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

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:** 10 a.m. – 12 noon
**DATE:** APRIL 4, 2006
**PLACE:** DEPARTMENT OF CONSUMER AFFAIRS (NOTE: NEW LOCATION)
El Dorado Conference Room (Second Floor)
1625 N. Market Boulevard
Sacramento, CA 95834

This committee meeting is open to the public and is 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 Candy Place at (916) 574-7912, at least five working days before the meeting. Ms. Place can provide further information prior to the meeting and can be contacted at the telephone number and address set forth above. This notice is posted at www.pharmacy.ca.gov

Opportunities are provided for public comment on each agenda item.

### Meeting Agenda

***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.***

| | | |
|---|---|---|
| A. | Call to Order | 10 a.m. |
| B. | Consumer Fact Sheet Series with UCSF's Center for Consumer Self Care | |
| C. | Update on the Activities of the California Health Communication Partnerships | |
| D. | Joint Public Outreach with the Department of Health Services Office of AIDS to Increase Awareness of Access to Syringes in Pharmacies without a Prescription | |
| E. | Update Report of *The Script* | |
| F. | Reprint of the Notice to Consumers Poster | |
| G. | Pharmacy Law Online and in Lawbooks | |
| H. | Development of New Consumer Brochures | |
| I. | Miscellaneous Consumer Issues/Articles in the Media | |
| J. | Update on the Board's Public Outreach Activities | |
| K. | Adjournment | 12 noon |

*Meeting materials will be on the board's Web site by April 28, 2006*

# Agenda Item B

State of California | Department of Consumer Affairs

# Memorandum

**To:** **Communication and Public Education Committee** **Date: March 27, 2006**

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

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

Nearly two years ago, the board approved a proposal to integrate pharmacy students into public outreach activities. The project chosen was the development of a consumer fact sheet series by student interns. This project is being coordinated by the UCSF Center for Consumer Self Care.

By January 2005, the program had been initiated. As of January 2006, ten fact sheets had been developed, although not all have been distributed. The fact sheets contain general information on the topic, and contain questions consumers can discuss with their pharmacists on making wise decisions in the subject area.

Additionally, at the July 2005 Board Meeting, the board agreed to establish a joint Web site with the Center for Consumer Self Care to house the many fact sheets that should soon be developed through this collaboration because 11 students have agreed to develop three fact sheets each during this school year. The Center for Consumer Self Care will develop and maintain the Web site. The board will appear as cohost. As of this time, no work has yet begun on this Web site.

The fact sheets that have been developed are:

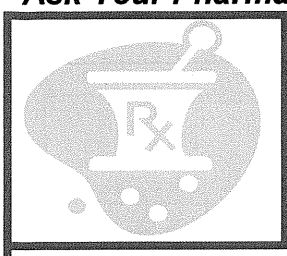
- Generic Drugs – High Quality, Low Cost
- Lower Your Drug Costs
- Is Your Medicine in the News?
- Antibiotics – A National Treasure
- Did You Know? Good Oral Health Means Good Overall Health
- Have You Ever Missed a Dose of Medication?
- What's the Deal with Double Dosing? Too Much Acetaminophen, That's What
- Don't Flush Your Medication Down the Toilet!
- Thinking of Herbals?
- Diabetes – Engage Your Health Care Team

All fact sheets have been reviewed (or re-reviewed by board staff). The first three have been recently revised again, and are through the review process of the board and department. They need to go back to UCSF.

The others have been edited by board staff and are on their way to Legal for its review. Again, after Legal signs off, they will go back to UCSF. This review should be completed shortly, and the fact sheets will be available online and distributed at public health events.

Dr. Soller of the UCSF Center for Consumer Self Care will attend this meeting to discuss the fact sheets. Between today and the time of the meeting, we hope to have final versions of all the fact sheets available for the committee's review.

*Ask Your Pharmacist*



# Lower Your Drug Costs

## So You Can Keep On Taking Your Medicines

It makes sense. Take your medicine just as your doctor says and for as long as your doctor says. But....

Drug costs are high. Everyone knows this, but it is especially hard on those living on a fixed income, such as seniors.

A study showed that 18 percent of people with chronic diseases like heart disease or diabetes could not buy at least one of their prescription drugs within the last year.

### Here are some hints on how to cut your drug costs.

1. **Ask your pharmacists for help.** Your pharmacist can work with your doctor to safely cut your drug costs. Bring a list of all medicines that you are taking.

2. **With your pharmacist, get the answers to these questions:**
   - Can I get my medicine in a generic form?
   - Is there a less costly drug that I can safely use for my condition?
   - Can I qualify for Medicare and therefore, be eligible for the Medicare Part D Prescription Drug Plan?
   - Ask if the pharmacy has special discount programs?
   - Ask of there are drug manufacturer or insurance programs that offer drug discounts?
   - Does my pharmacy offer mail order? Can I get a lower cost if I purchase a 90-day supply of my medicine?
   - Will my doctor prescribe a higher dosage, so I can use a pill cutter to cut the pills in half? (Note: this may not be an option for some medicines).
   - Do I really need the medicine? Do NOT decide this by yourself. Check with your doctor or pharmacist.

3. **Try contacting your community health center.** Community health centers may provide some help in lowering drug costs. Call 1-888-275-4722 (toll-free) to find a center near you.

University of California San Francisco
UCSF
School of Pharmacy

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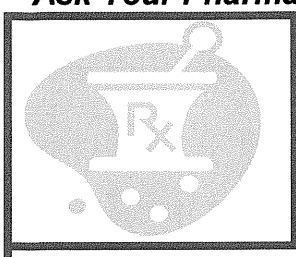
***UCSF Center for Consumer Self Care***
3333 California Street, San Francisco, CA 94143-0613

March 2006



# Generic Drugs

...real medicines at high quality, low cost

## What Is a Generic Drug?

A drug patent gives a drug company the sole right to sell a new drug. The company sells its new drug under its own brand name. By law, other companies cannot sell this drug until the term of the patent is over. When the patent term ends, other drug companies may then sell that drug, but not under the same brand name. These types of drugs are called generics, or generic drugs.

The generic drug has the same active ingredient as the brand name drug, but it may not look like the brand name drug. The generic drug usually has its own shape or color. This does not affect how it works. For example, Cipro is the brand name drug containing the active ingredients, ciprofloxacin. The generic version is also sold as ciprofloxacin.

### They are the same as brand name drugs...

When used as directed, a generic drug is the same as a brand name drug:

- It works the same way in the body
- It is as safe.
- It has the same use.
- It is taken the same way.
- It has the same quality.

