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

NOTICE OF MEETING and AGENDA
Communication and Public Education Committee

Contact Person: Virginia Herold
(916) 574-7911

Time: 1:30 – 3:30 p.m.
Date: January 8, 2007
Place: Department of Consumer Affairs
First Floor Hearing Room
1625 N. Market Boulevard
Sacramento, CA 95834

This committee meeting is open to the public and will be held in a barrier-free facility in accordance with the Americans with Disabilities Act. Any person with a disability who requires a disability-related modification or accommodation in order to participate in the public meeting may make a request for such modification or accommodation by contacting Karen Abbe at (916) 574-7946, at least five working days before the meeting.

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

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

Call to Order 1:30 p.m.

1. Consumer Fact Sheet Series with UCSF's Center for Consumer Self Care
2. Update on the Activities of the California Health Communication Partnership
3. Update Report of *The Script*
4. Development of New Consumer Brochures
5. Development for a New Notice to Consumers as Required by AB 2583 (Nation, Chapter 487, Statutes of 2006)
6. Miscellaneous Consumer Issues/Articles in the Media
7. Update on the Board's Public Outreach Activities
8. Board's Staff Newsletter, Second Edition

Adjournment 3:30

Meeting materials will be on the board's Web site by January 3, 2007

Agenda Item 1

State of California **Department of Consumer Affairs**

Memorandum

To: **Communication and Public Education Committee** **Date: January 2, 2007**

From: **Board of Pharmacy – Virginia Herold**

Subject: **Development of Fact Sheet Series for Consumers**

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

The UCSF's 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.

So far, nine fact sheets have been developed. These fact sheets have been translated by the board into Spanish, Vietnamese and Chinese, and are available on the board's Web site.

Bill Soller, PhD, of the UCSF Center for Consumer Self Care is overseeing this project. At the last committee meeting, Dr. Soller provided four new fact sheets. The committee recommended changes which were provided to Dr. Soller. The board's new consumer outreach analyst has reviewed the modified fact sheets, and several additional changes will need to be made.

In this tab section are the four draft fact sheets.

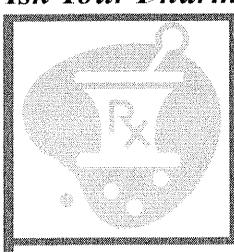
At this meeting, I would also like to encourage a discussion on where the committee and the Center for Consumer Self Care wishes to go with these fact sheets. Over the last few years, a number of fact sheets have been proposed, and nine have been developed. At one point, we had hoped to develop a joint Web site with the UCSF Center for Consumer Self Care to house the fact sheets we intended to develop.

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.

Here are the nine fact sheets that have been developed (and that were recently translated):

The fact sheets that have been developed are:

- 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



An aspirin a day ?

... maybe...check it out!

FACT: Four out of five U.S. families will be touched by stroke.

FACT: Every 45 seconds, someone has a stroke. Every 3 minutes, someone dies of one.

FACT: Aspirin is approved for prevention of stroke and heart attacks.

Should I Be Taking Aspirin Everyday?

- Only your healthcare provider can decide if daily aspirin is right for you. Your health provider can:
  - Assess your risk factors.
    - Aspirin may cause bleeding from the stomach or brain. Your health provider can assess your possible risk for these side effects.
  - Discuss the benefits of daily aspirin.
  - Recommend the right treatment plan.

Take an Active Role

- To see if daily aspirin is right for you, schedule a visit with your healthcare provider.
- Ask your pharmacist about aspirin. Did you know?
  - Taking some medicines (e.g., coumadin, warfarin) with aspirin can cause serious bleeding problems.
  - Ibuprofen (Advil) may block aspirin's action on the blood. Aspirin prevents strokes by stopping blood platelets from sticking together.
  - Aspirin does not mix with some herbals.
  - There is more than one type of aspirin product. Talk with your pharmacist about which one is right for you.

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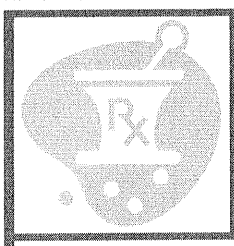

Uncommon Sense for the Common Cold

FACT: Colds account for more visits to the doctor than any other condition..

FACT: Adults average 2 to 4 colds a year. Kids average 6 to 8 colds a year.

FACT: Colds are highly contagious. They spread when droplets of fluid containing cold viruses are transferred by touch.

FACT: The most common cold symptoms are runny nose, congestion, sneezing, scratchy throat, cough.

Care for your self...

...by caring for others. Share these tips with your family.

1. Avoid close contact with those who have a cold. This is important in the first days of a cold, when they are most likely to be spread.
2. Wash your hands: after touching someone with a cold; after touching something they have touched; after blowing your own nose. Wash your child's toys after play.
3. Keep your fingers away from your nose and eyes. This helps you to avoid infecting yourself with cold viruses you may have picked up.
4. Put a second towel and a second tube of toothpaste in the bathroom, for use by those without a cold to use.
5. Cover your nose and mouth with a tissue when you cough or sneeze. Throw the tissue away and wash your hands.
6. Avoid contact with those who may be at greater risk if they get a cold. This includes people with asthma or other chronic lung disease.
7. Ask your pharmacist for tips about which medicines to use for your symptoms.
8. Talk to your health provider if:
   - Your cold symptoms are unusually severe;
   - You get high fever, ear pain, or sinus headache;
   - Your cough gets worse while your other symptoms improve; or
   - If you have a flare-up of any chronic lung problem, such as asthma.

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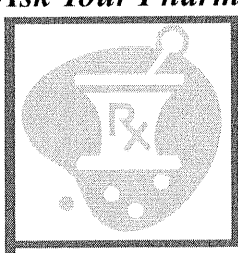

Put the Chill on Myths about Colds and Flu

MYTH: **Antibiotics can help treat the flu...a myth.**

FACT: Antibiotics kill bacteria, not viruses. Viruses cause cold and flu. Antibiotics will not help you get over flu or colds sooner. Overuse can make antibiotics less effective, because bacteria can become resistant to them.

MYTH: **Large doses of vitamin C keep you from catching a cold or the flu; vitamin C cures flu and colds...all myths.**

FACT: Vitamin C has not been shown scientifically to cure or prevent flu or colds.

MYTH: **Feed a fever, starve a cold...both myths.**

FACT: Your body needs more fluids if you have the flu or a cold. Drink plenty of fluids (water, juice). Eat enough to satisfy you. Drink hot fluids to help ease cough and sore throat.

MYTH: **Herbal remedies are effective treatments for colds...a myth.**

FACT: The scientific support for use of herbals to treat or prevent flu and colds is not convincing..

MYTH: **Chicken soup and spiked drinks are effective treatments for flu or colds...a myth.**

FACT: Chicken soup may be delicious, but it's not been shown scientifically that chicken soup can cure the common cold or flu. Spiked drinks (hot toddies, whiskey and lemon, etc.) contain alcohol, which should be avoided when you are sick.

Help in Deciding How to Treat Flu and Colds

FACT: Your pharmacist knows which medicines are best to help relieve each of the symptoms of colds and flu. Ask your pharmacist.

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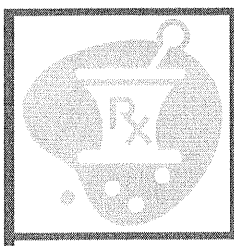

Medication Errors

Mistakes happen...Protect your self!

FACT: Almost 100,00 people die each year because of medication errors.

FACT: It is one of the nation's top health priorities to make our health care system safer.

FACT: Studies show that most medication errors involve the wrong drug or the wrong dose. People who take an active role tend to get better results.

To lower your risk...

1. **Take part in every decision about your health care.**
   - You have the right to question anyone who has a part in your care.
   - Learn more about your condition. Use the Web or a public library.

2. **Do not assume all who have a part in your heath care know everything about you.**
   - Tell your doctor and pharmacist about everything you are taking.
   - Make sure your doctor and pharmacist know about any allergies you may have.

3. **Ask for information about your medication that you can understand.**
   - Make sure you can read the prescription that your health provider writes for you.
   - Talk to your pharmacist, so you know about how to take your medicines.
     - When you get your prescription, ask if it is the one your doctor prescribed.
     - Medicine labels can be hard to understand. Ask your pharmacist for help.

