage drops to 35 percent for women when street drugs are involved.

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This story is taken from Health & Science News at sacbee.com.

Docs: Avoid giving young children medicines

By JOSEPHINE MARCOTTY -- Minneapolis-St. Paul Star Tribune
Published 3:45 pm PDT Thursday, April 26, 2007

The urge to help a stuffed-up, feverish child feel better and sleep is almost overwhelming, and there is a whole drug industry out there that knows it.

Just walk down the cold-remedy aisle in any drugstore and you'll see dozens of products for children that promise to fix every combination of cough, sniffle and sneeze.

Resist.

Ignore the cute pictures of babies in diapers and the endearing little cartoon characters. There is increasing evidence that these products don't work well, and in very small children the drugs can be harmful.

The Food and Drug Administration last month said it is launching a broad review of the safety of cough and cold remedies marketed for children. The FDA was pressured to do so by a group of pediatricians and public health advocates who said that the drugs have never been studied in children, and are largely ineffective.

A recent study by the Centers for Disease Control and Prevention found that between 2004 and 2005, 1,519 kids under age 2 nationwide were rushed to emergency rooms after taking over-the-counter medications. Three babies died.

"I'm against using these products in kids less than 2 years old," said Don Uden, a professor in the College of Pharmacy at the University of Minnesota. "And I never use them myself."

In fact, the pediatricians who petitioned the FDA urged the agency to order manufacturers to stop marketing the drugs for children under age 6. The labels on most of the drugs give recommended dosages for children by age group, but say parents should first check with doctors before giving them to children age 2 or younger.

Kids might get cold medications a lot more often than adults because they get an estimated six to 10 colds per year, far more than adults. One study found that in a single 30-day period, a third of all children in the United States were given over-the-counter cold medications.

But increasingly doctors and national medical organizations are saying don't give them to children at all. Last year the American College of Chest Physicians advised parents not to give cough and cold medications to children, and the American Academy of Pediatrics tells parents to stay away from them as well.

Doctors say that the drugs are rarely dangerous, even when kids get too much. But just as adults can have bad reactions to the drugs, so can kids. Pseudoephedrine and other decongestants can make kids jumpy and anxious, and antihistamines can make them dehydrated and sleepy, for example.

The Consumer Healthcare Products Association, the trade organization that represents the drug makers, says the medications are safe and effective when used according to the labels. They have been on the market for decades, and are used by millions of people, the group said in a public statement in early March.

At issue are combination drugs that include a variety of ingredients: pain killers, decongestants, antihistamines, cough suppressants and expectorants. The problem, say critics, is that the doses for kids are based on those for adults, but are adjusted by average weight in the age group. At best, say doctors, the doses are educated guesses.

And like hundreds of other drugs that came on the market before 1970, these have never been tested in kids for safety or effectiveness. The little research that has been done shows that generally they are not much better than placebos in treating symptoms.

And while they are generally safe when given in the right doses, it's easy to overdose. Sometimes kids get two different brands that claim to treat different symptoms, but they often contain the same ingredients. As a result, kids get too much.

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Engineers building drug filled tooth

-- The Associated Press
Published 10:02 pm PDT Tuesday, April 3, 2007

NEW YORK (AP) Instead of settling for the bling of gold, a more practical person seeking a false tooth might eventually be able to get one that can deliver drugs.

Researchers in Europe and Israel, funded by the European Union, are working on a tiny drug-dispensing system called IntelliDrug that goes into a person's mouth - with the ultimate goal of getting the parts small enough to fit into a replacement tooth placed in the back like a molar. The device can release a specific amount of medicine at certain intervals, ensuring that the patient gets the proper dosage at the right time.

Patients, on average, follow instructions on taking drugs only half the time, even for people who need them to survive, said Dr. Andy Wolff, an Israeli dentist who initially came up with the concept. Patients often forget or find it too inconvenient to take medicine, especially in the middle of the night. He believes the device will rectify the problem by automating the process.

Wolff's company, Saliwell Ltd., and German microelectronics institute HSG-IMIT are two of 15 organizations involved with the development of the device. The project is funded by a program that promotes cooperation between EU nations and Israel. The organizations include universities, companies, research institutes and hospitals. One notable name is Spanish telephone company Telefonica SA, which is helping with the communications technology side of the development.

By placing the device in the mouth, the drug can be delivered directly into the bloodstream through the lining of the cheek and around the mouth, a surface that is porous enough to absorb the medicine. Saliva, meanwhile, mixes with the drug and carries it to the lining more consistently than just swallowing a pill every few hours.

"Why in the mouth? It's very accessible, it's very permeable, not like your skin," Wolff said.

The treatment of diabetes is one area where delivering drugs can be advantageous. People with diabetes must take regular injections of insulin to maintain low blood-glucose levels. Instead of pricking their skin, patients can wear the IntelliDrug device for a little while.

The device consists of a stainless steel housing, a pump and custom valves to regulate the drug flow, a microprocessor, batteries, and a reservoir for the drug pill. It is currently a block the size of two teeth and strapped to the side of teeth so it hugs the inside of the cheek. Developers hope to ultimately turn it into a replacement tooth.

The unit can be removed from the mouth, where a technician can refill the drug reservoir, clean the system, and replace the battery if needed.

IntelliDrug also has a communication port that allows the user to control the device via remote control with hopes of eventually linking it with a cellular phone or to a nearby hospital or care center.

"This approach combines dentistry with software, communication and technology," Wolff said.

Ongoing clinical trials, on pigs, have been successful. Dr. Axel Schumacher, who is helping design the pumps, said he hopes to have a prototype ready for human testing by the end of the year. Schumacher works for the research institute HSG-IMIT, which is based in southern Germany.

So far, the prototypes can only be worn for a limited period. There are hopes that when the components become small enough, they can become a permanent fixture.

The concept of IntelliDrug could solve the problem of compliance, said Dr. Charles Smith, professor of pharmacy at the Medical University of South Carolina. While he isn't familiar with the device, he said, "Having an automated delivery system might be interesting."

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Release Date:March 27, 2007

Patients Say Drug Leaflets Are Hard to Read, Understand

By Laura Kennedy, Contributing Writer
Health Behavior News Service

Patients report that leaflets provided with prescription drugs do not meet their needs, according to a new systematic review. Instead, poor layout and complex language often hinder communication.

Review studies confirm that written drug information does not improve patient understanding of their medications. Many people would like information that better helps them evaluate potential benefits and harms of a drug treatment.

"If you're going to have safe and effective medicines use, then we need to give patients the tools to do that job," says lead author D.K. Raynor, Ph.D., of the University of Leeds in England.

The reviewers emphasize that patients want written information in addition to — not instead of — spoken instructions from their health care professionals.

According to the Partnership for Clear Health Communication, nearly half of all American adults have difficulty understanding and using health information.

fact, the organization says, literacy skills are a stronger predictor of an individual's health status than age, income, employment status, education level or racial/ethnic group.
The review is published in the latest issue of *Health Technology Assessment*, the international journal series of the *Health Technology Assessment* programme, part of the National Institute for Health Research in the United Kingdom.

The authors reviewed 70 quantitative and qualitative studies carried out in the United Kingdom, Europe, Australia and the United States. They also conducted two patient workshops and delved into texts on information design to identify best practices.

The studies varied considerably in setting and timing, and reporting of interventions and methodological quality was often poor, the review authors say. For this reason, the experts detailed their findings in a nearly 200-page monograph rather than pooling the data for statistical analysis.

One key finding was an apparent dichotomy between prescriber and patient views of the fundamental purpose of drug leaflets, the authors say.

Some providers see increasing treatment compliance as a primary function. In contrast, patients say an informed decision not to take a medicine is also an acceptable result.

"Patients see the role of written medical information as guiding them in terms of which medicine is right for them and, if they take the medicine, how best they can use it," Raynor said. To that end, patients would also like to see more balance between benefit and harm information.

Current drug information focuses too heavily on warnings and adverse effects of the medication, Raynor said. "Patients also need to know how it might benefit them and how likely it is to benefit them."

Exactly how to convey the likelihood of benefits and harms most clearly remains in question. Verbal descriptors like "rare" or "common" are too vague, according to the review.

Yet, more scientific terminology like percentages or "numbers needed to treat" can also confuse the lay public. More research is needed in how best to communicate probability data to consumers, the reviewers say.