### ...But they cost less!

Generic drugs cost less than brand name drugs. The U.S. Center for Medicare and Medicaid Services says, if people use generic drugs, they can save at least 59 percent in drug costs.

### Their quality is ensured by the FDA

- Each generic drug is tested. It must enter the bloodstream at the same rate and extent as the brand name drug.
- Generic drugs must also be tested to show they are stable, and just like the brand name drug, are good until the expiration date.
- A generic drug must have the same active drug ingredients, and the same strength and quality as the brand name drug.
- FDA inspects the factories where generic drugs are manufactured.
- FDA decides whether generic drugs are safe and of high quality before they are sold in the USA.

### Ask Your Pharmacist!

University of California San Francisco
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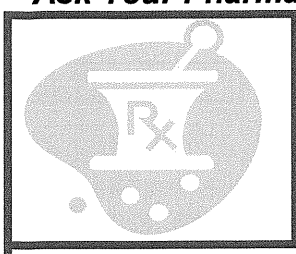
March 2006



# Is Your Medicine in the News?

It's not unusual for the media to pick up on a possible safety problem with a popular medicine. After all, nothing is more precious than our health. So, consumers are always interested to hear or read news about their medications.

It's not a surprise that a new safety problem may arise with a medicine. When a new drug is approved by the Food and Drug Administration, not all is known about its safety. This is because the drug has not been studied in a large enough population to identify rare side effects. When drugs are newly approved, only those side effects found in about 1 percent or more of the patients are typically known.

## A Common Sense Approach

Here are some steps to take to help make the right decision about your medicines:

1) **Don't panic**. Usually a safety debate about a popular drug relates to reports of rare effects.
2) **Contact your doctor or pharmacist** — personally, by telephone, or by email.
3) **Have a list of things to ask your doctor or pharmacist.** If you can, send a copy of your questions before your visit.
4) **Tell your doctor or pharmacist exactly how you take your medicines.** Be sure to say if you are not following directions, taking more than you should, forgetting dosages, etc.
5) **Ask the following questions**:
   - Do you think the benefits of my taking this medicine outweigh the risks?

### *More questions to ask:*

- What risks might I face in taking this medicine?
- Are there alternative medicines to the one I am taking?
- Are there alternatives to some of my medicines, such as lifestyle changes? Should I try these? What do I need to do to be successful with non-drug alternatives?
- If I have to continue to take this medicine, what side effects should I look out for, and when should I call about them?
- In summary, would you review the best course of action for me? (Take notes, if you need to.)
- Can we set up an appointment in 1 to 3 months to review what we've decided and see how I am doing?

University of California San Francisco
UCSF
School of Pharmacy

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March 2006

# Agenda Item C

State of California | Department of Consumer Affairs

# Memorandum

**To:** **Communication and Public Education Committee** **Date: March 27, 2006**

**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 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.

There have been no meetings or conference calls of this group since December. However, Dr. Soller, the director of the Center for Consumer Self Care, plans to attend this meeting of the Communication and Public Education Committee, where he will be able to update us about forthcoming projects.

The third effort of this group was last fall's cancer screening campaign, which was among the most successful campaigns (in terms of the number of messages published and aired) by The North American Précis Syndicate. Based on the success of this effort, the partnership will again seek funding to promote cancer screening as a fall initiative.

Another planned campaign of the partnership is generic medicines, and the California Retailers Association and board staff will be working with Dr. Soller on behalf of the partnership to promote the use of generics. The current plan is to follow a program along the lines of "Generics Makes Sense [Cents,$]," a campaign to raise awareness among consumers about cost-savings of generic medicines.

Other items proposed for future campaigns:

- Talk to Your Pharmacist Campaign "Say Yes" [to Consultation]"
  Dr. Soller will seek input on ideas, materials and other information that might help define a campaign strategy.
- "It's Your Life II" – Fall 2007 Breast and Prostate Cancer Awareness Campaign
- Antibiotic Resistance – Poster/brochure outreach to hospital waiting rooms
- New Prescribing Information – related to new initiative by FDA to provide easier to read/use format for Rx labeling. Dr. Soller is gathering information from the FDA on this.

# Agenda Item D

State of California | Department of Consumer Affairs

# Memorandum

To: Communication and Public Education Committee

Date: March 28, 2006

From: Virginia Herold

Subject: Implementation of SB 1159 -- Legalizing Nonprescription Syringe Sales

As you will remember, at the January meeting of this committee, the committee had a presentation by the Department of Health Services Office of AIDS on implementation of SB 1159, which authorizes the sale of 10 syringes to individuals without a prescription if the county has authorized a "Disease Prevention Demonstration Project."

The committee supported the assistance of the board in distributing information about the new requirements to pharmacies and pharmacists. (Actually the board's efforts to provide public education about this program began in the October 2005 *The Script,* when the board published an article about SB 1159 (Vasconcellos, Chapter 608, Statutes of 2004) – attached.)

Following our January meeting, the Office of AIDS provided the board with materials about the program that were distributed from the board's information booth at the CPhA Outlook in February. The materials were well received and all copies were distributed.

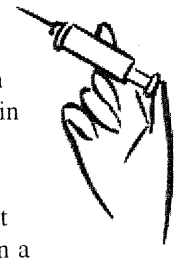
At the April Board Meeting in response to a request by this committee, Tom Stopka of the Office of AIDS will present a PowerPoint presentation about the program.

Unfortunately Mr. Stopka is unable to attend our committee meeting. However, the Office of AIDS recently prepared a brochure that they would like the board to assist in distributing to pharmacists and pharmacies. Their staff is also interested in obtaining the committee's comments on the brochure, which is attached. The goal of the brochure is to answer frequently asked questions about the program by pharmacists and to raise awareness among pharmacists about the program and their role in it.

The board can publish this brochure in our newsletter and place it on our Web site for downloading. Staff has also suggested that the Office of AIDS consider mailing this brochure to all pharmacies, or seek the Pharmacy Foundation of California's approval to include in a mailing of *The Script* to all California pharmacists.

Lastly as an update, at the October 2005 Board Meeting, the board agreed to assist in a study being conducted by the Department of Health Services' Office of AIDS and UCSD to evaluate Senate Bill 1159 that allows local health jurisdictions to authorize nonprescription syringe sales by pharmacies to prevent HIV and Hepatitis. The funding for this project was recently denied. Another grant proposal is being considered.