4. **When in the hospital:**
   - Choose a hospital where many patients have had the procedure.
   - Ask about the medicines and treatments you're given.
     - Ask your health team to double-check.
   - When you are discharged...
     - Ask your health provider to explain all the details of the treatment plan you should use at home.
     - Leave the hospital knowing what medicines you are to take, how to take them, and when you're able to return to normal activities.

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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

State of California | Department of Consumer Affairs

Memorandum

To: **Communication and Public Education Committee** **Date: January 2, 2007**

From: **Board of Pharmacy – Virginia Herold**

Subject: **California Health Communication Partnership Meeting Update**

The board is a founding member of California Health Communication Partnership. This group is spearheaded by the UCSF's Center for Consumer Self Care to improve the health of Californians by developing and promoting consumer health education programs and activities developed by the members in an integrated fashion.

The function of the group is to develop and/or disseminate integrated public information campaigns on priority health topics identified by the partnership members. Other active members of the group are the Medical Board of California, the Food and Drug Administration, CPhA and California Retailers Association. For example, pharmacists, nurses, physicians will receive information from their respective regulatory boards or associations that will mesh with concurrent public outreach efforts.

There have been three major campaigns since the formation of the group about three years ago.

The last campaign ended this fall, and was the second year of the cancer screening campaign, which aimed at educating the public about the need for and importance of breast cancer or prostrate cancer screening. The campaign was titled: "It's Your Life, Do it Today." Outside funding from a private foundation enabled the use of a vendor that specializes in distributing prewritten consumer columns for small and typically weekly newspapers. There were also public service announcements intended for airing on radio. This greatly expands the exposure and reach of the campaign.

The first year of the cancer screening campaign was highly successful in terms of print media publication, due principally through the use of this vendor.

However, there has not been a meeting of the partnership in the last three months. At the last meeting, the partnership intended development of future outreach efforts for generic medicine and diabetes and aspirin. Also, under consideration by the board is the importance of public education campaigns about pharmacist-to-patient consultation since many consumers are not aware of this requirement and the importance of seeking and following a pharmacist's knowledge of drug therapy and how this can benefit their health. The committee also suggested that some form of outreach to educate other health care providers about a pharmacist's requirement to consult would benefit both providers and patients.

Also discussed at the last meeting was that written information provided to patients with their prescription medication is only read by 44 percent of patients surveyed.

These issues may also be topics for the future.

A copy of CPhA's video "Priceless" will be shown during this meeting as an example of what public education could be done about the value of pharmacist's care.

Agenda Item 3

State of California | Department of Consumer Affairs

Memorandum

To: Communication and Public Education Committee

Date: December 29, 2006

From: Virginia Herold

Subject: Update on *The Script*

The January 2007 issue of *The Script* has been written and was sent to the State Printing Plant for printing on December 28. The issue will be mailed in January to pharmacies and wholesalers. The focus is on new pharmacy law and regulations.

Again, Board Analyst Victor Perez, instead of the graphics unit of the State Printing Plant, graphically designed this issue.

Agenda Item 4

State of California | Department of Consumer Affairs

Memorandum

To: **Communication and Public Education Committee**

Date: January 2, 2007

From: **Board of Pharmacy – Virginia Herold**

Subject: **Development of New Consumer Brochures and Materials**

On December 1, Karen Abbe, the board's new public and licensee education analyst, started with the board. Since then Ms. Abbe has been busy learning the nuances of the board, and has begun looking at our consumer education materials.

The restoration of Ms. Abbe's position restores one of two similar positions that were lost due to hiring freezes in 2001. Ms. Abbe's main focus for the time being will be to develop consumer and licensee educational materials. Hope Tamraz will continue to work on the board's newsletter for licensees (*The Script*) as a retired annuitant.

1. Consumer Materials

Ms. Abbe will soon initiate work on the following projects.

Board of Pharmacy Informational Brochure

The board lacks an adequate descriptive brochure about its mandate, jurisdiction, licensees and complaint handling processes. Ms. Abbe is working o this brochure, which may become two brochures, as one of her first projects.

Prescription Drug Discount Program for Medicare Recipients

The board has started revision of the "Prescription Drug Discount Program for Medicare Recipients" 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 brochure needs to be meshed with the Medicare Part D Plan benefits that became available to beneficiaries in 2006.

Informational Fact Sheets for Applicants
While the following information is available to applicants who read the pharmacist examination application materials, some applicants do not read this information or retain it.

- Information about applying for the CPJE or a California intern pharmacist

license specifically for pharmacists licensed in other states
- Information about how foreign graduate can qualify for a pharmacist license in California

Under review for possible development are:
- The Beers list of medications that should not be provided to elderly patients
- Update of Facts About Older Adults and Medicines (revision)

2. Information on Preventing Prescription Errors

One of the hottest topics in the popular media recently has been medical errors, including medication errors.

The board has been actively involved in a number of activities aimed at reducing errors, including our quality assurance program requirements that mandate that pharmacies evaluate every prescription error.

Ms. Abbe is working with me for a segment of the board's Web site to address medication errors. It will include data such as that presented at the July 2006 Board Meeting on prescription error data identified by the board through investigations of consumer complaints. It will also include information from other sources – ways to prevent errors, frequently confused drug names, etc. It will have links to other Web sites as well.

We hope to have this section of the Web site developed by the July Board Meeting.

Agenda Item 5

State of California | Department of Consumer Affairs

Memorandum

To: **Communication and Public Education Committee**

Date: December 29, 2006

From: **Board of Pharmacy – Virginia Herold**

Subject: **Development of a New Notice to Consumers**

Assembly Bill 2583 (Nation) was enacted as Chapter 497, Statutes of 2006. The bill requires the board to add to the Notice to Consumers a statement that describes a patient's right to obtain medication from a pharmacy:

1. even if a pharmacist has ethical, moral or religious grounds against dispensing a particular drug, in which case protocols for getting the patient the medication is required.
2. unless based upon the pharmacist's professional training and judgment that dispensing a drug is contrary to law or the drug would cause a harmful drug interaction or otherwise adversely affect the patient's medical condition.
3. unless the medication is out of stock or not available from the pharmacy.
4. unless the patient cannot pay for the medication or pay any required copayment.

The information that must be displayed on the Notice to Consumers must be promulgated in a regulation.

As an alternative to displaying the Notice to Consumers poster in a pharmacy, the pharmacy may print the same information on a written receipt (Business and Professions Code section 4122).

At the October Board Meeting, the board voted to create a second Notice to Consumers poster to contain this supplemental information.

Staff has been working on language for the additional notice. There are two versions developed – version A and version B. **At this meeting, the committee needs to select and refine a version to advance to the board for discussion and future release as a proposed regulation.**

Meanwhile, our graphics designer has produced several new formats for the poster, which I will share with the committee at the committee meeting for informational purposes. I believe that we should reprint both posters in a new format once the regulation language has been formally adopted as a regulation and approved as by the Office of Administrative Law

Here is a proposed timeline to develop the new Notice to Consumers – it will take about one year:

January 8:	Communication and Public Education Committee makes suggested changes to the required Notice to Consumers
January 31:	(January Board Meeting): Board reviews, modifies and sets for regulation notice the proposed language
Feb. 15:	Staff releases the proposed amendments to section 1707.2 for the required 45 days of public comment
April 18:	(April Board Meeting): Board adopts final language as a regulation
June 1:	Board submits rulemaking file to the Department of Consumer Affairs for review
August 1:	Board submits rulemaking to the Office of Administrative Law for review
October 1:	OAL approves rulemaking file Board initiates printing of new Notice to Consumer posters (English) Board has regulation language translated into additional languages
Nov. 1:	Regulation takes effect
Dec. 1:	Board distributes printed Notice to Consumer posters (English) to California pharmacies Board obtains translated versions and makes these available on Web site for downloading.

In this section I am also including the chaptered version of AB 2583, and an 8.5" X 11" Notice to Consumers (which is smaller than the actual poster size that must be displayed in pharmacies).

Version A

Notice to Consumers

Talk to your pharmacist, and know your rights

Information from your pharmacist is important to your health. Your pharmacist is highly educated in drug therapy management. A pharmacist is required to talk to you about any prescription medicine the first time it is prescribed. The pharmacist will also answer your questions about your medicine at any time.