Raynor said that studies showed that poor layout of drug leaflets is a particular problem in the United States: "The information can be very dense, and the headings can be very indistinct. It can be very difficult to navigate."

To help drug companies produce more user-friendly consumer information, the authors reviewed six texts

recommended by experts in information design to identify best practices. Recommendations include
- Use short, familiar words and short sentences.
- Use short headings that stand out.
- Use the largest possible type size.
- Leave plenty of white space.
- Use bullet points to organize lists.

"That's probably one of the most important parts of the review," Raynor said.
"This resource can help make leaflets in the way that patients find them useful."

In 2005, the European Union took an important step forward by requiring pharmaceutical companies to test their leaflets on patients before they begin marketing a product.

"Some [European] companies have started to realize how important the leaflets are," Raynor said. "Changing them and making them more valued for patients really is in their interests."

One U.S. company that is following suit is Pfizer, Inc.

"We moved all of our patient education materials around our brand down to the sixth-grade reading level," said Barbara DeBuono, M.D., the company's senior medical advisor for public health. She is also board chair at the Partnership for Clear Health Communication.

"Health literacy is not only the ability to read and understand information, but to act on the information," DeBuono added. "There's nothing more de-motivating for a patient than to find the information confusing, unintelligible and inaccessible."

The review authors call for more robust, patient-focused research on improving content, delivery and layout of written drug information. They add that none of the studies in the current review covered Web-based medicines information, which will surely be an emerging field of study in the future.

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FOR MORE INFORMATION
Health Behavior News Service: Lisa Esposito at (202) 387-2829 or hbns-editor@cfah.org

Raynor DK, et al. A systematic review of quantitative and qualitative research on the role and effectiveness of written information available to patients about individual medicines. *Health Technology Assessment* 11(5), 2007.

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Publisher Ed

Kaiser Daily Health Policy Report

Tuesday, April 03, 2007

Prescription Drugs

Debate Continues Over Access to Experimental Medications for Terminally Ill

USA Today on Monday examined the debate over whether patients with terminal illnesses should have expanded access to experimental medications -- an issue currently under consideration in a lawsuit before the U.S. Court of Appeals for the District of Columbia. Patient advocates -- such as the Abigail Alliance for Better Access to Developmental Drugs, which filed the lawsuit against FDA -- maintain that patients with terminal illnesses "have nothing to lose" when they take experimental medications, but agency officials and many physicians "are concerned that even terminal patients are as likely to be harmed as helped by such drugs," *USA Today* reports. In addition, pharmaceutical companies and researchers have raised concerns that expanded access to experimental medications might reduce the number of patients available to participate in clinical trials. Howard Fine, chief of brain cancer research at the National Cancer Institute, said, "Ethically speaking, who has the right to say to a patient: You have no right to try this medicine even though you're dying, even though you're well informed?" Fine, who said that he did not speak on behalf of NCI, added, "Where are (drug makers) going to send these drugs? The local doc down the street? And who's going to educate the doctor?" Arthur Caplan, chair of the Department of Medical Ethics and director of the Center for Bioethics at the University of Pennsylvania, said that he supports efforts to expand access to experimental medications for patients with terminal illnesses. However, he said, "You don't want to put more weight than is appropriate" into the results of a Phase I clinical trial, which only determines the safety of experimental medications. Caplan added that patients with terminal illnesses might extend their lives by only six months with experimental medications and also might "lose six months" (Rubin, *USA Today*, 4/2).

Pubic Ed

Disease is our enemy. Working to save lives is our job.

PRESS RELEASES

PhRMA Statement on PDUFA and Drug Safety

Washington, D.C. (March 27, 2007) — Pharmaceutical Research and Manufacturers of America (PhRMA) President and CEO Billy Tauzin issued the following statement today on drug safety and PDUFA reauthorization:

"The significant increases called for in Prescription Drug User Fee Act (PDUFA) funding proposed by the Food and Drug Administration (FDA) would provide the resources necessary to improve and modernize the agency's already strong drug safety monitoring system. The FDA today devotes fully half of its pharmaceutical review budget to product safety and user fees in recent years have been used to hire more agency drug safety officers.

"The FDA -- in this year's PDUFA reauthorization proposal -- has again recommended funding for more safety officers in its Office of Surveillance and Epidemiology (formerly the Office of Drug Safety). Agency officials have also proposed greater access to large medical data bases that can be used to identify safety issues quickly and accurately. And they are recommending development of more modern and efficient methods for evaluating drug safety.

"In addition, the FDA has already proposed to Congress more funding through PDUFA to various FDA programs that address how to assess specific safety issues -- such as liver toxicity -- in clinical trial designs and benefit/risk evaluations of new medicines. Finally, the FDA -- in its January response to a drug safety report from the Institute of Medicine -- stressed that many different interested parties, including agency and pharmaceutical research company experts, have for years been working on new scientific approaches for detecting, understanding, predicting and preventing the side effects of drugs.

"When it comes to patient safety, there is always room for improvement. But the FDA, in its PDUFA proposal to Congress and IOM response statement, makes clear that efforts to improve drug development and safety have been underway for years and now even more promising safety initiatives have been proposed as part of reauthorizing PDUFA this year.

"FDA officials are proposing to make a good system even better. The fact is the combined efforts of the agency and America's pharmaceutical research companies over the years have resulted in the United States having the world's best drug safety record. About three percent of medicines have been withdrawn from the American market for safety reasons over more than 20 years. The vast majority of American patients continue to receive safe and effective treatments."

The Pharmaceutical Research and Manufacturers of America (PhRMA) represents the country's leading pharmaceutical research and biotechnology companies, which are devoted to inventing medicines that allow patients to live longer, healthier, and more productive lives. PhRMA companies are leading the way in the search for new cures. PhRMA members alone invested an estimated $43 billion in 2006 in discovering and developing new medicines. Industry-wide research and investment

reached a record $55.2 billion in 2006.

PhRMA Internet Address: www.phrma.org

PhRMA en Español: www.nuestraphrma.org

For information on how innovative medicines save lives, visit: www.innovation.org

For information on the Partnership for Prescription Assistance, visit: www.pparx.org

For information on the danger of imported drugs, visit: www.buysafedrugs.info

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Public Ed

OP-ED CONTRIBUTOR

Patents Over Patients

By RALPH W. MOSS
Published: April 1, 2007

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State College, Pa.

WE could make faster progress against cancer by changing the way drugs are developed. In the current system, if a promising compound can't be patented, it is highly unlikely ever to make it to market — no matter how well it performs in the laboratory. The development of new cancer drugs is crippled as a result.

The reason for this problem is that bringing a new drug to market is extremely expensive. In 2001, the estimated cost was $802 million; today it is approximately $1 billion. To ensure a healthy return on such staggering investments, drug companies seek to formulate new drugs in a way that guarantees watertight patents. In the meantime, cancer patients miss out on treatments that may be highly effective and less expensive to boot.

In 2004, Johns Hopkins researchers discovered that an off-the-shelf compound called 3-bromopyruvate could arrest the growth of liver cancer in rats. The results were dramatic; moreover, the investigators estimated that the cost to treat patients would be around 70 cents per day. Yet, three years later, no major drug company has shown interest in developing this drug for human use.

Early this year, another readily available industrial chemical, dichloroacetate, was found by researchers at the University of Alberta to shrink tumors in laboratory animals by up to 75 percent. However, as a university news release explained, dichloroacetate is not patentable, and the lead researcher is concerned that it may be difficult to find funding from private investors to test the chemical. So the university is soliciting public donations to finance a clinical trial.

The hormone melatonin, sold as an inexpensive food supplement in the United States, has repeatedly been shown to slow the growth of various cancers when used in conjunction with conventional treatments. Paolo Lissoni, an Italian oncologist, helped write more than 100 articles about this hormone and conducted numerous clinical trials. But when I visited

INSIDE NYTIMES.COM

him at his hospital in Monza in 2003, he was in deep despair over the pharmaceutical industry's total lack of interest in his treatment approach. He has published nothing on the topic since then.

Potential anticancer drugs should be judged on their scientific merit, not on their patentability. One solution might be for the government to enlarge the Food and Drug Administration's "orphan drug" program, which subsidizes the development of drugs for rare diseases. The definition of orphan drug could be expanded to include unpatentable agents that are scorned as unprofitable by pharmaceutical companies.

We need to foster a research and development environment in which anticancer activity is the main criterion for new drug development.

Ralph W. Moss writes a weekly online newsletter about cancer.