# Program Required for Furnishing Hypodermic Needles and Syringes Without a Prescription



A new law went into effect on January 1, 2005, requiring a program for furnishing hypodermic needles and syringes without a prescription. The goal of the law is to further efforts across the state to prevent the spread of HIV, Hepatitis C and other blood-borne diseases by allowing pharmacies to sell sterile syringes without a prescription if one of the following conditions is met:

1. The person is known to the pharmacist to have a medical need for a syringe; **or**
2. If the pharmacy is located in a county or city that has authorized non-prescription syringe sale and established a Disease Prevention Demonstration Project (DPDP).

In cities and counties with a DPDP, pharmacies that opt to participate in the project may sell ten or fewer syringes to individuals 18 years of age or older without a prescription. Pharmacies participating in a DPDP are not required to make any record of syringe sale to customers without a prescription, nor are pharmacists required to record any information about the sale or the customer. Additionally, there is no requirement for pharmacists to require identification from the customer, although they may do so if the customer appears to be under the age of 18. These provisions of the law expire on December 31, 2010. (Business and Professions Code sections 4145 and 4147, Health and Safety Code section 11364).

As of June 2005, eight counties and two cities have approved a DPDP: Alameda, Contra Costa, Los Angeles, Marin, San Francisco, Santa Cruz, Yolo, Yuba counties and the cities of Los Angeles and West Hollywood. More than twenty other areas are in the process of establishing a DPDP.

For pharmacies that choose to participate in a DPDP, the law requires the pharmacy to:

1. Register with the city or county health department;
2. Certify that the pharmacy will provide the purchaser with written information or verbal counseling on how to access drug treatment, how to access testing and treatment for HIV and Hepatitis C virus, and how to safely dispose of sharps (needle and syringe) waste;
3. Store hypodermic needles and syringes so that they are available only to authorized personnel; and
4. Provide for the safe disposal of hypodermic needles and syringes. Safe disposal of sharps can be done by providing an on-site safe hypodermic needle and syringe collection and disposal program; furnishing or making available for purchase mail-back sharps disposal containers that meet state and federal standards; or furnishing or making available for purchase personal sharps disposal containers.

If you would like more information about establishing a DPDP in your county or city, or would like to find out about an existing program, please contact Alessandra Ross, California Department of Health Services, Office of AIDS, at (916) 449-5796, or e-mail her at *aross@dhs.ca.gov*.

## Participating Counties

*(As of February 2006)*

Alameda
Contra Costa
Los Angeles City and County
Marin
San Francisco City and County
San Mateo
Santa Cruz
Solano
Sonoma
Yolo
Yuba
Santa Clara
Humboldt
Santa Barbara

**More Information is Available at:**

www.syringeaccess.com

**Or Contact the California Department of Health Services, Office of AIDS:**

Alessandra Ross, MPH,
Program Implementation
(916) 449-5796

Steven Burke, RPh,
Pharmacist
(916) 449-5553

Tom Stopka, MHS,
Research and Evaluation
(916) 449-5828

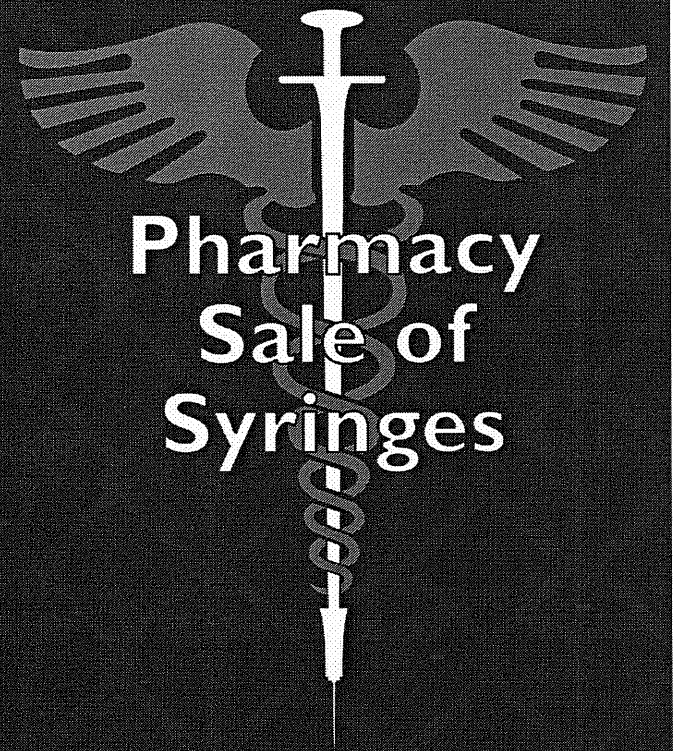
**California State Board of Pharmacy:**

(916) 574-7900

**HIV/AIDS Hotline:**

(800) 367-AIDS
or
www.AIDShotline.org

# CALIFORNIA



# Pharmacy Sale of Syringes

## Over-the-Counter Syringes in California

# What is SB 1159?

Senate Bill (SB) 1159 was signed by Governor Arnold Schwarzenegger and went into effect January 1, 2005. This legislation allows for the creation of a **Disease Prevention Demonstration Project** (DPDP) in cities and counties that authorize such a program. An authorized DPDP **permits certified pharmacies to sell syringes** (up to 10) **over-the-counter to individuals** 18 years of age or older. This legislation will further efforts across the state to prevent the spread of HIV, hepatitis, and other blood-borne diseases.

Pharmacists play an important and often unrecognized role in public health, as health educators and key informants to their communities. As respected members of the medical profession, pharmacists have the ability to positively influence the health behaviors of their patients.

**Participating pharmacies are required to:**

- Register with the county
- Store-syringes behind the counter
- Provide for disposal through either:
  - On-site syringe disposal program
  - Furnishing or selling mail-back sharps containers, or
  - Furnishing or selling personal sharps containers.

# Frequently Asked Questions

**Does each pharmacist need to register with the county?**

*No, the pharmacy itself is registered, not the pharmacist.*

**Do I need to ask for i.d. from the customer?**

*No, i.d. is not required in order to purchase syringes, however sale of syringes is not authorized to any persons under the age of 18 without a prescription.*

**Do I need to keep a log of my syringe sales?**

*No, SB 1159 eliminates the requirement to keep a log of syringe sales when syringes are sold without a prescription.*

**Will this attract criminals and crime to my pharmacy?**

*Among participating California pharmacies, there have been no reports of unruly or criminal behavior associated with pharmacy sale of syringes.*

# Common Concerns/Benefits:

**Syringe Sharing**

- Increased use of pharmacies as a syringe source is associated with a decline in syringe sharing.
- HIV infection rates among injection drug users (IDUs) were twice as high in cities that required prescriptions for syringe purchase as compared to cities that did not.