Before taking any prescription medicine, talk to your pharmacist; be sure you know:

1. What is the name of the medicine and what does it do?
2. How and when do I take it – and for how long? What if I miss a dose?
3. What are the possible side effects and what should I do if they occur?
4. Will the new medicine work safely with other medicines, vitamins, and herbal supplements I am taking?
5. What foods, drinks, or activities should I avoid while taking this medicine?

Remember to ask your pharmacist if you have any questions.

Under California law:

1. You generally have a right to receive any medicine or medical equipment legally prescribed or ordered for you.
2. A pharmacist may not provide prescribed medicine to you if:
   - Providing the drug or device would cause a medical problem or adversely affect your health; or
   - The medicine or medical equipment is not in stock; or
   - He or she refuses on ethical, moral or religious grounds to dispense the drug or device to you; or
   - Appropriate payment is not provided.
3. If a medicine or device is not in stock or a pharmacist refuses to provide them, this pharmacy must take steps to ensure that you get the drug or device in a timely manner.

If you are denied medicine or medical equipment by the pharmacy, ask the pharmacist why.

Also, at your request, this pharmacy will provide its current retail price of any prescription medicine without obligation. You may request price information in person or by telephone. If you are requesting price information on more than five drugs, you may be required to submit your request in writing, and a response will be made in writing after a reasonable period of time, for a reasonable fee. There is no requirement that this pharmacy respond to more than three such multiple-drug price requests from anyone within a six-month period.

Ask your pharmacist if a lower cost generic drug is available to fill your prescription. Prescription prices for the same drug vary from pharmacy to pharmacy. One reason for differences in price is differences in services provided.

Logo and address information

Version B

Notice to Consumers

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

You have the right to receive medicines and devices legally prescribed or ordered for you after proper payment unless providing them to you:

- is against the law

  OR

- will cause a harmful interaction with drugs prescribed to you

  OR

- will affect your health in a negative way

This pharmacy may refuse to fill a prescription for ethical, moral or religions reasons, but we are required to help you get the prescription filled by another pharmacy. We will also help you if we do not have the drug or device in stock.

Any questions? Ask the pharmacist!

(logo) (address and info) (state seal)

Notice to Consumers

Before taking any prescription medicine, talk to your pharmacist; be sure you know:

1. What is the name of the medicine and what does it do?
2. How and when do I take it – and for how long? What if I miss a dose?
3. What are the possible side effects and what should I do if they occur?
4. Will the new medicine work safely with other medicines and herbal supplements I am taking?
5. What foods, drinks or activities should I avoid while taking this medicine?

Ask your pharmacist if you have additional questions.

At your request, this pharmacy will provide its current retail price of any prescription without obligation. You may request price information in person or by telephone. Ask your pharmacist if a lower cost generic drug is available to fill your prescription. Prescription prices for the same drug vary from pharmacy to pharmacy. One reason for differences in price is differences in services provided.

BE AWARE & TAKE CARE

Talk to your Pharmacist!

California State Board of Pharmacy

(916) 574-7900 • www.pharmacy.ca.gov

1625 N. Market Blvd, Suite N219, Sacramento, CA 95834

OSP 02 72011

Assembly Bill No. 2583

CHAPTER 487

An act to amend Sections 733 and 4122 of the Business and Professions Code, relating to healing arts.

[Approved by Governor September 26, 2006. Filed with Secretary of State September 26, 2006.]

LEGISLATIVE COUNSEL'S DIGEST

AB 2583, Nation. Dispensing prescription drugs and devices: refusal to dispense.

Existing law prohibits a health care licentiate from obstructing a patient in obtaining a prescription drug or device, and requires the licentiate to dispense drugs and devices pursuant to a lawful prescription or order, except in specified circumstances, including on ethical, moral, or religious grounds asserted by the licentiate if certain requirements are met. Existing law authorizes the California State Board of Pharmacy to issue a citation for a violation of these provisions and authorizes its executive officer to issue a letter of admonishment for their violation. Existing law, the Pharmacy Law, requires every pharmacy to prominently post a notice to consumers provided by the board concerning the availability of prescription price information, the possibility of generic drug product selection, and the types of services provided by pharmacies. A violation of the Pharmacy Law is a crime.

This bill would require the consumer notice posted in pharmacies to also contain a statement describing patients' rights relative to access to prescription drugs or devices. By changing the definition of a crime, this bill would impose a state-mandated local program.

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

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

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

SECTION 1. Section 733 of the Business and Professions Code is amended to read:

733. (a) No licentiate shall obstruct a patient in obtaining a prescription drug or device that has been legally prescribed or ordered for that patient. A violation of this section constitutes unprofessional conduct

by the licentiate and shall subject the licentiate to disciplinary or administrative action by his or her licensing agency.

(b) Notwithstanding any other provision of law, a licentiate shall dispense drugs and devices, as described in subdivision (a) of Section 4024, pursuant to a lawful order or prescription unless one of the following circumstances exists:

(1) Based solely on the licentiate's professional training and judgment, dispensing pursuant to the order or the prescription is contrary to law, or the licentiate determines that the prescribed drug or device would cause a harmful drug interaction or would otherwise adversely affect the patient's medical condition.

(2) The prescription drug or device is not in stock. If an order, other than an order described in Section 4019, or prescription cannot be dispensed because the drug or device is not in stock, the licentiate shall take one of the following actions:

(A) Immediately notify the patient and arrange for the drug or device to be delivered to the site or directly to the patient in a timely manner.

(B) Promptly transfer the prescription to another pharmacy known to stock the prescription drug or device that is near enough to the site from which the prescription or order is transferred, to ensure the patient has timely access to the drug or device.

(C) Return the prescription to the patient and refer the patient. The licentiate shall make a reasonable effort to refer the patient to a pharmacy that stocks the prescription drug or device that is near enough to the referring site to ensure that the patient has timely access to the drug or device.

(3) The licentiate refuses on ethical, moral, or religious grounds to dispense a drug or device pursuant to an order or prescription. A licentiate may decline to dispense a prescription drug or device on this basis only if the licentiate has previously notified his or her employer, in writing, of the drug or class of drugs to which he or she objects, and the licentiate's employer can, without creating undue hardship, provide a reasonable accommodation of the licentiate's objection. The licentiate's employer shall establish protocols that ensure that the patient has timely access to the prescribed drug or device despite the licentiate's refusal to dispense the prescription or order. For purposes of this section, "reasonable accommodation" and "undue hardship" shall have the same meaning as applied to those terms pursuant to subdivision (*l*) of Section 12940 of the Government Code.

(c) For the purposes of this section, "prescription drug or device" has the same meaning as the definition in Section 4022.

(d) The provisions of this section shall apply to the drug therapy described in paragraph (8) of subdivision (a) of Section 4052.

(e) This section imposes no duty on a licentiate to dispense a drug or device pursuant to a prescription or order without payment for the drug or device, including payment directly by the patient or through a third-party

payer accepted by the licentiate or payment of any required copayment by the patient.

(f) The notice to consumers required by Section 4122 shall include a statement that describes patients' rights relative to the requirements of this section.

SEC. 2. Section 4122 of the Business and Professions Code is amended to read:

4122. (a) In every pharmacy there shall be prominently posted in a place conspicuous to and readable by prescription drug consumers a notice provided by the board concerning the availability of prescription price information, the possibility of generic drug product selection, the type of services provided by pharmacies, and a statement describing patients' rights relative to the requirements imposed on pharmacists pursuant to Section 733. The format and wording of the notice shall be adopted by the board by regulation. A written receipt that contains the required information on the notice may be provided to consumers as an alternative to posting the notice in the pharmacy.

(b) A pharmacist, or a pharmacist's employee, shall give the current retail price for any drug sold at the pharmacy upon request from a consumer, however that request is communicated to the pharmacist or employee.

(c) If a requester requests price information on more than five prescription drugs and does not have valid prescriptions for all of the drugs for which price information is requested, a pharmacist may require the requester to meet any or all of the following requirements:

(1) The request shall be in writing.

(2) The pharmacist shall respond to the written request within a reasonable period of time. A reasonable period of time is deemed to be 10 days, or the time period stated in the written request, whichever is later.

(3) A pharmacy may charge a reasonable fee for each price quotation, as long as the requester is informed that there will be a fee charged.