More Articles in Opinion »

Tips

To find reference information about the words used in this article, double-click on any word, phrase or name. A new window will open with a dictionary definition or encyclopedia entry.

Past Coverage

F.D.A. Approves Glaxo Cancer Drug (March 14, 2007)
Studies Show Anemia Drugs May Harm Cancer Patients (February 27, 2007)
Lobbying For Vaccine To Be Halted (February 21, 2007)
THE WAY WE LIVE NOW: 2-11-07:QUESTIONS FOR DR. ANDREW C. VON ESCHENBACH; Put to the Test (February 11, 2007)

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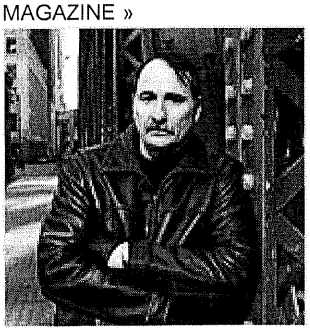

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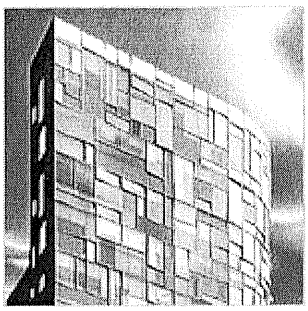

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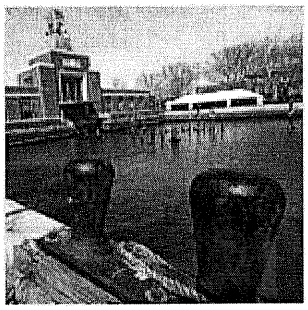

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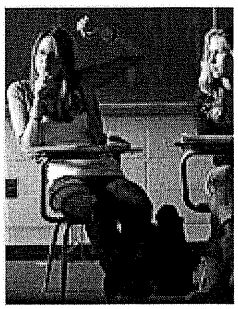

For Girls, It's Be Yours and Be Perfect, Too

"Joshua Room"
<Joshua.Room@doj.ca.gov>
06/12/2007 04:06 PM

To "Virginia Herold" <Virginia_Herold@dca.ca.gov>
cc
bcc
Subject FDA citing that article

Preventing Errors with Tablet Splitting

FDA Patient Safety News: Show #54, August 2006

Splitting tablets is a common practice where tablets of a higher strength than the patient needs are broken in half, or even quarters, to provide the correct dose. This is often done to reduce costs, since the higher strength tablet sometimes costs about the same as the lower strength one. In some cases the hospital may not stock the lower strength of a particular medication, and in other cases the patient may not be able to swallow a whole tablet.

But unless certain precautions are taken, tablet splitting can lead to medication errors. If the patient is splitting the tablets at home, he or she can become confused about the dose. Patients often forget to split their tablets, or they can split them again after they've been pre-split in the pharmacy. Some patients may not have the visual acuity or motor skill to do the splitting properly. Even when split well, the pieces can crumble or be uneven in size.

Patients may not be the only possible source of error. When the prescription is written as "1/2 tablet," the pharmacist can confuse this with "1-2 tablets," which could lead to a fourfold overdose.

ISMP suggests several ways to prevent errors with tablet splitting:

• Be sure that the tablet in question is suitable for splitting. If in doubt, check with the manufacturer.

• Ensure the patient has the understanding, skill and motivation to split the tablets. You may have to enlist a family member or caretaker to do this.

• If the tablets are to be split at home, provide the patient or family with a tablet splitter to improve accuracy.

• For inpatients, the pharmacy staff should dispense the tablets already split, rather than relying on nurses to do this on the floor.

• Prescribers should order the strength in milligrams when possible, to avoid misreading an order for "1/2 tablet" for "1-2 tablets."

Additional Information:

ISMP Medication Safety Alert. Tablet Splitting: Do it only if you "half" to and then do it safely. May 18, 2006.
http://www.ismp.org/Newsletters/acutecare/articles/20060518.asp

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

"Joshua Room"
<Joshua.Room@doj.ca.gov>
06/12/2007 04:05 PM

To "Virginia Herold" <Virginia_Herold@dca.ca.gov>
cc
bcc
Subject Article on Tablet Splitting with useful summary of topic and recommendations

[IMAGE]

Tablet splitting: Do it only if you "half" to, and then do it safely

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From the May 18, 2006 issue

Problem: Most oral medications are available commercially in the dosage strengths most commonly prescribed for patients. Occasionally, the patient's exact dose is not available commercially, so more than one tablet or just part of a tablet may be needed. While using more than one tablet for a single dose is customary, tablet splitting has become more commonplace in the past 5 years for several reasons:

- Different tablet strengths often cost about the same. Patients who cannot afford their medications have received a higher strength tablet with directions to take ½ tablet (or even ¼ tablet) per dose (1).
- Some health insurers have denied payment of prescriptions for the lower strength of certain drugs, thus requiring patients to receive the higher strength tablet and split it in half for each dose (1).
- Some healthcare organizations have not purchased all commercially available strengths of oral medications. Thus, some of the drugs may require tablet splitting for patient-specific doses in the inpatient setting.
- Patients may not be able to swallow whole tablets (2).

A recent article in the Veterans Administration (VA) Topics in Patient Safety newsletter (2) and a 2002 article on the American Society of Consultant Pharmacists website, Tablet Splitting for Cost Containment, authored by Thomas Clark (1), offer several pitfalls with splitting tablets that clearly suggest it is not the safest option if the patient-specific dose is available commercially.

Patient factors. First, it is easy for patients to become confused about the correct dose. One woman learned this when she was admitted to the hospital with unstable angina and hypertension. Her physician found that she had been taking the wrong dose of lisinopril. She

was supposed to be taking 5 mg BID, but the prescription label said there were 10 mg tablets in the bottle. When the physician looked inside, he saw both pink and peach tablets, some of which were split in half. Initially, the patient had been taking a 20 mg tablet BID. When her physician lowered the dose to 10 mg BID, she had the new prescription filled. The patient then cut the leftover 20 mg tablets in half and put them in the same bottle that held the 10 mg tablets. Later, her physician lowered the dose to 5 mg BID. Instead of filling the new prescription for 5 mg tablets, she tried to find all the 10 mg tablets to split them in half, but some remained whole.

In this case, no one could be certain of the dose the patient had been taking before she was hospitalized. But a study by the VA showed that most people took too much medication because they forgot to split their tablets (2). Between January 2001 and April 2005, the VA's National Center for Patient Safety database included 442 reports related to pill splitting. Of those, 38% were considered adverse events, mostly occurring in outpatient settings (65%). Two-thirds of the patients received more than the intended dose. Pharmacists caught these errors because the patients came in too soon to refill their prescriptions. A quarter of the medications were high-alert drugs. About 9% of patients were harmed by these mistakes; 2% required hospitalization. In more than half of the events, the involved doses were available commercially.

Clark identified a few additional risks with tablet splitting (1):

- A pharmacist might misread a prescription written for 1/2 tablet as 1-2 tablets.
- Patients may assume the tablets have already been split when they have not, or split them again when they have been split already (especially if the pharmacy inconsistently splits the tablets upon refill).

- Patients may not have the visual acuity or manual dexterity needed to split the tablets.
- Patients may get confused and split the wrong medication, or get tired of splitting the tablets and stop taking it.
- To maximize cost savings, the patient may have been told to split the tablets in half, but the directions on the prescription may list "1 tablet" for each dose. These directions could mislead the patient or other healthcare providers who use the prescription label as a source of information when gathering a patient's medication history.
- Split tablets crumble more easily.

Medication factors. Some medications or formulations are not suitable for splitting, including:

- Enteric-coated/extended-release tablets
- Very small tablets
- Asymmetrical tablets
- Capsules
- Teratogenic medications (e.g., bosentan).

Clark cites various studies that suggest that the accuracy of split tablets is questionable, even if the tablet is scored.1 In one study, 94 volunteers were asked to split 10 tablets of hydrochlorothiazide 25 mg; 41% of the split tablets deviated by 10% of the correct weight, and 12% deviated by more than 20%. After the study, two-thirds of the volunteers said they would be willing to pay more for commercially available tablets in the correct strength. Other research cited by Clark corroborates the significant variation in tablet halves with rates of inaccuracy ranging from 5-72%.