**Needle-Stick Injuries & Safe Disposal**

- Accidental needle-sticks decreased among law enforcement officers by 66% after pharmacy access legislation in Connecticut.
- Needle sightings among sanitation workers decreased after implementation of the Expanded Syringe Access Program in New York.

**Cost-Effectiveness**

- Average lifetime cost for treating a person with AIDS is approximately $195,000.
- Treatment of chronic liver disease related to HCV is approximately $20,000 per person per year.
- Reducing the number of injection drug use-related HIV/AIDS and HCV cases can reduce the economic burden on county-funded care and treatment programs.

# Agenda Item E

State of California | Department of Consumer Affairs

# Memorandum

To: Communication and Public Education Committee

Date: March 27, 2006

From: Virginia Herold

Subject: Update on *The Script*

The next issue of the newsletter is being developed for publication in July 2006.

In response to comments made by the Communication and Public Education Committee and at the February Board Meeting, the board will resume listing disciplinary actions taken. The name of the licensee will be listed along with the disciplinary action.

The board will also publish statistics on the top 10 corrections ordered during inspections and the types of fines the board has issued under the citation and fine program.

There will also be an article on the new CE policy for attending committee meetings.

Currently the Pharmacy Foundation of California is looking for a sponsor to fund the printing and mailing of the January 06 *The Script.*

# Agenda Item F

State of California | Department of Consumer Affairs

# Memorandum

To: Communication and Public Education Committee

Date: March 27, 2006

From: Virginia Herold

Subject: Notice to Consumers

California Code of Regulations Section 1707.2 requires that pharmacies display a "Notice to Consumers" poster that contains five questions that patients should understand about taking their medications. This poster and its five questions have been required to be posted in pharmacies since 2002, and are important to encourage patients' improved understanding their drug regimens.

Because of the board's new business address and telephone number, the board recently updated the poster to reflect this new information. The board is now mailing these new posters to the state's 6,000 community pharmacies, along with a letter from Board President Goldenberg emphasizing the importance of pharmacist to patient consultation and the requirement to display this poster.

A copy of the letter and poster are included with this memorandum. The poster's real size is 17 x 22 inches. The poster has also been translated into Spanish, Chinese, Vietnamese, Russian and Korean. The board's addresses on these posters have been changed as well.

The cost of this printing and mailing is $18,000.

# 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

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

March 28, 2006

Dear California Community Pharmacy:

I am pleased to provide you with one copy of the board's new "Notice to Consumers" poster. This poster has been revised to reflect the new board address and telephone number.

California law requires that this notice be posted in the pharmacy or printed on the back of customer receipts. If posted in the pharmacy, the poster must be displayed in an area conspicuous to and readable by prescription drug consumers.

The requirement to post this Notice to Consumers is intended to aid the public in learning more about their prescription drug regimens. The changes were made by amendments to California Code of Regulations, Division 17, Title 16, Section 1707.2(f), and have been in effect since September 8, 2002. A copy of the full text of the regulation can be obtained from the board's Web site (www.pharmacy.ca.gov) under "Pharmacy Law and Regulations."

The board has translations of this poster in additional languages (Chinese, Korean, Russian, Spanish, Vietnamese). The camera-ready versions of these posters are available for downloading from the board's Web site if you have patients that may be assisted by such information. Please note, however, that the English version of the poster in its full size needs to be posted in your pharmacy unless this information is printed on customer receipts.

We are pleased with the posters and believe they aid patients in learning important information about their medications from their pharmacists.

Sincerely,

STANLEY GOLDENBERG, RPH, FASCP
President
California State Board of Pharmacy

# Agenda Item G

State of California | Department of Consumer Affairs

# Memorandum

To: Communication and Public Education Committee

Date: March 28, 2006

From: Virginia Herold

Subject: Availability of Pharmacy Law Online and via Lawbooks

Pharmacy law is detailed and complicated. The board strongly encourages licensees to seek out answers to their legal questions by accessing pharmacy law.

Licensees of the board have a number of choices when they seek to obtain copies of pharmacy law.

1. The board has on its Web site a copy of all pharmacy laws and regulations. The address is http://www.pharmacy.ca.gov/laws_regs/lawbook.pdf.

   There are several advantages of using this source for Pharmacy Law. It is free. It also contains a detailed index, developed and used by board staff, that is not published in either lawbook.

2. LawTech publishes a lawbook, and also has a cd version available for sale. Ordering information is available via a link from the board's Web site or by calling 1-800-498-0911 X 5.

   The cost for this Lawbook is $21.99.

   LawTech has published our lawbook for the last six years.

3. Lexis/nexis has also produced its first version of our lawbook. Again, there is also a cd version of this publisher's lawbook also available.

   This lawbook is available for $22, by calling 1-800-833-9844.

The board will promote this information in its next newsletter.

# Agenda Item H

State of California Department of Consumer Affairs

# Memorandum

**To:** **Communication and Public Education Committee** **Date: March 28, 2006**

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

**Subject:** **Need for New Consumer Brochures**

1. Consumer Materials

   Board staff has developed new consumer brochures and fact sheets. There are four that are ready for distribution, each is enclosed:

   - "Medicare Part D – Selecting a Prescription Drug Plan"
   - "Children and Their Medicines"
   - "Do You Sometimes Forget to Take Your Medicines"
   - "New Easier to Read Prescription Drug Information"

   Under 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. Center for Health Improvement Report: "Opportunities for Improving the California Pharmacist-Patient Consultation Process"

   The board was a sponsor of a recent survey on the mandated pharmacist to patient consultation process and its effects on Californians aged 65 and over.

   The study is now complete and the findings were released in November to a group of stakeholders involved in health policy. Board President Goldenberg, Vice President Powers, Patricia Harris and myself attended this meeting.

   The board received the final report following the February Board Meeting. The final report will be provided to the board for the April Board Meeting.

- Tips that may allow you to reduce your drug expenses:

    1. Talk to your health care provider or pharmacist, and ask if generic medicines could save you money. Generic medicines are the same medicines as their brand name counterparts, but are available at lower cost.

    2. Ask your provider or pharmacist if another, less costly, medicine could provide a similar therapeutic treatment for you.