(4) No pharmacy shall be required to respond to more than three requests as described in this subdivision from any one person or entity in a six-month period.

(d) This section shall not apply to a pharmacy that is located in a licensed hospital and that is accessible only to hospital medical staff and personnel.

(e) Notwithstanding any other provision of this section, no pharmacy shall be required to do any of the following:

(1) Provide the price of any controlled substance in response to a telephone request.

(2) Respond to a request from a competitor.

(3) Respond to a request from an out-of-state requester.

SEC. 3. No reimbursement is required by this act pursuant to Section 6 of Article XIII B of the California Constitution because the only costs that may be incurred by a local agency or school district will be incurred because this act creates a new crime or infraction, eliminates a crime or

infraction, or changes the penalty for a crime or infraction, within the meaning of Section 17556 of the Government Code, or changes the definition of a crime within the meaning of Section 6 of Article XIII B of the California Constitution.

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Agenda Item 6

State of California

Department of Consumer Affairs

Memorandum

To: Communication and Public Education Committee

Date: December 27, 2006

From: Virginia Herold

Subject: Miscellaneous Consumer Issues and Articles in the News

I am adding to this packet several articles of consumer interest that are not under review by one of the board's other strategic committees. During this meeting, the committee can review and discuss these items in the event it wishes to propose future action at the next committee meeting.

Also, please feel free to submit items to me that you wish to have included in future Communication and Public Education Committee packets.

Public Ed

kaisernetwork.org

Access to Care Issues, Physician Training, Other Problems Contributing to I
Health Issues for Elderly, Experts Say

Daily Health Policy Report

Email this story to a friend.
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Prescription Drugs | Seniors More Likely To Experience Medical Error From Prescription Drug Than Younger Patients, Study Finds
[Sep 14, 2006]

Patients older than age 65 experience a drug error rate nearly seven times greater than those younger than 65, according to an analysis released Wednesday by prescription benefit manager Medco Health Solutions, the *AP/Detroit News* reports. For the study, researchers analyzed Medco's drug insurance claims from 2.4 million adults in 2004. Drug errors were noted in cases when a patient was prescribed a drug that was incompatible with medicines already being taken; when a drug could exacerbate another medical condition; or when an incorrect dosage was prescribed, according to Glen Stettin, Medco senior vice president. Researchers found that seniors were at the greatest risk of prescribing errors, and the error rate for seniors increased for those patients who were treated by more doctors and prescribed more drugs. Seniors treated by two doctors received an average of 27 prescriptions per year and were at risk of 10 errors on average. Those treated by five doctors received an average of 42 prescriptions per year and were at risk of 16 errors. According to Medco's analysis, nearly one-quarter of seniors receive prescriptions from five or more doctors. Stettin said, "With more physicians providing care to patients, more prescriptions are being written," and "the more medications you take, the more potential there is for them interacting with each other." He added that there is "clearly a communication breakdown between prescribers." Although pharmacies regularly cross-check for potentially dangerous interactions when filling a prescription, experts say that step alone is insufficient to prevent harmful drug interaction. John Burton, director of the Johns Hopkins Geriatric Education Center in Baltimore, said primary care physicians' "priority each visit has to be a review of the medicines. That's what I think quality primary care demands" (Gold,

Public Ed

Los Angeles Times
latimes.com.

http://www.latimes.com/news/printedition/la-fi-medid25sep25,1,4308359.story

ID Theft Infects Medical Records

Victims face bogus bills and risk injury or death. Privacy laws make such fraud hard to pursue.

By Joseph Menn
Times Staff Writer

September 25, 2006

After shoulder surgery last year, Lind Weaver was stunned when hospital bill collectors demanded that she pay for the amputation of her right foot.

"Either you didn't do the surgery, or you did a really [shoddy] job of it," Weaver told them, sending along notarized photos of her toes, all still attached. "Either way, I'm not paying."

But the 56-year-old retired schoolteacher quickly discovered she was dealing with something more nefarious than a simple clerical error: An identity thief had obtained medical care under Weaver's name and had the bill sent to her insurer.

A year later, Weaver is still trying to catch errors in her medical records and clear the hospital bills fraudulently run up in her name.

"It became a 40-hour-a-week job," Weaver said. "I put my phone to my ear and sat there listening to elevator music."

Although the most typical of the millions of identity theft cases in the U.S. each year involve credit cards, a 2003 federal report estimated that at least 200,000 instances involved medical identity fraud. Experts believe that the rising cost of healthcare is driving more identity theft, and that many people are unaware they have become victims unless they receive a hospital bill or query from their insurer.

"There's no reason to assume the patients ever find out," said Harvard University management professor Malcolm Sparrow, an expert on regulatory agencies who has written books on healthcare fraud. "The bulk presumably remain invisible."

With their medical records compromised, victims of this kind of fraud face a greater risk of injury or even death if doctors make treatment decisions based on bad information. Files might list incorrect prescriptions or the wrong blood type. Or, as in Weaver's case, an erroneous diagnosis of diabetes.

Bad information can also put careers and insurance at risk. Many employers, including more than a third of the Fortune 500 companies, demand access to medical records when making hiring, promotion or benefits decisions, according to the nonprofit Patient Privacy Rights Foundation. Health and life insurance companies routinely scan medical files or payout reports before issuing new policies.

Victims, though, often find that clearing their medical records of bad information is much more difficult than fixing credit reports, which are centralized in three major credit bureaus.

Consumers have the right to obtain one free credit report annually, and to demand an investigation of information they believe is fraudulent or incorrect. Unverified reports must be removed promptly.

Medical records, in contrast, can be scattered across dozens of doctors' offices, hospitals and clinics. And federal privacy rules intended to protect private information can make it difficult for patients to even obtain their own records when identity theft is suspected.

"These privacy rules might put you in a situation where you can't even investigate," said Wilma Kidd, chief privacy officer at WellPoint Inc., the largest U.S. health insurer for employees and other groups.

A big reason most people never find out about erroneous records is the Health Insurance Portability and Accountability Act of 1996. The law can make it difficult for patients to see their own medical records, since the penalties for improper disclosure prompt some hospitals to set up roadblocks including demands for multiple forms of identification.

The bitter twist on medical identity theft is that once a person tells a keeper of records that someone else's data might be intermingled, the file becomes even harder to obtain. Why? Because it includes another person's medical history, which many hospitals argue can't be turned over without consent.

Even when patients do see their records, they have no automatic right to fix errors they find.

As she battled collection agencies last year, Weaver fought to see her medical files. She suspected that someone had used her identity to obtain a foot amputation, but hospital officials wouldn't help.

Weaver marched into the hospital waiting room in Bunnell, Fla., and started shouting that the doctors didn't know who their patients were. That got her service in a hurry. After she was shown to a consulting room and given the file, she soon thought she had weeded out her impostor's medical history.

In May, Weaver suffered a heart attack at her home in Palm Coast, Fla., and was in and out of consciousness.

When she awoke in her hospital room two days later, a nurse asked Weaver what drugs she had been taking to treat her diabetes. Weaver has never had diabetes, a disease that can lead to foot problems severe enough to require amputation.

"They could have given me insulin," Weaver said. "There's a whole different heart procedure that covers people with diabetes."

Diabetes experts said those procedures would have been unlikely to threaten Weaver's life. A hospital spokeswoman declined to answer questions about Weaver's case.

Weaver doesn't know how her identity was compromised, but identity fraud is easy when so many in the medical field have access to intimate records and patients are admitted without having to prove who they are.

At New York homeless shelters, state Medicaid identification cards once could be rented for as little as $2 a day, said Harvard's Sparrow, who has seen overlapping pregnancies claimed under the same name. In Veterans Affairs hospitals, some eligible veterans have their identities assumed by brothers or cousins who have easy access to their documents, said Richard Ehrlichman, the department's assistant inspector general.

Sometimes it's the doctors who commit identity fraud to collect insurance payments for work they didn't perform.

A Boston-area psychiatrist, Richard Skodnek, was convicted a decade ago of fraud after falsifying diagnoses, treatment sessions and entire patient histories. His victims, some of whom discovered that their insurance benefits had been exhausted, had to struggle to clear their records.

In perhaps the most sensational case, a Chicago podiatrist under grand jury investigation for exaggerating the work he performed shot and killed one of his patients in 2002 when she refused to lie on his behalf. Ronald Mikos was convicted of the murder last year.