Safe Practice Recommendations: Healthcare providers should make every effort to use commercially available oral tablets when available in both inpatient and outpatient settings. However, tablet splitting may still be necessary if the drug is not commercially available in the patient-specific dose, or if the

patient's inability to afford the medication as an outpatient outweighs the risks involved with tablet splitting. Under these circumstances, consider the following suggestions from Clark, the VA, and ISMP:

Verify suitability. Before prescribing, dispensing, or administering half tablets, check drug references to ensure that it is safe. If unsure, contact the manufacturer.2
Select patients carefully. Establish criteria to screen patients before prescribing or dispensing half tablets to ensure they have the required level of understanding, ability, and motivation to split the tablets (1,2). Ensure that the patient understands the risks associated with tablet splitting. If the patient cannot be expected to split his or her own tablets, enlist the aid of a qualified family member. (Note: It may not be legal in some states for a pharmacist to split tablets if the dose is available commercially [1]).

Dispense split tablets for inpatients. For hospitalized patients, pharmacy staff should dispense exact doses by either splitting tablets and repackaging them or preparing an oral solution in a unit-dose oral syringe for each dose. Nurses should not be expected to split the tablets.

Keep it clean. Patients and healthcare providers who split tablets should wash their hands first. Healthcare providers should also wear gloves. If a tablet-splitting device is used, it should be washed afterwards to remove any powder or particles.

Prescribe by weight. Prescribers should order the medication strength and dose in "mg" when possible to avoid misreading an order for a "1/2" tablet as 1-2 tablets.

Counsel patients. Establish a system to ensure patient counseling when prescriptions for medications that require half tablets are picked

up at community pharmacies, even if the pharmacist has split the tablets for the patient (2).

Provide the right tools. If patients must split tablets at home, provide them with a tablet-splitting device to improve the accuracy (2).

Provide discharge education. If patients are receiving half tablets while in the hospital, advise them regarding the dose they should take after discharge and whether this requires split or whole tablets.

References: 1) Clark TR. Tablet splitting for cost containment. August 2002. Available at: www.ascp.com/advocacy/briefing/tabletsplittingcontainment.cfm. **2)** Sales MM, Cunningham FE. Tablet splitting. Veterans Administration Topics in Patient Safety (TIPS). 2006;6(3):1,4.

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Public Ed

Kaiser Daily Health Policy Report

Friday, March 30, 2007

Coverage & Access

Most People Who Have Used Retail Clinics Are Satisfied With Care, Poll Finds

Most U.S. residents who have visited a retail-based health care clinic -- increasingly present in chains like CVS, Wal-Mart and Target -- were satisfied with their visits, although people remain concerned about the quality of care at such clinics, according to a *Wall Street Journal* Online/Harris Interactive poll, the *Wall Street Journal* reports. The online survey conducted between March 20 and March 22 polled 2,441 U.S. adults about their use of in-store clinics. Retail clinics provide basic health care services, such as strep throat tests, flu shots and physicals, without an appointment and often are open during weekend and evening hours. Of the 5% surveyed who had used a retail clinic, the poll found that:

- 42% said their health insurer covered all or a portion of the costs;
- 22% were uninsured at the time of the visit;
- 83% were satisfied with the convenience of the clinics;
- 90% were satisfied with the quality of care;
- 80% were satisfied with the cost, which typically ranges from $25 to $60 for a visit;
- 44% visited the clinic for a vaccination;
- 33% wanted treatment for a common medical condition, such as an ear infection, cold, strep throat, skin rash or sinus infection; and
- 19% went for a preventive screening test for chronic conditions, such as hypertension, high cholesterol, diabetes or allergies.

Sixty-four percent of those polled said they would be concerned about the qualifications of staff at a retail clinic not run by physicians, compared with 71% who expressed similar concerns in an October 2005 poll. In addition, 68% said they would be concerned that a serious medical problem might not be accurately diagnosed at retail clinics, down from 75% in a 2005 poll (Bright, *Wall Street Journal*, 3/29).

Public Ed

Karen Abbe/Pharmacy/DCANotes
03/12/2007 02:21 PM

To Virginia Herold/Pharmacy/DCANotes@DCANotes
cc
bcc
Subject Washington Post: A Dangerous Mix

washingtonpost.com

A Dangerous Mix

Some Drugs Don't Go Together; Web Sites May Help Flag Them.

By January W. Payne
Washington Post Staff Writer
Tuesday, February 27, 2007; HE01

You're taking a couple of prescription medications and you develop a cold -- so you head to the nearest pharmacy to get something for your headache, cough and stuffy nose.

Not so fast, experts advise. Mixing medications can be dangerous-- even deadly, a fact highlighted by the death in November of popular R&B singer Gerald Levert. An autopsy determined that Levert, 40 -- who reportedly had been suffering from a shoulder problem, pneumonia and the effects of surgery in 2005 to repair a severed Achilles tendon -- died of accidental acute intoxication caused by a mixture of the pain medications Darvocet, Percocet and Vicodin, the anxiety medicine Xanax and two over-the-counter antihistamines.

A report this month by the Centers for Disease Control and Prevention found that deaths from accidental drug interactions rose 68 percent between 1999 and 2004, continuing a steady climb since the early 1990s. Unintentional drug poisonings accounted for nearly 20,000 deaths in 2004, said the CDC, making the problem now the second-leading cause of accidental death in the United States, after automobile accidents. "Prescription drugs, especially prescription painkillers, are driving the prolonged increase," the report stated.

Experts advise patients to consult their doctors and pharmacists before adding new medications -- prescription or over-the-counter -- or herbal remedies to their regimens. "Many of the products you can buy OTC today were still prescription [medications] just a few years ago," so don't underestimate their strength, said Catherine M. Polley, senior vice president and chief policy officer at the American Pharmacists Association.

The Internet provides a growing repository of information about drug interactions. But the depth and quality of such information vary greatly by site.

Online "drug interaction checkers" -- available on the Web sites of such major medical centers, retailers and pharmacies as Caremark, the University of Maryland Medical Center, Drugs.com, Eckerd, Discovery Health, Drugstore.com and Express Scripts -- allow patients to plug in the names of their medications and produce a report that typically lists their possible interactions with certain foods, alcohol and other drugs. (See sidebar for addresses of drug interaction checkers and other online resources.)

But the absence of a Web warning doesn't mean a drug combination is generally safe -- or, more important, safe for you, say Polley and others. Many factors, including a patient's health and medical history, can affect safety, and the Web sites warn patients to consult their doctors for specific advice about their medications.

Even when online reports warn of the potential for harmful interactions, it's possible that the medications may still be combined -- under a doctor's eye. Cancer patients, for example, and those with severe injuries may require more than one strong painkiller, said Kathy Vieson, an oncology pharmacist and vice

Public Ed

Karen Abbe/Pharmacy/DCANotes
03/12/2007 08:24 AM

To Virginia Herold/Pharmacy/DCANotes@DCANotes
cc
bcc
Subject San Diego Union-Tribune: Sometimes, sharing can be dead wrong

The San Diego Union-Tribune.

SANDI DOLBEE EVERYDAY ETHICS

Sometimes, sharing can be dead wrong

March 10, 2007

It started as a bad headache. Someone offered her a couple of painkillers. She felt better for a little while. Someone else offered her pills from a prescription for migraines.

They all meant well. Truly they did. Except the headache was only a symptom. The wife and mother, who shrugged off suggestions to go to the doctor, died last month. A spinal tap showed she had meningitis.

Dr. Margaret McCahill nods her head sympathetically as she listens to the story. It's sad, she says, because the sharing of prescription pills certainly was done out of kindness and concern.

But it's also a case that McCahill says underscores an important lesson: "It's really quite dangerous for people to share their medications."

McCahill, a family physician and psychiatrist, is the director of the combined family medicine-psychiatry residency program at UCSD's School of Medicine. As a longtime doctor and professor, she has her own stories.

She tells of a woman with hyperthyroid disease who had no insurance and couldn't afford treatment. Her three sisters also had the malady and were sharing their drugs with her. "They said, 'Here's our sister, we love her, we want her to be in good health,' so they variably shared their medication."

But the sisters didn't take the same dosage. "By the time we saw her, she was in a lot of distress," says McCahill.

McCahill wants to make it absolutely clear that sharing prescriptions is illegal. As the warning labels on the bottles point out, federal law prohibits the transfer of the drug to anyone other than the patient. "We (health care providers) know it is illegal to share, so we have to say, 'No, never share,'" she says.