    3. Ask your provider or pharmacist to review all the medicines you are taking to see if you still need to take all of them. Sometimes, patients remain on a medicine when they no longer need to be, or one medicine may duplicate the treatment of another medicine you are also taking. However, **do not discontinue any medicine without your health care provider's permission.**

**Be Aware & Take Care! Talk to Your Pharmacist!**

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916-574-7900
*www.pharmacy.ca.gov*

# Medicare Part D

## Selecting a Prescription Drug Plan

**Beginning January 1, 2006, Medicare recipients became eligible for membership in an insurance plan to help pay for their prescription drugs.**

## How to find a plan:

- Make a list of all prescription medicines you take. Write down the name and strength of each medicine: e.g., verapamil, 240 mg.
- Locate your Medicare card. You will need this information when selecting your plan.
- Go online to the government's Web site, *www.medicare.gov*, or ask someone you trust to protect your privacy to help you access the site.

If you cannot use the Internet yourself, contact the Health Insurance Counseling and Advocacy Program (HICAP) at 1-800-434-0222.

HICAP provides free, impartial help in dealing with Medicare and long-term care insurance issues. Because of the high volume of HICAP calls, callers will be asked to leave a message for a return call. California's HICAP Web site is sponsored by the California Health Advocates and is located at *www.calhealthadvocates.org.*

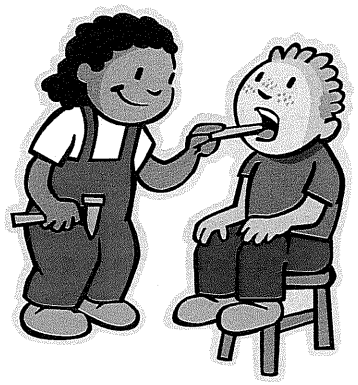
Some pharmacists and other health care providers may be available to assist you. Ask for assistance if you need it.

**Note**: If you already have prescription drug coverage from another health plan, be sure to check with your current plan or with HICAP before selecting any prescription drug plan. In some cases, selecting a prescription drug plan could terminate other health coverage you may have.

- Compare the different plans available—look at the amount you will have to pay each month as a monthly enrollment charge and the amount you will have to pay as a co-payment for each medicine.

*Continued…*

# Children and Their Medicines



- Always keep all medicine and food supplements out of children's reach. Some supplements, such as iron, are toxic to children.

- Use child-resistant caps, and never leave the containers uncapped.

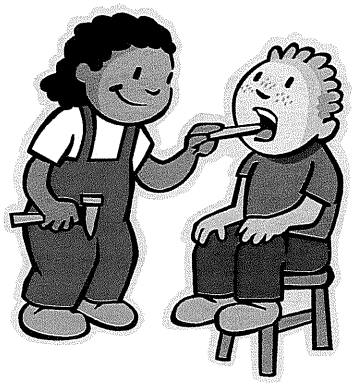
- Examine dose cups carefully. Cups may be marked with various measurement units and may not use standard abbreviations. Follow label directions. Never substitute a cup from another product.

- When using a dosing syringe with a cap, discard the cap before use.

- Never guess when converting measuring units—from teaspoons or tablespoons to ounces, for example. Your pharmacist is a good source for help with conversions.

*Continued...*


# Children and Their Medicines



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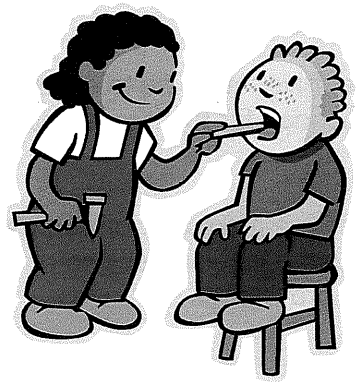

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*Continued...*

- Never try to remember the dose used during previous illnesses; read the label each time.

- Always check with the healthcare provider (e.g., doctor, registered nurse, nurse practitioner, physician assistant or pharmacist) before giving a child more than one medicine at a time.

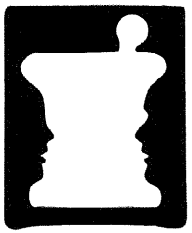
- Never give medicine to children unless it is recommended for them by a healthcare provider.

- Never use medicine for purposes not mentioned on the label, unless so directed by a healthcare provider.

- Check with the healthcare provider before giving a child aspirin products. Never give aspirin to a child or teenager who has or is recovering from chickenpox, flu symptoms (nausea, vomiting or fever), or flu. Aspirin may be associated in such patients with an increased risk of Reye syndrome, a rare but serious illness.

This information was prepared by the Federal Citizen Information Center of the U.S. General Services Administration and provided by:

**BE AWARE & TAKE CARE**



**TALK TO YOUR PHARMACIST!**

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

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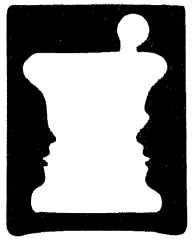

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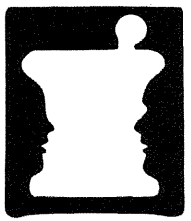

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Sacramento, CA 95834
(916) 574-7900
*www.pharmacy.ca.gov*

| Name of Medicine/ Directions | SUN | MON | TUE | WED | THU | FRI | SAT |
|---|---|---|---|---|---|---|---|
| | | | | | | | |
| | | | | | | | |
| | | | | | | | |
| | | | | | | | |
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This information prepared by Federal Citizen Information Center, Pueblo, CO, and provided by:

California State Board of Pharmacy
1625 North Market St., Suite N 219
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(916) 574-7400
*www.pharmacy.ca.gov*

# Do you sometimes forget to take your medicines?

Thirty to 50 percent of patients do not use medicines as prescribed. Forgetting to take your medicine as directed by your health care provider is considered medication misuse, and such misuse can interrupt your drug therapy and may affect your health.

In the U.S., the costs of prescription medicine misuse and adverse reactions total more than $20 billion per year. Add lost productivity to that, and the annual costs shoot up to $100 billion, according to the National Pharmaceutical Council, Inc., of Reston, VA.

## Medication Misuse Among Older Adults

Two of the more common reasons for medication misuses among older adults are:

- **Forgetting to take doses**, and
- **Taking doses at the wrong time.**

If you are 64 or older, chances are that you are taking several prescription medicines—often that must be taken at different times—so it may be difficult to remember which medicine to take when. Having a system in place for remembering to take your medicines on schedule can help you get the maximum benefit from them.

One of the easiest ways to stay on schedule is to have a written record of your medicines, the times to take them, and an indication that they have been taken.