Many insurance companies have hotlines for reporting fraud against them, and they sometimes refuse to pay suspicious hospital bills. But that often doesn't do the identity theft victims any good: They still have to make their own cases to the hospitals, the bill collectors and the credit agencies.

In Weaver's case, getting the insurance company involved made things worse.

After Weaver realized she was being billed for an amputation she never had, she told her insurance company, which refused to pay as well. In the hospital's eyes, that left Weaver responsible for the whole $66,000 surgery bill, instead of just her deductible.

Collection agencies didn't care about her explanation. Each tacked on a fee and resold the collection contract to the next agency down the line. That made correcting Weaver's credit report especially difficult, because after she established that she wasn't responsible for one amount billed on a certain day, the credit bureau would receive notice of a new amount with a different date, even though it was based on the same bogus debt.

Even when identity theft victims avoid health complications, the legal side effects can be terrible.

Anndorie Sachs of Salt Lake City found that out in April during a phone call from Utah's social services department. The social worker told Sachs that her hospitalized infant had tested positive for methamphetamine. The state planned to take away the baby, along with her siblings at home.

Sachs, a mother of four, said that she hadn't delivered a baby in two years.

"I was freaking out," said Sachs, 27. "She was not going to believe a word. She said: 'You're Anndorie Sachs. You're on the birth certificate. We know your other kids are being exposed to this too.' "

After the social worker grilled Sachs' 7-year-old about whether her mother had been to the hospital lately, the agency relented.

Months earlier, Sachs' driver's license was stolen from her husband's car. It eventually emerged that a woman named Dorothy Bell Moran had used that license when she checked into the hospital to give birth. Already wanted on other charges related to identity theft, authorities said, Moran hadn't

wanted to use her own name for fear of getting caught. (She was later arrested on the earlier charges.)

Sachs had to hire a lawyer to disentangle the legal and medical records, and she is still fighting a collection agency over the medical bill.

As with Weaver and other victims interviewed, the Utah hospital cited the health insurance law and refused to show Sachs her files after she told them someone else's paperwork was included. After Sachs went to the local media, officials agreed to delete both women's records.

Just to be safe, when Sachs contracted a kidney infection, she chose a hospital that neither she nor the impostor had used. But some records had been shared electronically, and the hospital had the impostor's blood type down as Sachs' — setting up a possible fatal error. Fortunately, staffers had drawn blood and double-checked. When they reviewed other data with Sachs, she found they also had the wrong emergency contact name and number.

The increased use of electronic records such as the ones that dogged Sachs could worsen the spread of medical errors caused by identity theft.

In the last year, the Senate and the House have passed broad bills pushing for wider use of electronic health records. Supporters, including many big technology firms and insurers, said the plan would increase efficiency, reduce error rates and provide earlier warnings about public health problems.

Such a system could also make correcting medical errors easier — but only if patients catch them beforehand, and only if the service providers agree to change them.

As the web of electronic distribution expands beyond the current pilot projects, more people will see medical records. That could increase identity theft while making existing errors harder to resolve, said Joanne McNabb, chief of the California Office of Privacy Protection.

"There is added risk that we've seen all over the place with electronic data," McNabb said. "It can go to the wrong place at the wrong time very easily."

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(INFOBOX BELOW)

Keeping tabs on health records

Under the federal law known as the Health Insurance Portability and Accountability Act of 1996, medical providers have wide latitude to disclose records to others in the field, as long as they tell the patient they are doing so. They are also supposed to show the patient most of those files, with limited exceptions such as the notes of mental health professionals. But hospitals worried about fraud often demand multiple forms of identification and set up other bureaucratic hurdles to patient viewing. They can refuse patient access altogether if someone else's records are intertwined with the patient's.

To guard against identity theft, patients should:

- *Ask to see their medical files from each provider on a regular basis;*
- *Scan medical and insurance bills for services, medicine and equipment they didn't receive;*
- *Demand an annual list from their health insurance company of benefits that have been provided.*

If medical records have been compromised:

- *Ask the healthcare providers to delete the incorrect information and contact everyone they have shared that information with, as required by the health insurance act;*
- *Ask the providers for a list of those recipients, and follow up with them;*
- *Clean up records with the health insurer and make sure the provider has not passed along improper benefit reports to insurance databases;*
- *Scrutinize credit reports for unpaid medical bills;*
- *File a police report;*
- *Contact the Federal Trade Commission and state health and insurance departments.*

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Sources: World Privacy Forum, Times research

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PARTNERS: ktla Hoy

Kaiser Daily Health Policy Report

Monday, September 18, 2006

Prescription Drugs

AARP Launches $500,000 Ad Campaign To Promote Legislation To Allow U.S. Residents To Purchase Medications From Abroad

AARP on Sunday launched a $500,000 advertising campaign calling for Senate action on a bill that would permit consumers to buy U.S.-made prescription drugs from Canada and eventually from other countries, such as Australia, Japan and nations within the European Union, the *AP/Des Moines Register* reports. The ads will appear in newspapers and on radio in cities including Baltimore; Indianapolis; Anchorage, Alaska; and Des Moines, Iowa. According to David Certner, AARP legislative policy director, the campaign will focus on 14 states where senators have indicated support for reimportation. The legislation, sponsored by Sen. Byron Dorgan (D-N.D.), currently has bipartisan support from 31 co-sponsors. The ads are intended to urge people to lobby their senators to co-sponsor the bill. Certner said U.S. residents are purchasing medications from abroad "right now regardless of the law," adding, "We want to make sure the system is as safe as we can make it." However, the Pharmaceutical Research and Manufacturers of America said AARP is endangering patients by pushing Congress to pass legislation that would allow potentially unsafe drugs to be reimported from other countries. Ken Johnson, senior vice president of PhRMA, said, "The FDA has repeatedly stressed that it cannot guarantee that imported medications from Canada are safe. And Canadian health officials have acknowledged the severity of the counterfeiting crisis within their borders" (*AP/Des Moines Register*, 9/18).

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Hundreds of unapproved drugs sold by prescription

Updated 9/18/2006 12:37 AM ET

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Enlarge By Mike Derer, AP

Rosalee Jones of Irvington, N.J., holds the medications she takes everyday at the Home Sweet Home senior center in Elizabeth, N.J. The Food and Drug Administration is warning consumers to be wary of unapproved drugs that might harm their health.

By Rita Rubin, USA TODAY

They have official-sounding names, like Lodrane XR Suspension and Cortane B.

They're listed in the *Physician's Desk Reference* and advertised in medical journals.

You can buy them in drugstores, in person or online, but only if you have a doctor's prescription. They even have generic competitors.

Yet, what looks like a Food and Drug Administration-approved drug and sounds like an FDA-approved drug might not really be an FDA-approved drug. And that little-known fact means consumers — not to mention doctors and pharmacists, who are often as ignorant of the drugs' status as patients are — should beware, the FDA says.

Unapproved drugs, which, the FDA says, make up nearly 2% of all prescription drugs on the market, might not only be ineffective but also might actually be harmful. Over the years, the agency has learned of dozens of deaths linked to some of them. For now, the FDA says, it is targeting only the most dangerous because it lacks the resources to get all of them off the market.

The agency estimates that several hundred unapproved active ingredients, including antihistamines, narcotics and sedatives, are in prescription drugs sold in the USA. Many of them have been used since before 1962, when an amendment to the Food, Drug, and Cosmetic Act required that drugs be proven effective. (The original law, enacted in 1938, said only that drugs had to be proved safe.)

Those several hundred unapproved active ingredients translate into a couple of thousand unapproved prescription products or more. They're marketed for a range of ailments: colds and coughs, ear infections, hot flashes and pain. But their makers never submitted scientific data that convinced the FDA of their safety and effectiveness.

"We have concerns about their safety, about their quality, about their labeling," says Deborah Autor, the FDA's director of compliance. "Just because people think something works doesn't necessarily mean that it does."

'UNAPPROVED' PRICES VARY

Makers of medications that have not been approved by the Food and Drug Administration say the money they have saved by not going through the regulatory process enables them to offer lower prices. But a check of walgreens.com shows that's not always the case. Even among unapproved drugs, some are considerably cheaper than others:

A combination of a barbituate called butalbital and acetaminophen, a pain reliever, used to treat tension headaches.