Are there any exceptions? Is it ever ethical to break this law?

McCahill offers a hypothetical scenario. Let's say some people are traveling together and one of them loses his Clonidine, an anti-hypertensive drug that can be life-threatening if the patient abruptly stops taking it. Another person on the trip also takes Clonidine and has the exact same dosage. In this case, when sharing would prevent a potentially lethal problem, this is a risk that many people would feel justified in taking.

"But you see, there's a big difference," she adds. "The people who were sharing did not make a medical diagnosis. They did not make a medical judgment."

There are other hazards in sharing a prescription drug - too many to list here. The bottom line: Keep your medicine cabinet closed and take the person to the doctor. Sometimes, our decisions aren't just a matter of right and wrong. Sometimes, they're a matter of life and death.

Sandi Dolbee: (619) 293-2082; sandi.dolbee@uniontrib.com

Kaiser Daily Health Policy Report

Thursday, March 29, 2007

Prescription Drugs

Studies Show About 50% of People Fail To Take Medication as Directed

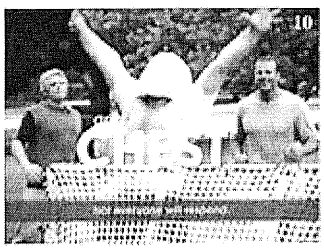
USA Today on Thursday examined how multiple studies have shown that only about half of people with chronic conditions in the U.S. and other developed countries continue to take medication as directed. For example, a study published in the January issue of *Drugs & Aging* found that 20% to 30% of patients taking daily or weekly osteoporosis medication quit six to 12 months after they began. A similar study published in the January issue of *Cancer* found that 22% of breast cancer patients taking the drug tamoxifen to reduce the risk of recurrence stopped taking the medication by the end of one year. The study also found that more than one-third of patients had stopped taking tamoxifen after three-and-a-half years. According to *USA Today*, "Reasons for this lack of adherence ... are complex, and quick fixes are few." Physicians say the "problem cuts across all socioeconomic groups" and often goes unrecognized, *USA Today* reports. Authors of the tamoxifen study -- from Trinity College in Dublin, Ireland -- wrote that decreased social support and declining memories might be reasons why older patients stopped taking their medications. Alexandra Papaioannou, a geriatrician at McMaster University and author of the osteoporosis medication study, said that side effects and fear of the drugs were the primary reasons patients stopped taking their medication. In addition, memory problems, depression and a daily regimen of multiple pills might have deterred patients from sticking to their prescriptions, Papaioannou said. She added that patients should be provided with written, as well as oral, instructions for medication and that doctors should inform family members of the prescribed regimen to ensure that patient follow it. "Adherence is a huge problem, costing billions of dollars," Papaioannou said, adding, "Obviously, if you don't take the drug, you won't have the full benefit" (Rubin, *USA Today*, 3/29).

Karen Abbe/Pharmacy/DCANotes
01/22/2007 09:11 AM

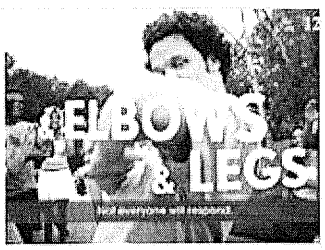
To Virginia Herold/Pharmacy/DCANotes@DCANotes
cc
bcc
Subject New York Times: Showdown Looms in Congress Over Drug Advertising on TV

The New York Times

Showdown Looms in Congress Over Drug Advertising on TV



And chest



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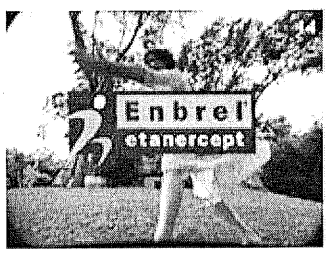
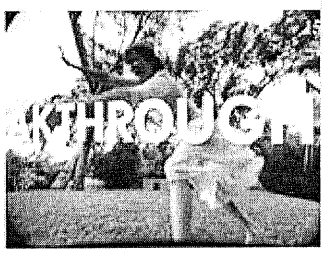
and legs?



Enbrel.


It's a breakthrough

By MILT FREUDENHEIM

Drug advertising aimed at consumers, a fast-growing category that reached $4.5 billion last year, will face hard scrutiny in the new Congress, according to industry critics in both the House and Senate.

The consumer ads will be on the griddle early in this session at hearings on the user fees that manufacturers pay to speed the reviewing of new drugs by the Food and Drug Administration. The user fee law will die in the fall unless Congress acts to renew it.

The pharmaceutical industry, which often gets what it asks for from Congress and the executive branch, seeks to renew the law and add a new set of user fees that would be pay salaries for additional F.D.A. employees to evaluate all consumer drug ads, before they are shown on television.

Both the industry and its critics agree that there should be a pause before the advertising starts – to allow time for doctors to learn about a new drug. The companies want the delay to be left up to them, but critics say the F.D.A. should require a wait of up to two years. Criticism of direct-to-consumer advertising has intensified since 2004, after Merck withdrew Vioxx, a heavily advertised painkiller, after a clinical trial showed that it sharply increased the risk of heart attacks and strokes.

"From the beginning , everyone, including the company, agreed that not everybody ought to be getting Vioxx," said Helen Darling, president of the National Business Group on Health, an organization of large employers. "But the ads implied there was a widespread need for it."

Spending on consumer drug advertising, meanwhile, has been growing robustly, from $1.1 billion in 1997 to $4.2 billion in 2005, according to a recent report to Congress by the Government Accountability Office.

In the first nine months of 2006, spending rose 8.4 percent to $3.29 billion, on track toward $4.5 billion for the year, according to TNS Media Intelligence, an advertising research firm.

Spending on the ads faltered in 2005 after soaring 27 percent in 2004, before Vioxx was withdrawn, said David Kweskin, a senior executive at the firm. "Now they are in a catch-up phase."

Two independent government watchdog groups sharply criticized consumer drug advertising recently, and a separate survey Jan. 9 commissioned by the PricewaterhouseCoopers accounting and consulting firm indicated that skepticism is widespread among the public, too. Only 1 in 10 consumers said the direct-to-consumer, or D.T.C., ads could provide useful information to a large audience, the survey said. (Consumer drug advertising is not permitted in most of the world, except New Zealand and the United States.)

The pharmaceutical industry itself acknowledges having an image problem.

"It would be naïve to not acknowledge the fact that D.T.C. advertising is also a lightening-rod in the health care debate in this country," said Billy Tauzin, the former congressman who is now president and chief executive of the Pharmaceutical Research and Manufacturers of America, in a speech to venture capitalists last spring. There is "one great problem" that the manufacturers face, he said: "in a word, it is trust."

"While individual patients find the information useful in discussions with their physicians," he added in his speech, "patients, physicians and consumers generally express unhappiness with D.T.C. advertising."

Mr. Tauzin's organization issued voluntary guidelines for consumer ads, which took effect last year. Under the guidelines, the companies have promised to hold off on consumer advertising of a new medicine for an unspecified "appropriate" period. That would allow time to tell doctors about risks and benefits, before television and Web site viewers see an ad and demand a prescription.

Twenty-seven members of the pharmaceutical manufacturers organization have endorsed the guidelines, but it is hard to figure exactly how long the delays in advertising will run. Bristol-Myers Squibb has said that it would delay for 12 months. Johnson & Johnson and Pfizer said they would wait six months. The manufacturers group cannot say how other companies have interpreted the guidelines, a spokesman said.

But according to TNS Media Intelligence, the companies have actually been waiting 15 months, on average, since the Vioxx debacle.

Critics say that even after F.D.A. approval, the full safety profile of a new drug cannot be known until it has been widely used for a number of years.

But the manufacturers' guidelines have to be voluntary, said Daniel E. Troy, a former chief counsel of the F.D.A., because the Supreme Court has "struck down restrictions on advertising of tobacco, alcohol, gambling and unapproved compounded drugs."

The agency sent 15 warning letters to drug companies regarding ads in 2005 and a total of 22 complaints last year.

The F.D.A. told AstraZeneca, for example, to "immediately cease" a "misleading superiority claim" in a 2005 TV commercial. The ad said AstraZeneca's Crestor was "clearly the best" in a "head to head" test with the three largest-selling cholesterol drugs.

Emily Y. Denney, an AstraZeneca spokeswoman, said that by the time the letter was received, in March 2005, the ads were no longer running. The company defended its message in the advertising as "appropriate."