The chart opposite is an example of how to set up a medicine reminder chart. Record your medicines and the times you are supposed to take them. Checking off the medicines as you take them lets you know you are on track with your therapy.

**Other memory aids include:**

- Pill boxes with easy-to-open compartments for each day of the week (available at your pharmacy);
- Having a friend or caregiver telephone you to remind you when it is time to take your medicine;
- Color coding each medicine with colored dots and placing matching colored dots and the dosing time on your calendar.

## Multiple Medications Check-off Chart Example

| Name of Medicine/ Directions | MON | TUE | WED |
|---|---|---|---|
| Medicine # 1<br>Once in **A.M.** | 8 | 8 | 8 |
| Medicine # 2<br>3 times a day | 8 2 8 | 8 2 8 | 8 2 8 |
| Medicine # 3<br>Once at **bedtime** | 10 | 10 | 10 |
| Medicine # 4<br>Once a week | 8 | | |

## 8. How Supplied / Storage and Handling

The different strengths and physical description of the medicine are listed here with the required temperatures for proper storage to ensure the medicine's effectiveness until its expiration date.

## 9. Patient Counseling Information

Patients should read this section carefully. This section is intended to help inform healthcare professionals about the medicine they are prescribing for their patients. They should provide this important information to their patients at the time of prescribing. Additionally, pharmacists counsel the patient or caregiver if the medicine is dispensed for the first time or if the dosage has changed.

## What if I have questions?

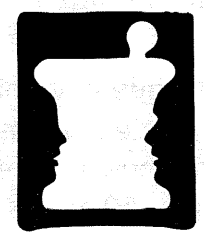
If you have questions, you should discuss them with your physician, pharmacist, or other healthcare provider at the time of service.

If you have additional questions, remember to **Ask Your Pharmacist!**

This information was based on material prepard by the U.S. Food and Drug Administration (FDA) and provided by:

California State Board of Pharmacy
1625 N. Market Blvd., Suite N 219
Sacramento, CA 95834-1924
(916) 574-7900
*www.pharmacy.ca.gov*

**Be Aware & Take Care**



**Talk to Your Pharmacist**

# New Easier-to-Read Prescription Drug Information

Each year, approximately **2.2 million preventable adverse events** (illnesses and emergency hospital admissions) and more than **106,000 deaths** occur in U.S. hospitals*, many as a result of confusing medical information. Consequently, the U.S. Food and Drug Administration (FDA) has directed drug manufacturers of new or recently approved prescription drugs to make the information provided with these drugs easier-to-read, less complicated and/or confusing, making it more useful to both physicians and patients.

*Institute of Medicine, National Academy Press 2000

**While much of the material included with prescription drugs is directed toward health professionals, it also includes easy-to-read information that is very important to the patient or patient's caregiver.**

## What is Prescribing Information?

The prescribing information approved by the FDA contains information necessary for the safe and effective use of a prescription drug; it answers such questions as:

- **What diseases or conditions does the drug treat?**
- **What are the risks?**
- **What dose is needed?**
- **Which patients should not receive the drug?**
- **What other drugs should not be taken together with the drug?**
- **What side effects can occur?**
- **How should the drug be stored?**

## Some Highlights of the Prescribing Information

### 1. Drug Name/Form and Black Box Warning, if any

The first item of the prescribing information is the name of the medicine and its description (e.g., capsules, tablets, liquid), followed by a warning enclosed in a black line box **if** the medicine can cause life-threatening reactions or mental changes, such as thoughts of suicide.

**Black line boxed warnings are serious and should be read by both the prescriber and the patient or patient's caregiver.**

### 2. Indications and Usage

This section describes the symptoms or conditions that this prescription is intended to treat. It also lists and describes important limitations on the drug's use.

### 3. Dosage and Administration

The proper dosage amount for the condition to be treated is listed along with information about how to take the medicine. For example: *50 mg once daily with food.*

### 4. Contraindications

A contraindication is a condition or factor that increases the risk involved in using a particular drug. This section lists any conditions or disorders that should **not** be treated with this particular medicine.

### 5. Warnings and Precautions/ Adverse Reactions

This section lists any unwanted and/or dangerous results from the drug's use. It also recommends the monitoring of the patient's reaction to the drug for any symptoms of such results.

Potential adverse reactions (illnesses, conditions or mental changes caused by the drug) are listed in this section, followed by directions for reporting an adverse reaction to the drug's manufacturer or to the FDA.

### 6. Drug Interactions

Listed here are any prescription or over-the-counter medicines or food supplements that should not be taken with this drug.

### 7. Overdosage

Information in this section is relates to cases and outcomes of overdosages of this drug. A poison control number is also provided.

# Improving the California Pharmacist-Patient Consultation Process

POLICY BRIEF
Center for Health Improvement
JANUARY 2006

## Older Californians at Risk

This Center for Health Improvement (CHI) issue brief summarizes the findings of a two-year study (2004-2005) to examine the mandated pharmacist-patient consultation process and its effects on Californians aged 65 years and older. This is a timely issue, given the recent addition of prescription drugs to the federal Medicare program and anticipated expansion in participation of the benefit. By May 16, 2006, 4.3 million California seniors must make a critical decision about their drug coverage.[1] The CHI study's focus on seniors is also important since persons aged 65 and older are prescribed twice as many medications as persons under 65.[2] Approximately 90% of older persons take at least one prescription drug, and among them, nearly half use five or more different drugs.[3] Older adults have more chronic diseases and multiple conditions, thus the consultation process becomes more relevant and complex. Finally, persons 65 and older constitute a more vulnerable population.[4]

## SURVEY FINDINGS

| | |
|---|---|
| **Provide directions for use and storage of the medication*** | 93.1% |
| **Discuss precautions and relevant warnings, including common severe side or adverse effects or interactions that may be encountered*** | 86.9% |
| **Describe the importance of compliance with the medication directions*** | 81.1% |
| Verify the name and description of the medication | 88.1% |
| Discuss any precautions for preparation and administration of the medication by the patient, including self-monitoring drug therapy | 81.8% |
| Discuss serious potential interactions with known nonprescription medications | 59.6% |
| Discuss therapeutic contraindications | 59.0% |
| Discuss action to be taken in the event of a missed dose | 39.1% |

Respondents were asked how often these events occurred during an average consultation for patients 65+: the scale was "rarely ever," "occasionally," "sometimes," "often" and "always." Figures above reflect the sum of the responses for "often" and "always"

*Required.