BUCET (approved)	BUPAP (unapproved)
100 capsules, $39.39	100 tablets, $64.99

A combination of a butalbital, acetaminophen and caffeine used to treat tension headaches.

FIORICET (approved)	ANOLOR 300 (unapproved)

60 tablets, $83.99	60 tablets, $46.99

A combination of the antihistamines chlorpheniramine and phenyltoloxamine and phenylephrine, a decongestant, prescribed to relieve congestion, sneezing and watery eyes as a result of colds, flu or hay fever. There are no FDA-approved medications containing phenylephrine.

NALEX-A (unapproved)	CHLOREX-A (unapproved)
30 tablets, $32.99	30 tablets, $22.99

Sources: walgreens.com, fda.gov

CASE OF AN UNAPPROVED DRUG

Susan Sherry says she and her colleagues at Community Catalyst were "blown away" to learn that Estratest, a combination of estrogen and testosterone that has long been prescribed to treat menopause symptoms, has never been approved by the Food and Drug Administration.

"It literally left me speechless," says Sherry, deputy director of the Boston-based health advocacy group.

In the first half of 2006, women in the USA spent nearly $90 million on unapproved estrogen-plus-testosterone pills, says IMS Health, a pharmaceutical information company. Estratest, made by Solvay Pharmaceuticals, represented 75% of the market.

In an e-mail to USA TODAY, Solvay spokesman Neil Hirsch said the company "stands behind the safety and efficacy of Estratest brand products. After more than 40 years of patient use and 39-plus million prescriptions written for the product, Estratest continues to serve as an important therapeutic alternative."

Yet, in April 2003, the FDA stated in the Federal Register that it no longer believed there was "substantial evidence" of the hormone combination's effectiveness. The FDA invited manufacturers to ask for a hearing if they disagreed. Solvay and Breckenridge, maker of Syntest, quickly did so. The hearing has yet to be held, so the makers can keep selling their products.

In 2003, some consumer groups, part of Community Catalyst's Prescription Access

The 'time-tested' standard

In their defense, makers of unapproved prescription drugs say the medications must be safe and effective or else doctors wouldn't keep prescribing them. The companies say wading through the FDA's regulatory process would cost millions of dollars, an expense they'd have to pass on to consumers.

"Quality products at a price the patient can afford" is the motto of one such company, ECR Pharmaceuticals of Richmond, Va., maker of Bupap headache reliever and other unapproved prescription products. CEO E. Claiborne Robins Jr. is the great-grandson of Alfred Hartley Robins, whose 19th-century apothecary grew into giant drugmaker A.H. Robins. Robins was CEO of A.H. Robins when it was sold to American Home Products, later Wyeth, in 1989.

If Pharmics Inc. had to get FDA approval, CEO Paul Bagley says, it "would put us out of business." He says his Salt Lake City company sells only $500,000 worth of products a year, such as prescription O-Cal Prenatal vitamins.

" 'Unapproved' sounds horrible," Bagley says. "A lot of these products have been on the market for 50 years. ... They've been time-tested better than a lot of the new products approved by the FDA."

That's not good enough, says Kenneth Kaitin, head of the Tufts Center for the Study of Drug Development in Boston: "I want a product the FDA has authorized. The FDA is not infallible, but it's the best thing we've got for ensuring the quality of our drug supply."

Blansett Pharmaceuticals' website implies that its unapproved products, such as Cortane B ear drops, are of higher quality than approved versions. The Little Rock company's strategy is "to reformulate existing pharmaceutical products for the purpose of improving safety, efficacy and patient compliance," its website says.

Just because an unapproved prescription drug has the same ingredient as an approved drug doesn't mean it's safe and effective, Kaitin says. A single ingredient at a certain dose might be, but add another ingredient or double the dose, he says, "and you've got an unapproved drug."

And, Kaitin says, even if the ingredients are identical to an approved product's, consumers can't trust they're effective without the FDA checking whether a long-acting pill really works for 24 hours or whether a drug can stand up to medicine chest humidity.

FDA has to pick its battles

Why doesn't the FDA just pull all unapproved drugs off the market? "It's a resource-intensive process," so the agency must focus on potentially dangerous drugs, Autor says.

Most recently, the FDA cracked down on unapproved products containing the antihistamine carbinoxamine. In June, the agency told their makers to seek approval or stop production by Sept. 7. FDA spokeswoman Susan Cruzan said Friday that all of the manufacturers had agreed to comply.

Litigation Project, sued Solvay in California Superior Court in Los Angeles. The suit partly seeks to stop "false and misleading advertising related to the marketing and sale" of Estratest. "Physicians all over the country think this is an approved drug," says Steve Berman, a Seattle attorney for the plaintiffs.

The Washington, D.C.-based National Women's Health Network petitioned the FDA last month to ban estrogen-plus-testosterone pills. The petition notes that one Estratest or Syntest pill contains as much as eight times the testosterone in one Intrinsa testosterone patch, developed to treat low libido in women. Concerned about long-term safety, an FDA advisory panel unanimously recommended not approving Intrinsa in 2004.

Reid-Provident, now Solvay, did seek approval for Estratest and lower-dose Estratest H.S. in 1981, but the FDA has never acted on those applications.

The FDA had received reports linking unapproved carbinoxamine products to 21 deaths of children under age 2. Labeling for the two approved products, Palgic and Carbinox Maleate, both made by Mikart, Inc., of Atlanta, says they're not to be used in children under 2.

Last winter, two infants died in Kane County, Ill., after ingesting Carbaxefed RF drops prescribed by their pediatricians, says Loren Carrera, chief deputy coroner. The drops contained carbinoxamine, pseudoephedrine, a decongestant, and dextromethorphan, a cough suppressant.

Chang Lee, vice president for clinical research at Morton Grove Pharmaceuticals in Illinois, said last week that his company stopped making Carbaxefed DM RF drops in January and that the company had "no knowledge" of the infants' deaths.

The coroner ruled the deaths accidental as a result of intoxication by pseudoephedrine and dextromethorphan. "The prescription was written correctly for the size and age of the child," but the families gave too big a dose, Carrera says. As the FDA's Autor notes, though, correct doses for unapproved drugs aren't known, because the necessary studies haven't been done.

Richard Foster, head of marketing for URL/Mutual Pharmaceuticals of Philadelphia, says unapproved quinine sulfate products, used to treat malaria, contain one-half to double the dose found in his company's Qualaquin, the only approved quinine sulfate drug.

Too little of any drug could be ineffective, while too much could be dangerous. Quinine sulfate can cause abnormalities in the heart's electrical system that can, in rare instances, lead to potentially fatal irregular heartbeats. The higher the dose, the greater the risk.

Qualaquin's label mentions the heart risk, but the unapproved products' labels do not, says Mutual CEO Richard Roberts, adding that over the years, the FDA has received reports of 23 deaths linked to those drugs.

Roberts says his company sold an unapproved quinine sulfate product "for years" but decided to seek FDA approval to corner the market. Because quinine sulfate is potentially dangerous, Roberts says, his company assumed the FDA would ban unapproved products once an approved version became available.

The FDA approved 324-milligram Qualaquin capsules in August 2005. But Mutual, waiting for the FDA to ban unapproved competitors, did not launch its drug until July. "We just felt we couldn't wait anymore," Roberts said. "We've invested millions of dollars in researching this product and going through the regulatory process. ... So far it's only been a financial loss for us."

Roberts says most pharmacists don't realize that some drugs they dispense are unapproved. In July, his company commissioned a nationwide survey of 500 pharmacists. It found that 91% of them thought all of the products they dispense are FDA-approved.

Mutual filed court motions in mid-August against the seven makers of unapproved quinine sulfate. So far, Roberts says, all but one have agreed to stop selling their products by Nov. 15. He says the only holdout is Teva Pharmaceuticals, which sells Quinamm. In an e-mail, spokeswoman Denise Bradley said Teva could not comment "in light of the pending litigation."

Roberts says his company was inspired to seek FDA approval by Adams Respiratory Therapeutics, maker of over-the-counter Mucinex, an extended-release guaifenesin pill. The FDA approved Mucinex in July 2002 and then told makers of unapproved versions, all of which required a prescription, to stop selling their products by Dec. 1, 2003, which they did.