Another F.D.A. letter told Amgen, a biotechnology company, to stop running commercials for Enbrel, a treatment for the skin disease psoriasis, that the F.D.A. said minimized "serious risks" associated with the drug. Amgen immediately withdrew the commercial.

Last year, the company obtained F.D.A. approval of the contents of a new Enbrel television ad before showing it, David Polk, an Amgen spokesman said. Corporate lawyers say such advertising is protected by the First Amendment under a doctrine of commercial free speech. But some experts say the limits of the protection are murky.

The closest approach to clarity was in 2002 when the Supreme Court rejected, by a 5-to-4 vote, a federal restriction on advertising by pharmacists who make their own compounds.

"It is a giant game of chicken between the government and the industry," said R. Alta Charo, a law professor and bioethics specialist at the University of Wisconsin in Madison. "I don't believe either side really wants to see a definitive case go to the Supreme Court because neither side is willing to take the risk that they will lose."

Professor Charo was a member of a committee of experts of the Institute of Medicine, which examined drug safety issues at the request of the F.D.A. Last fall, the committee called on Congress to give the F.D.A. new authority over advertising, including the power to require a two-year moratorium on advertising before approving a new drug.

"I think the Congress has clearly indicated its strong interest and concerns about the F.D.A. and drug safety for consumers," said Sheila P. Burke, a longtime Republican health policy expert who headed the Institute of Medicine committee. "Broad-scale advertising can sometimes lead to a rapid increase in the use of a drug" that raises the risk of harm for patients, she said.

F.D.A. regulators would be granted the power to require moratoriums under a bill sponsored by Senators Edward M. Kennedy and Michael B. Enzi, the chairman and ranking Republican member of the Senate Health, Labor, Education and Pensions Committee.

"Patients deserve the best and most accurate information about the medicines they take," Senator Kennedy said in a statement. "An essential part of any drug safety proposal must be to give the F.D.A. the authority and resources it needs to oversee direct-to-consumer advertising, and to allow the F.D.A. to impose conditions or limits on that advertising, where needed to protect the public health."

Testifying for the pharmaceutical industry last year, Dr. Adrian Thomas, a vice president of Johnson & Johnson, insisted that "the important First Amendment issues that arise from banning truthful speech, even for a period of time, must be carefully considered before legislating in this area."

The Government Accountability Office said last November that the F.D.A. should be doing a better job of overseeing consumer drug ads. Now, the F.D.A. reviews only a small fraction of the advertising, picking and choosing without proper priorities, the G.A.O. said.

The G.A.O. report had been requested by three influential senators: Bill Frist, a doctor, before he stepped down as Republican leader of the Senate; Charles E. Grassley, now the ranking Republican on the finance committee, and Herb Kohl, a Democrat who heads an appropriations subcommittee that oversees the F.D.A.

Representative Henry A. Waxman, a California Democrat who is chairman of the House Oversight and Reform Committee, added a further criticism: that the F.D.A. had been slow to crack down on drug ads that included "false and misleading" claims, he said in a telephone interview.

F.D.A. officials said they had to deal with 54,000 drug promotions each year, aimed at both doctors and consumers.

"We are seriously considering all of the recommendations" of the Institute of Medicine report, said Thomas Abrams, director of the F.D.A.'s division of drug marketing, advertising and communications.

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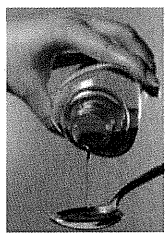
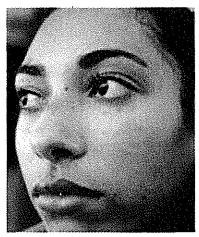
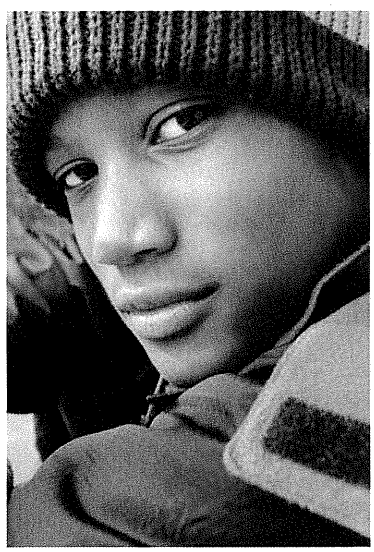
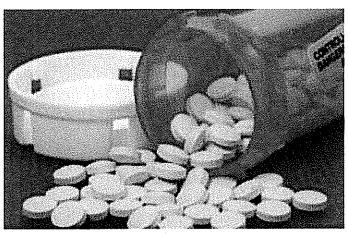
The Partnership for a Drug-Free America®









Getting High on Prescription and Over-the-Counter Drugs Is Dangerous

A guide to keeping your teenager safe in a changing world

www.drugfree.org

THE NEW PARTY DRUGS

Prescription and over-the-counter (OTC) medications are fast becoming the new "party" drugs for many teenagers.

But many parents, who may be aware of their children's familiarity with illegal street drugs, do not have "pharming"—that is, their kids' using prescription and OTC drugs for recreational use—on their radar screens, even though nearly one in five teens has used powerful narcotic pain relievers for nonmedical reasons.

FRIGHTENING STATS

A survey of teenagers by the Partnership for a Drug-Free America found that:

- 1 in 5 teens has tried Vicodin, a powerful and addictive narcotic pain reliever
- 1 in 10 has tried OxyContin, another prescription narcotic
- 1 in 10 has used the stimulants Ritalin or Adderall for nonmedical purposes
- 1 in 11 teens has admitted to getting high on cough medicine

Nor are parents aware that their own medicine cabinets and home computers are potential sources of these drugs for teenage abuse.

Prescription and OTC drugs are important and beneficial products that every year improve and save countless lives. They are effective, and they are also safe—but only if used as medically intended.

We're NOT talking about kids mistakenly taking the wrong dose of legal medicines or taking a stronger-than-necessary medicine for an ailment. We're talking about drug abuse—kids using prescription and OTC drugs on purpose in order to get high.

If your teen gets in the habit of using medicines that are not medically intended for him or her, or of taking higher-than-recommended doses just for fun, bad things can happen: Dramatic increases in blood pressure and heart rate, organ damage, addiction, difficulty breathing, seizures, and possibly death.

For more information, visit www.drugfree.org

Why is this increase in teenage prescription and OTC drug abuse happening now?

Awareness and access. Mainly for good reasons, our society is very familiar—and more and more comfortable—with prescription pharmaceuticals and OTC medicines. Products come to market, their images advertised in newspapers, magazines, and on television and the Internet, with educational programs to raise our understanding of the conditions they treat. Many new drugs replace older ones with safer and more effective formulations.

Caught in the Web

Then there's the Internet, which has been at the center of an explosion of information of all kinds, good and bad. You can find useful information on the Web about the risks from the nonmedical, recreational use of prescription and OTC drugs. But you can also learn how to abuse them. Many websites describe for would-be abusers what kinds of cough syrup they should buy, how much to take, and how to extract its intoxicating ingredient.

Most disturbingly, it is as easy for a teenager to buy narcotic pain relievers like Vicodin or stimulants like Adderall or sedatives like Xanax over the Internet as it is to buy a book or CD. Enter "no prescription Vicodin" in your Web browser's search bar, and you'll find numerous websites ready to sell your son or daughter various prescription drugs—without the nuisance of an actual prescription or even asking your child's age—delivered to your home in an unmarked package.

But the most immediate source of prescription and OTC drugs is your own medicine cabinet or the medicine cabinets in the homes of your child's friends. New and expired or forgotten prescriptions or last winter's OTC flu medicines could be inviting targets for the teenager looking to get high.

What to Do?

Some parents need to consider their own drug behavior. If you're casual about using prescription or OTC drugs, even if you're not looking to get high, you can set a bad example. Medications should be used by the person for whom they're prescribed, to treat the conditions for which they're prescribed. Don't use your kid's Ritalin to give you the energy and focus to complete a difficult work assignment. Regard these drugs seriously, and it's a good bet your child will, too. Start by taking an inventory of the drugs in your medicine cabinet.

It's up to you to educate yourself about the real dangers of prescription and OTC drug abuse and to discuss these risks with your teen. Kids need to hear from parents that **getting high on legal prescription and OTC drugs is not safer than getting high on illegal street drugs.**

And reaching out to have that discussion is not just an idle suggestion. It works. Research shows that kids who learn a lot about drug risks from their parents are up to half as likely to use drugs as kids who haven't had that conversation with Mom and Dad.