Recent attention by the Institute of Medicine[5] has significantly raised the visibility of medical errors overall. Problems related to prescriptions drugs comprise one source for such errors. For example, in an analysis of adverse drug events (ADEs) occurring in a population of older adults in an ambulatory setting, 27.6% of the documented ADEs were deemed preventable.[6]

The CHI study found two key areas for improving the consultation: 1) pharmacist time and compensation, and 2) pharmacist-patient communication, as well as pharmacist-physician communication.

## Federal and State Mandate

The state of California Board of Pharmacy (Board) enacted regulations in August 1990 that required the pharmacist-patient consultation for all new or changed prescriptions. These regulations preceded the federal mandate and were also more stringent (the federal mandate required counsel to Medicaid recipients upon receipt of a new prescription).[7] The regulation was enacted to ensure that necessary dialogue occurs between patients and medication experts to promote safe and effective medication use. Previously, the only California study to examine the effectiveness of the counseling regulations was conducted in the early 1990s.[8,9]

## Methodology for Examining the Regulation

The CHI study consisted of five components: 1) a literature review, 2) a review of Board inspection and complaint data, 3) a statewide survey of pharmacists, 4) focus groups of pharmacists, physicians and patients, and, 5) a policy roundtable convening. The written survey of pharmacists involved sampling 3,000 of the roughly 5,000 California-licensed community pharmacies. A 32.4% response rate was achieved. The independent/chain pharmacy ratio was 45.4% to 54.6%, generally reflecting the state distribution. Kaiser Permanente Foundation outpatient pharmacies were also included in the study.

## Findings About the Regulation

The California regulation describes two required components for every consultation:

- Directions for use and storage and the importance of compliance with directions; and,
- Precautions and relevant warnings, including common severe side or adverse effects or interactions that may be encountered.

In addition, the regulation specifies optional components where deemed warranted by the pharmacist.

**Technology Innovations**

**Komoto Pharmacy, an independent community pharmacy in Delano, utilizes a robotic dispensing machine, filling approximately 35% of the total prescription volume. Owner Brian Komoto, Pharm.D., noted, "the new technology has improved the accuracy of filling prescriptions and given our pharmacists more time to spend with patients."[12]**

## Pharmacist Time & Compensation

The findings from the survey, focus groups and policy roundtable all identified time and compensation as critical barriers to maximizing the pharmacist-patient consultation.

- 56.8% of the survey respondents indicated that the pharmacist's lack of time was a significant barrier.
- 42.3% indicated that insufficient compensation specific to the consultation was a significant barrier.

The issue of time and compensation as barriers to the consultation are consistent with findings from studies in both New York and Massachusetts.[10,11]

## Formulary Problems

Pharmacists in the focus groups discussed time-consuming activities that may have no clinical bearing on the consult, specifically, administrative time spent dealing with prior authorization issues. For example, pharmacists submit a prescription for insurance approval, are then notified of the need for prior authorization, and then have to contact the prescribing physician. Physicians also noted that the prior authorization process was unwieldy and time-consuming for them and their staff.

Further, as formularies have become more complex, some pharmacists now rely on electronic devices to submit information for prescription approval. One focus group participant described that his pharmacy is charged $.13 per transmittal, and that if the prescription is rejected as not covered by the formulary, his pharmacy still bears the transmittal charges.

## Pharmacy Technician Staffing Ratio

Staffing ratios were identified as an important factor that affects time available for consultation. In particular, participants described how the pharmacist-pharmacy technician staffing ratio statute[13] adversely impacts small, independent pharmacies that might only have one pharmacist on duty. Some pharmacists advocated for less stringent ratios, as is the case in other states, so that technicians could alleviate the pharmacist from non-clinical duties. For pharmacies with one pharmacist on duty, one pharmacy technician is allowed. For each additional pharmacist, two additional technicians are allowed (two total pharmacists, three total technicians; three total pharmacists, five total technicians; etc.).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### Time & Compensation Recommendations

- **Consider changing the pharmacist-pharmacy technician staffing ratio.** Currently, the pharmacist-technician ratio limits small, independent pharmacies from maximizing technician assistance. Other states have less stringent or no ratios regulating the staffing of pharmacy technicians. The National Association of Boards of Pharmacy surveyed pharmacists and found that "having more technicians available to assist with dispensing duties would increase pharmacist time for patient counseling."[15]
- **Continue to examine California regulations that might discourage the use of technology.** Stakeholders at the policy roundtable expressed interest in examining current policies and regulations that affect technology use in California. Participants noted that the promotion of technology did not have to come at the expense of pharmacists, but that technology can assist pharmacists by freeing them from administrative and other activities.
- **Create financial incentives based on pharmacists' performance.** As is occurring with hospitals and physicians, financial incentives awarded to pharmacists can encourage continued quality improvement. Performance measures could include patient satisfaction, dispensing efficiency, and additional services such as medication compliance monitoring, disease management counseling, medication profile review among others.

### Communication Process

Survey, focus group and policy roundtable findings also identified communication as a critical barrier to the consultation. A distinct gap exists in communication among pharmacists, consumers and physicians.

### Pharmacist-Patient Communication

Communication issues in the pharmacist-patient relationship revolve around patient education. There is a need to educate patients about the changing medication system, pharmacy profession, and the value pharmacists provide in the healthcare system.[14]

California pharmacists spoke of the need to educate consumers about the process of navigating formulary issues, including communicating back to the physician, time needed to obtain prior authorization and coordination with changing formularies.

Patients also need to understand the importance of the clinical information that pharmacists can provide, and that patient participation in the consultation is critical. Nearly a quarter of the survey respondents rated the "patient's refusal to participate" as a significant barrier.

Survey results showed that older patients waived the consultation 50% of the time "sometimes", "often" or "always". Patients in the focus group mentioned that sometimes they felt embarrassed when the pharmacist "makes the long journey from behind the counter, around the corner to talk to me". Policy roundtable participants discussed how the design of consult spaces may affect senior comfort levels.

Pharmacy Setting: The Research Design of the Kaiser Permanente/USC Patient Consultation Study". Clinical Therapeutics, 17(6):1188-1206.

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**Pharmacist-Physician Communication**

Survey results reveal that nearly a third of the respondents spend between 10-25% of their time communicating with physicians. Focus group results indicated that this communication is inefficient at best: sending and receiving faxes, calling and leaving messages. Both pharmacists and physicians described frustration at communication with each other and shared the opinion that improvement was necessary in order to better deliver care.