In May 2004, the FDA approved another version of the drug, Adams' Mucinex DM, a non-prescription extended-release product containing guaifenesin and dextromethorphan, but it has not yet banned unapproved versions, says Janet Barth of

Adams, in Chester, N.J.

ECR Pharmaceuticals makes the prescription drug Nasatab LA (for long-acting), an unapproved competitor of OTC Mucinex D, launched in October. Both drugs contain guaifenesin and pseudoephedrine.

Taking Nasatab through the FDA regulatory process would cost up to $10 million, says Davis Caskey, ECR's managing director. And that, Caskey argues, would not be money well spent. "All of us are in business to make a living," he says. "The endpoint is we want to supply quality drugs for a reasonable price."

Posted 9/18/2006 12:30 AM ET

Updated 9/18/2006 12:37 AM ET

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Coverage & Access | Health Officials Announce Physician Quiz Campaign To Help Reduce Medical Errors
[Oct 24, 2006]

HHS and other health officials on Monday announced a new campaign designed to limit surgical complications by encouraging patients to quiz their doctors about medical procedures, *CQ HealthBeat* reports. The campaign, which is part of the Surgical Care Improvement Project, aims to reduce surgical complications by 25% by 2010. The campaign features a tip sheet that advises patients on how they can lower their surgical risks by talking with a member of their surgical team, including their doctor, nurse or anesthesiologist. The tip sheet includes advice on asking questions about antibiotic use and hair removal to avoid infections, as well as about blood clots, hand washing and other medications. According to the tip sheet, patients should "speak up" if they have questions or concerns about a procedure. AARP and the National Partnership for Women and Families will distribute the tip sheets. Carolyn Clancy, director of HHS' Agency for Healthcare Research and Quality, said, "Patients need to take an active role in their health care, especially when it comes to having surgery. They need to be well-informed and ask lots of questions, and the materials developed by SCIP will help them know where to get information and what to ask." Mark Lema, president-elect of the American Hospital Association, said, "We will encourage patients to use this tip sheet to talk to their caregivers about the care that's right for them." Thomas Russell, executive director of the American College of Surgeons, said, SCIP "is about bringing all the members of the surgical team together and implementing known measures, which will decrease adverse events that are preventable and no longer acceptable" (Reichard, *CQ HealthBeat*, 10/23).

Public ed

Brand Name Extensions Can Cause Confusion

Some over-the-counter (OTC) medication product lines employ brand name extensions (the same brand name used for products containing different ingredients), which could lead to confusion or patient harm.

For example, Kaopectate, the antidiarrheal agent, is now also available as a stool softener containing docusate calcium. Similarly, Dulcolax (bisacodyl) is a stimulant laxative now available as a stool softener containing docusate sodium. There is also a liquid formulation available that contains the laxative/antacid magnesium hydroxide.

Colonoscopy Concerns

Recently, a patient needing a colonoscopy was handed printed instructions by his physician's office staff that called for a bottle of magnesium citrate and two tablets of "Dulcolax" each day for two days before the colonoscopy. Although bisacodyl is needed for the bowel prep, only the brand name Dulcolax appeared in the printed instructions. Later, at the pharmacy, the patient was directed to the laxative aisle where he purchased the Dulcolax stool softener.

On the first day, he took two Dulcolax, but on the second day, his son, a pharmacist, recognized that his father was taking the stool softener (docusate sodium), not the laxative. The son drove to the pharmacy to purchase bisacodyl and found the two Dulcolax products side-by-side. His father completed the bowel prep properly and successfully underwent the colonoscopy.

New Formulations

The Institute for Safe Medication Practices (ISMP) was alerted to a new formulation of **Maalox** (aluminum-magnesium hydroxide and simethicone) labeled as **Maalox Total Stomach Relief**. This new product's package looks very similar to regular Maalox (see photo), but its ingredients are quite different. Maalox Total Stomach Relief contains *only* bismuth subsalicylate.

A pharmacist suggested that her grandfather, who was recovering from orthopedic surgery, take Maalox to control his nausea and upset stomach. Two days later, her grandfather developed black stools, which can be a sign of possible gastrointestinal bleeding. This concerned the pharmacist because her grandfather had also been receiving low molecular weight heparin and aspirin since his surgery.

However, the pharmacist's mother had unknowingly purchased the Maalox Total Stomach Relief product with bismuth subsalicylate. She saw the name Maalox and thought she had the right product. When the pharmacist checked the ingredients, the cause was apparent; bismuth subsalicylate can cause black stools and black tongue.

In reviewing the product labels, it's easy to see the potential for mix-ups. The product is packaged in a white plastic container that is the same size and shape as regular Maalox. "Maalox" is listed prominently on the front label panel of each product. Unfortunately, in the case of Maalox Total Stomach Relief, the bismuth subsalicylate content statement is much less prominent. Additionally, a banner in the upper corner proclaims, "Great new look. Same great Maalox."

However, with totally different ingredients, this is a misleading statement because the product only contains bismuth subsalicylate. The new product is also labeled as *"Maximum Strength,"* which could lead consumers to believe that it just works faster or is stronger than the original product, labeled *"Regular Strength."* Warnings pertaining to bismuth subsalicylate are listed on the back label panel in a very small font size, so it's easy to overlook the noteworthy side effects (such as black stools and black tongue) and warnings related to use by patients receiving oral anticoagulants and patients allergic to aspirin.

A loophole in the Code of Federal Regulations (CFR) allows companies to market designated OTC products without specific approval of the product names by the Food and Drug Administration (FDA). Without FDA's review, companies can capitalize on a well-known, trusted, brand name and use it for any product, including an entire line of OTC products with different ingredients. Unfortunately, marketing considerations can sometimes override safety considerations and, unless harm is well documented, FDA can do nothing to require a name change.

Many prescribers as well as community pharmacists may not be aware of the active ingredient(s) in these newer products. It is important that pharmacists are readily available to speak with patients when they select OTC medications. ☐

This article has been provided by the Institute for Safe Medication Practices (ISMP) and has previously appeared in the ISMP Medication Safety Alert! *Community/ambulatory Care Edition. This e-newsletter is a monthly compilation of medication-related incidents and error-prevention recommendations designed to inform and alert community pharmacy practitioners to potentially hazardous situations that may affect patient safety. Individual subscription prices are $45 per year for 12 monthly issues. Discounts are available for organizations with multiple pharmacy sites. For more information contact ISMP at 215-947-7797 or e-mail to community@ismp.org.*

Reasons For Not Filling	
Patient-perceived lack of need	42%
Too costly	27%
Changed by physician	20%
Concerned with side effects	17%
Insurance did not cover	16%
Used OTC instead	8%
Forgot to fill	4%
Other	13%

Filled, Directions Not Followed	
Forgot to take	79%
Ran out of Rx	19%
Too costly	9%
Patient-perceived lack of need	9%
Side effects	7%
No improvement seen	3%

Totals more than 100% due to multiple mentions

Prescriptions Not Filled, Not Taken

More than one-third of all patients do not fill every prescription they receive, and the non-fill level for some conditions was nearly half, according to a study by Wilson Health Information and the J. Scott Group.

"While 65 percent of study respondents reported that they did fill all prescriptions received, the percentage is misleading as an indicator of compliance in that 65 percent [of those] did not comply with prescriber directions, either not taking all of the medication, or not taking as directed, the study said.

The study of 32,000 patients identified the non-fill level for 55 diseases or conditions. For about 14 of them, including depression, anxiety, migraine, and ulcers, the non-fill level was roughly 50 percent. (See box above.)

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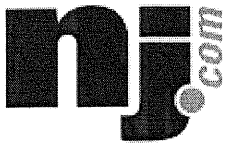

Everything Jersey

The Star-Ledger

Industry seeks cheaper ways to develop drugs

Monday, December 11, 2006

BY THERESA AGOVINO
Associated Press

Pfizer and other drug companies have long justified the high prices they charge for new medicines by citing the staggering sums they must spend in the search for breakthrough discoveries.

But experts said this week that Pfizer's decision to abandon what it hoped would be a blockbuster cholesterol drug after spending $800 million on its development suggests that this economic model may no longer be viable.