Unfortunately, research also shows that fewer parents today are talking to their teenagers about drugs than they were only a few years ago.

It's time to turn that stat around. This brochure can help. So can the information found on the website of the Partnership for a Drug-Free America—www.drugfree.org—or at the other resources listed at the end of this booklet.

Quite simply, if you're not educating your children about any health risk they may encounter, you are not providing the protection they need in today's changing world.

What could be more basic to being a parent than protecting your child from harm?

Educate Yourself

If you're going to discuss prescription and OTC drug abuse with your kids, you need to know what you're talking about. You should be able to distinguish among the types and effects of drugs some teens use to get high. Some of these drugs are described below.

PRESCRIPTION (RX) DRUGS

Safe when used according to a doctor's instructions, **these medications should be taken only by the person for whom a doctor has prescribed them**. Using prescription drugs prescribed for others or without doctor's orders is unsafe and illegal.

Codeine

Pain Medications

Teenagers abuse narcotic pain relievers more than any other prescription medicine. Mentions of these very powerful drugs as reasons for emergency room visits have nearly tripled over the recent decade.

Vicodin *(hydrocodone)* ▪ ***OxyContin*** *(oxycodone)* ▪ ***Percocet*** *(oxycodone and acetaminophen)* ▪ ***Darvon*** *(propoxyphene)* ▪ ***Codeine***

Medically useful for:

- *Treating moderate-to-severe pain, such as after surgery or dental procedures.*

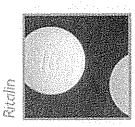
Abused by teens to:

- *Feel pleasure or sensations of well-being.*

Dangerous because:

- *Highly addictive. Over time, tolerance develops to certain effects of these drugs, resulting in the need to take more and more to get the same pleasant feelings. Addicted teens who suddenly stop using may go through withdrawal, a horrible physical experience of intense restlessness, muscle and bone pain, insomnia, diarrhea, vomiting, and cold flashes.*
- *Taken in overdose, breathing slows down and eventually stops, and death may occur. Time-released products like OxyContin, designed to deliver pain-relieving medication into the system slowly over hours, may be crushed and snorted, causing the drug to enter the system all at once, sometimes resulting in death.*
- *Taken in combination with other prescription or OTC drugs or alcohol, the risk of life-threatening respiratory depression is increased.*

Stimulants


Ritalin

These amphetamines increase the amounts of circulating brain chemicals that raise blood pressure and heart rate, speed up breathing, decrease appetite, and deprive the user of sleep.

Ritalin, Concerta *(methylphenidate)* ▪ ***Adderall*** *(mixed amphetamine salts)* ▪ ***Focalin*** *(dexmethylphenidate)* ▪ ***Dexedrine*** *(dextroamphetamine)* ▪ ***Meridia*** *(sibutramine)*

Medically useful for:

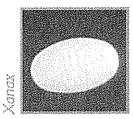
- *Treating attention deficit/ hyperactivity disorder (ADHD), narcolepsy; short-term treatment of obesity.*

Abused by teens to:

- *Feel especially alert, focused, and full of energy. May help them to manage stressful schoolwork or "pull an all-nighter."*
- *Suppress appetite in order to lose weight.*

Dangerous because:

- *Can be addictive.*
- *High doses taken over a short time can lead to feelings of hostility, intense fear, and paranoia.*
- *High doses may result in dangerously high body temperature and irregular heartbeat, with possible cardiovascular failure or seizures.*
- *Use in combination with OTC decongestants can result in dangerously high blood pressure or irregular heart rhythms.*
- *Can cause insomnia, digestive problems, and erratic weight change.*


Xanax

Sedatives, Sedative-Hypnotics, and Tranquilizers

Sedatives, sedative-hypnotics, and tranquilizers affect brain systems to produce a drowsy or calming effect, sometimes to the point of inducing sleep.

Benzodiazepine Receptor Agonists: ***Valium*** *(diazepam)* ▪ ***Xanax*** *(alprazolam)* ▪ ***Ativan*** *(lorazepam)* ▪ ***Klonopin*** *(clonazepam)* ▪ ***Restoril*** *(temazepam)* ▪ ***Ambien*** *(zolpidem)* ▪ ***Lunesta*** *(eszopiclone)*
Barbiturates: ***Mebaral*** *(mephobarbital)* ▪ ***Nembutal*** *(pentobarbital)*

Medically useful for:

- *Treating anxiety, severe stress, panic attacks, and short-term treatment of insomnia, as well as some types of seizure disorders and muscle spasms.*

Abused by teens to:

- *Feel calm and sleepy with less tension, anxiety or panic, feelings that go away as the body becomes drug-tolerant.*

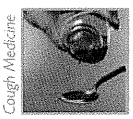
Dangerous because:

- *Can be addictive; when use is reduced or stopped, seizures and other withdrawal symptoms may follow.*
- *Can be deadly in combination with prescription pain medications, some OTC cold and allergy drugs, or alcohol.*

continued

OVER-THE-COUNTER (OTC) DRUGS

OTC drugs are available at any pharmacy without a prescription. Like prescription drugs, they're safe when used according to packaged instructions or when recommended by a doctor familiar with your medical history and other medications you may be taking.


Cough Medicine

Cough Medicines

Teens can get high by taking cough medicine in excess. What makes them high is a cough suppressant ingredient called dextromethorphan, or DXM for short, found in more than 100 OTC products. In syrups, tablets, capsules, lozenges, and gelatin capsules, DXM is found most often combined with other substances, such as antihistamines, expectorants, decongestants, and/or simple pain relievers.

Coricidin cough and cold tablets* ▪ *Contac cold, flu products* ▪ *Theraflu products* ▪ *Robitussin cough products* ▪ *Tylenol cold products *... and many others, including store brands. To know if a product contains DXM, look on the label for "dextromethorphan" in the list of active ingredients.*

Medically useful for:

- *Treating coughs and colds safely and effectively, when used according to directions.*

Abused by teens to:

- *Experience DXM's effects, which range from euphoria to feelings of enhanced awareness to distortions of color and sound to visual hallucinations to "out-of-body" sensations, when users lose contact with their senses.*

Dangerous because:

- *DXM's negative physical effects from overdose include rapid heartbeat, high blood pressure, diarrhea, seizures, panic, drowsiness, confusion, dizziness, blurred vision, impaired physical coordination, and coma.*
- *Some users may become violent.*
- *Side effects may be worse when DXM is used with other medications or with alcohol or illegal drugs.*
- *Overdoses of other ingredients found in DXM-containing medicines have their own serious side effects, including:*
  - *Acetaminophen (pain reliever) = liver damage.*
  - *Chlorpheniramine (antihistamine) = increased heart rate, lack of coordination, seizures, and coma.*
  - *Guaifenesin (expectorant) = vomiting.*
  - *Pseudoephedrine (decongestant) = irregular heartbeat, headaches, difficulty breathing, anxiety, and seizures.*

More Drugs, More Danger

Prescription and OTC drugs have side effects that range from the unpleasant to the dangerous for the teen using them recreationally. But the effects—and the dangers—are intensified when these drugs are combined with each other, with alcohol, or with illegal street drugs. Even when you take a medication at the recommended dose to treat a genuine medical condition, like an antihistamine for an allergy, its combination with a previously taken prescription or OTC drug can have deadly consequences.

Use an Expert

Further educate yourself about teenage recreational use of prescription and OTC drugs by talking directly to an expert about your concerns. If you find drugs or drug paraphernalia in your child's room, but you're not certain what they are, show them to your child's physician or your pharmacist. They are best able to identify suspect substances for you.

And if you need information quickly about the kinds of drugs teens may be abusing, how to talk to your child whom you suspect may be abusing drugs, or what to do if you know your child is definitely using drugs, visit www.drugfree.org.

WARNING SIGNS

Clues that your child may be abusing prescription or OTC drugs to get high:

- Visits to pro-drug Internet sites devoted to "how to" get and abuse prescription and OTC drugs.
- Cough or cold, prescription, or other unidentifiable medications among personal effects with no evidence of illness.
- Unexplained disappearance of medicines from medicine cabinet.
- Declining grades; loss of interest in hobbies and usual activities.
- Changes in friends, physical appearance, hygiene, and general behavior.
- Disrupted eating or sleeping patterns.