Put simply, the industry's approach to research is in desperate need of an overhaul, they say. Health plans are calling the shots about how much they'll pay for medicines, and they are very choosy about how much they'll spend. So drugmakers must find ways to produce new drugs more efficiently and cheaply.

The pharmaceutical industry's research system also isn't as productive as it once was. Despite a more than 6 percent rise in overall R&D spending last year to $39.7 billion, U.S. regulators approved only 20 drugs in 2005, down from 36 a year earlier.

"It is a tough time in the industry right now. Almost every company is having pipeline problems," said Kenneth Kaitin, director of The Tufts Center for the Study of Drug Development. "There has been no systematic change in the way companies bring products to market."

Drugmakers are trying to improve their performance, in part by conducting clinical trials and research in developing countries where costs are lower. They also are targeting niche diseases with small patient populations that don't require big drug trials. Plus, advances in technology and genetics are creating tools that streamline drug development.

But since health plans are unwilling to pay for "me-too" drugs or medicines that are similar to products already on the market, pharmaceutical companies have felt the need to explore unproven research paths in the quest for novel treatments.

"There is no low-hanging fruit anymore," said Steven Nissen, a cardiologist at the Cleveland Clinic, who was conducting a trial on torcetrapib for Pfizer. "Companies are reaching farther than ever."

Earlier this year, Bristol-Myers Squibb scrapped a diabetes drug that treated the disease in a new way, and AstraZeneca dropped development of a novel stroke medicine. Kaitin said as companies take more bet-the-farm chances, more spectacular failures are inevitable.

Pfizer's now-abandoned drug, torcetrapib, represented such a bet. By aiming for a new approach to raising good cholesterol, it was slated to fill the hole in the revenue stream at the world's largest drug company once Lipitor, a cholesterol treatment that brought in $12 billion in sales last year, loses its patent protection, as soon as in 2010. But Pfizer halted torcetrapib's development after a clinical trial showed patients taking it in combination with Lipitor had a higher risk of death and other problems than those taking Lipitor alone.

Uwe Reinhardt, an economics professor at Princeton University, said he thinks eventually the industry will migrate to smaller organizations producing drugs that affect smaller segments of the population. There are

signs of such changes already: Bristol-Myers cut its research areas to 10 from roughly 35 two years ago, in part to target the use of its research dollars.

In the meantime, new development strategies, aided by a better understanding of genetics and biology, are starting to be used.

Howard Goldsweig is testing a drug for pancreatic cancer that was developed through looking at the gene mutations of patients stricken with the disease. Only pancreatic cancer patients with the specific mutation the drug was developed around are eligible for the study.

The per-patient cost of an early stage cancer trial can rise to $50,000 so the ability to cherry pick the most appropriate individuals for a study represents significant savings, said Goldsweig, medical director of Averion International, a Southborough, Mass.-based company which conducts research for drugmakers.

Drug companies are increasingly using biomarkers, which are genes or other cellular signals that can help predict whether a drug will work in a specific patient, in an attempt to make clinical trials more efficient.

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Public Ed

Kaiser Daily Health Policy Report

Friday, December 01, 2006

Prescription Drugs

Patients Often Do Not Understand Usage Instructions on Prescription Drug Labels, Study Finds

Patients often do not understand usage instructions on prescription drug labels, according a study published in the current issue of the *Annals of Internal Medicine*, the *Chicago Sun-Times* reports. For the study, Terry Davis of Louisiana State University and colleagues presented five common prescription drug labels to 395 low-income adults in Chicago, Ill.; Shreveport, La.; and Jackson, Miss., and asked them, "How would you take this medicine?" All participants spoke English and had no vision or hearing problems. The study found that 46.3% of participants did not understand the usage instructions on at least one of the prescription drug labels. Among participants with a sixth-grade or lower reading level, 62.7% did not understand the usage instructions on at least one of the prescription drug labels, compared with 37.7% of those with a ninth-grade or higher reading level, the study found. Davis said that the study indicates physicians should provide more specific instructions to patients on prescription drug usage. "For example, saying 'Take one pill at 8 a.m. and one pill at 8 p.m.' is better than saying 'Take one pill every 12 hours,' which is confusing to a lot of patients," Davis said (Ritter, *Chicago Sun-Times*, 11/30).

The study is available online.

Kaiser Daily Health Policy Report

Thursday, December 14, 2006

Prescription Drugs

Number of Direct-to-Consumer Prescription Drug Advertisements Reviewed by FDA Has Decreased, GAO Report Finds

The number of direct-to-consumer prescription drug advertisements reviewed by FDA decreased by about half between the 1997-2001 period and the 2002-2005 period, and the length of time taken to draft and approve warning letters increased, according to a report released on Thursday by the Government Accountability Office, the *AP/Atlanta Journal-Constitution* reports. In the 2002-2005 period, FDA took an average of four months to draft and approve warning letters to pharmaceutical companies that had violated rules on DTC prescription drug ads, compared with an average of two weeks in the 1997-2001 period, the report found. In addition, the report found that FDA lacks an effective system to track and review the more than 10,000 DTC prescription drug ads and Web sites reported to the agency annually. HHS said that FDA, which currently has six staff members to review DTC prescription drug ads, cannot review all of the ads and must focus on those with the most potential to affect public health. In addition, HHS said that the longer reviews of DTC prescription drug ads allow FDA to develop a stronger legal foundation for warning letters. "As a result, companies take our letters more seriously and quickly react to the problems identified therein," HHS said in written comments to GAO. Sen. Herb Kohl (D-Wis.), who requested the report with Senate Majority Leader Bill Frist (R-Tenn.) and Sen. Chuck Grassley (R-Iowa), said, "If we are serious about protecting the health of consumers in our country, then we need an FDA capable of reviewing (direct-to-consumer) ads and taking swift action when necessary. This report tells us that we're nowhere close to that goal" (Bridges, *AP/Atlanta Journal-Constitution*, 12/14).

Agenda Item 7

State of California | Department of Consumer Affairs

Memorandum

To: Communication and Public Education Committee

Date: December 27, 2006

From: Virginia Herold

Subject: Public Outreach Activities

A board strategic objective is to provide information to licensees and the public. To this end, the board has a number of consumer materials to distribute at consumer fairs and attends as many of these events as possible, where attendance will be large and staff is available. An inspector generally attends these events along with consumer assistance staff from the board.

The board has a Power Point presentation on the board containing key board policies and pharmacy law. This is a continuing education course, typically provided by a board member and a supervising inspector. Questions and answers typically result in a presentation of more than two hours, and is well-received by the individuals present.

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

- Supervising Inspector Ming provided information on pharmacy law to 80 pharmacists and pharmacy technicians at a San Mateo Pharmacist Association on September 21.
- Supervising Inspector Ratcliff provided information on pharmacy law to the Sacramento Valley Society of Health System Pharmacists on September 28.
- Supervising Inspector Nurse provided information about California's pending changes to electronic pedigree requirements at the National EPCglobal conference in Los Angeles on October 19, 2006.
- Board Member Goldenberg will be a speaker at the California Association of Health Facilities Convention on November 13 in Palm Springs.
- Supervising Inspector Ming provided information about pharmacy law to UCSD students on November 13.
- Brenda Barnard and Karen Abbe attended an Ask a Pharmacist event at a HICAP event for seniors on December 8.

Future Presentations Planned:

- Board Inspector Kazebee will provide an update of new pharmacy law to the USC's School of Pharmacy Phi Delta Chi fraternity in January 2007.

- Supervising Inspector Ming will provide information on pharmacy law to the Indian Pharmacist Assocation on January 25, 2007.
- Interim Executive Officer Herold will provide information about the Board of Pharmacy as a keynote speaker at the CPhA's House of Delegates during their annual meeting on February 15, 2007.
- Supervising Inspector Ratcliff will provide information on pharmacy law to UCSF students on March 6, 2007.

Agenda Item 8

State of California | Department of Consumer Affairs

Memorandum

To: Communication and Public Education Committee

Date: December 29, 2006

From: Virginia Herold

Subject: Board Staff Newsletter

The board's The Communication Team (or TCT) exists to improve communication among staff, host staff biannual staff meetings and build and support a strong and positive team spirit for the board. The six members of the TCT are elected by staff and serve for two-year terms.

The staff periodically produces a staff newsletter. At this meeting, I will share the second issue of newsletter, which was released to staff in mid-December.