COMMUNICATE WITH YOUR KIDS

As a parent, you are in the best position possible to help steer your child away from intentionally abusing prescription and OTC drugs. Some tips:

Set an Example

Don't abuse prescription and OTC drugs yourself. Use drugs as the doctor intended. Don't medicate today's headache or the sore muscles from yesterday's golf game with the prescription pain medication your doctor gave you after last year's surgery. Such a casual attitude may reinforce the false assumption that, because they were made by a pharmaceutical company, these drugs automatically must be safe. If you have a physical complaint, see a doctor. But don't use another person's prescription drugs. Ever.

Use OTC medicines according to packaged instructions and your doctor's recommendations. More cough medicine will not make your cough go away any faster, but it can make you high, may cause liver damage, and worse: It tells your teenager that OTC medicines taken in excess are safe. That's wrong and dangerous.

Connect with Your Kids

Get and stay closely involved with your kids' lives as they go through middle school and into high school. You won't connect well with your kids about serious health issues if you haven't been interested in the day-to-day events of interest to them. Use part of your daily conversation to talk honestly about prescription and OTC drug abuse. Know the facts, clear up wrong information, but don't make it all a lecture: Listen to your children's questions and comments about their drug topics of concern.

Stop the Myth

Getting high with prescription and OTC medications is NOT safer than getting high with illicit street drugs. Prescription painkillers, stimulants, sedatives, tranquilizers, and OTC cough medicines are dangerous when used in excess and repeatedly to get high.

Help Your Child Make Good Decisions

Your child is more likely to be offered drugs by a friend than a stranger, and exposure to drugs can begin as early as age 12. He or she may be better equipped to avoid peer pressure to get high if there is a solid, explicit family policy against drug abuse to fall back on. Give your child the ammunition to make clear to his or her acquaintances that the consequences from abusing these drugs are too severe to risk it. Set clear and consistent rules for behavior, and help your child come up with firm but friendly responses to use with friends who might urge drug abuse. Remind your child that a real friend won't care if he or she does not abuse these medications.

SAFEGUARD YOUR MEDICATIONS

A main source for teenagers of prescription and OTC drugs is the family medicine cabinet. Think about it: Pharmaceuticals are much easier to get—just a walk down the hall or a peek into a friend's medicine cabinet—than illegal street drugs. Prescription and OTC drugs are beneficial and necessary, but if you are not in need of them right now, put them out of your teen's reach, just in case.

MEDICINE INVENTORY

- Do an inventory of the contents of your medicine cabinets, kitchen cabinets, bureau tops, or anywhere in the house where you may store medicines.
- If necessary, monitor the pill quantities and medicine levels in your prescription and OTC drug containers.
- Put drugs away. If you currently need these drugs, put them in a place where you can get to them easily but where your child is unlikely to look.
- If drugs in your house are left over from a previous condition or ailment, get rid of them.
- Urge your friends—especially the parents of your children's friends—to perform medicine inventories of their own.

ACT NOW!

If you suspect you have a kid in trouble, act now! Teenage drug abuse is tied to two basic urges:

1. The desire to experiment in order to feel good while wanting to follow the crowd to fit in.
2. The intention to self-medicate to help deal with the various sources of stress—schoolwork, relationships, or conflicts with friends or family members. Recent research estimates that as many as half of teens who abuse drugs also have mental health issues that need treating.

You DO have the power to influence your child's decision about whether or not to use prescription and OTC drugs for recreation. Research says that fear of upsetting parents is the number one reason why kids do not use drugs.

Intervention

If you're convinced your child has a drug abuse problem, consider an intervention. It doesn't have to be a formal confrontation; a simple but directed discussion will do. Here are some tips to keep the conversation going:

- Have your discussion when your child is not high and when you are calm and rational.
- Express your love and desire for your child's safety and well-being as the basis for your concern.
- Be as neutral and nonjudgmental as you can.
- Tell your child of the behavioral signs you've observed that made you concerned. Avoid direct accusations, but be open about your suspicions.
- Listen, listen, listen! Consider everything your child has to say. If he or she brings up a related problem, explain that you will address that issue next, but that what you need to talk about right now is prescription or OTC drug abuse.
- If you need help getting this conversation started, involve another family member, your child's guidance counselor, or a physician. Or check out the website of the Partnership for a Drug-Free America —www.drugfree.org—for more suggestions on raising the topic of drug abuse with your teen.

NEED HELP? GET HELP!

The Partnership for a Drug-Free America
www.drugfree.org • Comprehensive information, resources and tips from experts and other parents; opportunities to connect and share experiences with other families.

Substance Abuse and Mental Health Services Administration (SAMHSA)
www.samhsa.gov • Part of the U.S. Department of Health and Human Services: Provides information, statistics and articles on improving the quality and availability of drug and alcohol addiction treatment.

SAMHSA's National Clearinghouse for Alcohol and Drug Information (NCADI)
http://ncadi.samhsa.gov or 1-800-729-6686 • Part of the U.S. Department of Health and Human Services and the Substance Abuse and Mental Health Services Administration: A resource for federal government agency publications dealing with alcohol and drug use prevention and addiction treatment.

SAMHSA's Center on Substance Abuse Treatment (CSAT)
www.csat.samhsa.gov or 1-800-662-HELP • Part of the U.S. Department of Health and Human Services: Toll-free treatment referral hotline provides callers with information and listings of treatment and recovery services for alcohol and drug problems.

National Institute on Drug Abuse (NIDA)
www.drugabuse.gov • Part of the U.S. Department of Health and Human Services and one of the National Institutes of Health: Primary source of scientific studies and new discoveries on the effects of drugs of abuse and how best to prevent drug abuse and treat drug addiction.

National Institute of Mental Health (NIMH)
www.nimh.nih.gov • Part of the U.S. Department of Health and Human Services and one of the National Institutes of Health: Primary source of scientific research on mental and behavioral disorders.

GET HELP

The important first step with any health issue is to get a professional evaluation of your child's condition. If you think your child needs professional help, your doctor, hospital, or school nurse may be able to help. Or you can call **1.800.662.HELP** or visit **www.drugfree.org/intervention** and click on "Find Treatment."

The Partnership for a Drug-Free America®
www.drugfree.org

This brochure was sponsored by
Takeda Pharmaceuticals North America, Inc.

Agenda Item 6
Update on the Board's Public Outreach Activities

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

June 22, 2007

To: Communication and Public Education Committee

Subject: Update on the Board's Public Outreach Activities

Public and licensee outreach activities performed since the April report to the board include:

- Analyst Abbe and Inspector Wong staffed an information booth at the 2007 Consumer Protection Day Forum in San Diego on March 24/
- Supervising Inspector Ming provided information about pharmacy law to pharmacists at Anaheim Memorial Hospital on April 6.
- Board Member Goldenberg provided information about pharmacy law and the board's citation and fine program to the Diablo Valley Pharmacists Association Meeting on April 26.
- Supervising Inspector Coyne spoke about being a pharmacist to her grandson's junior high at a career day presentation on April 25.
- Board Member Schell presented FAQs about licensing issues to the San Diego Pharmacists Association on April 26.
- Debbie Anderson provided information about pharmacist licensure application and examination to Loma Linda graduating students on May 7.
- The board staffed a public information booth at the Family Safety and Health Expo at Safetyville, in Sacramento on May 12.
- Board Members Goldenberg and Conroy provided information about pharmacy law to the UOP graduating class on May 17.
- Supervising Inspector Ratcliff spoke to Sutter Hospitals' pharmacists about pharmacy law on May 18.
- Analyst Abbe staffed an information booth at the Sacramento Chapter of the American Diabetes Association Health Fair on May 19
- Executive Officer Herold hosted a poster display about California's pedigree requirements at the NABP Annual Meeting on May 20.
- Supervising Inspector Nurse provided information about California's electronic pedigree requirements for prescription medicine at the NABP Annual Meeting on May 22.

Future:

- Board Member Goldenberg will provide information about the board's citation and fine program to the Pharmacists Professional Society of San Fernando Valley on June 24.

- Board Member Ravnan will provide information about medication errors as part of panel discussion with Lyle Bootman and Michael Cohen hosted by *Drug Topics* in concert with the American Society of Health Systems Pharmacists annual meeting in San Francisco on June 26,
- Supervising Inspector Ming will provide information about pharmacy law to the Indian Pharmacist Association on September 15.
- 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.