**Communications Recommendations**

- **Develop an integrated, common message around the patient's right to a consult.** While multiple groups (e.g., state agencies, patient advocacy groups, pharmacist associations) have been working to improve patient education, the delivery is often through "pilot" projects limited to specific cities. A concerted statewide campaign, involving numerous stakeholders and multiple delivery methods, may improve education to both patients and physicians about the "patient's right" to a consultation and its clinical value.
- **Examine methods to improve communication between pharmacists and clinicians.** Outreach among stakeholders is vital to improving communication. Policy roundtable participants, particularly the California Medical Association and the California Pharmacists Association, spoke of the need for continued forums in order to work on communication issues and develop strategies to improve. Pharmacy and medical school curriculum can be improved to promote better communication and team efforts for delivering care.
- **Promote technology to reduce inefficiencies.** Policy roundtable participants considered the use of ePrescribing as a method of reducing the communication inefficiencies between pharmacists and physicians. Adoption of ePrescribing may simplify formulary complexities, as the physician could check prior to writing a prescription whether the medication is covered by the patient's insurance. ePrescribing built into an ambulatory computerized provider order entry system may also lead to reduced medication errors.[16]
- **Explore a process of patient follow-up that shares the results among the care team.** Currently certain pharmacies and physician offices use follow-up phone calls to patients regarding use and potential prescription side effects. Within a quality initiative, the sharing of the results between pharmacists and physicians, can improve communication among the three parties, promote coordinated care and improve compliance.

> One pharmacist noted that as the "last man on the totem pole", all of the consumer's frustrations came to him.

Center for Health Improvement

The Center for Health Improvement (CHI) is a national, nonprofit health policy center dedicated to improving population health and encouraging healthy behaviors.

This publication was funded in part by a grant from The California Wellness Foundation and supported by a grant from the California HealthCare Foundation.

**Patricia E. Powers, MPPA**
President and CEO

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Premier Pharmacists Network

# Agenda Item I

State of California | Department of Consumer Affairs

# Memorandum

To: Communication and Public Education Committee

Date: March 28, 2006

From: Virginia Herold

Subject: Miscellaneous Consumer Issues and Articles in the News

I am also 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.

**A Cancer Drug Shows Promise, at a Price That Many Can't Pay**
ALEX BERENSON
NY Times
February 15, 2006

Doctors are excited about the prospect of Avastin, a drug already widely used for colon cancer, as a crucial new treatment for breast and lung cancer, too. But doctors are cringing at the price the maker, Genentech, plans to charge for it: about $100,000 a year. That price, about double the current level as a colon cancer treatment, would raise Avastin to an annual cost typically found only for medicines used to treat rare diseases that affect small numbers of patients. But Avastin, already a billion-dollar drug, has a potential patient pool of hundreds of thousands of people — which is why analysts predict its United States sales could grow nearly sevenfold to $7 billion by 2009. Doctors, though, warn that some cancer patients are already being priced out of the Avastin market. Even some patients with insurance are thinking hard before agreeing to treatment, doctors say, because out-of-pocket co-payments for the drug could easily run $10,000 to $20,000 a year. Until now, drug makers have typically defended high prices by noting the cost of developing new medicines. But executives at Genentech and its majority owner, Roche, are now using a separate argument — citing the inherent value of life-sustaining therapies. If society wants the benefits, they say, it must be ready to spend more for treatments like Avastin and another of the company's cancer drugs, Herceptin, which sells for $40,000 a year....

http://www.nytimes.com/2006/02/15/business/15drug.html?_r=1&oref=slogin

**New Crisis Plans May Be Needed For Flu Pandemic**
ALLISON BISBEY COLTER
The Wall Street Journal
February 15, 2006

NEW YORK -- Many of the contingency plans Wall Street firms rely upon to stay in operation in the event of a natural disaster or terrorist attack may not be effective in the event of a flu pandemic, industry executives warn. In a global outbreak of a virulent strain of influenza, absenteeism would be extremely high, and supply chains could be disrupted as international borders are closed in an effort to contain the spread of the disease. Marjorie Gross, senior vice president and senior regulatory counsel of the Bond Market Association, said the global nature of the threat -- and the potential for social disruption and economic loss -- are in some ways similar to those posed by the threat of the Y2K computer bug. "If you spent a lot of time on Y2K, you should know more than we all do about avian flu," she said. Ms. Gross, who was speaking at the Bond Market Association's legal and compliance conference last week, said securities firms need to have contingency plans, not just for meeting the immediate needs of customers, but to be able to conduct business in a crisis that could last for several weeks.Panelists focused largely on the need to educate employees about the nature of the crisis and plan for and manage severe staffing shortages for an extended period of time. The U.S. government assumes that in a severe pandemic absenteeism due to illness, the need to care for family members or fear of infection could reach 40% during the peak weeks of outbreak, according to information posted on the Web site of the Centers for Disease Control and Prevention.....

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Public Ed

# Kaiser Daily Health Policy Report

**Thursday, January 19, 2006**

**Prescription Drugs**

## FDA Releases Revised Prescription Drug Inserts, Labels To Prevent Medication Errors

FDA on Wednesday issued a new rule that will require "major changes" to the design of package inserts for prescription drugs "with the hope of reducing errors in medication use," the *Washington Times* reports (Howard Price, *Washington Times*, 1/19). The current design of package inserts is "notoriously complicated," and "there is evidence that physicians don't always follow the labels' recommendations," the *Wall Street Journal* reports (Wilde Matthews, *Wall Street Journal*, 1/19). Under the rule, package inserts must include a new highlights section that summarizes the most important information required to ensure patient safety. The section must list safety warnings, summarize recent revisions to the warnings, provide information on how to use and dose the medication, and offer advice to physicians on instructions for patients (Harris, *New York Times*, 1/19). The section also must use "clear and concise" language, the Baltimore *Sun* reports (Rockoff, Baltimore *Sun*, 1/19). The rule also will require package inserts to include a table of contents, the initial date of FDA approval and a toll free number and online contact to allow patients to report adverse events (*Washington Times*, 1/19). In addition, diagrams of the chemical structures of medications and legal warnings will appear toward the end of package inserts (Bridges, *AP/Detroit Free Press*, 1/19). The rule, the first proposed revision to prescription drug packages in 25 years, will not affect the exterior of packages and will not require new information in the package inserts. Pharmaceutical companies must revise package inserts for new prescription drugs by June 30 and must revise the inserts for medications between one and five years old within seven years (Baltimore *Sun*, 1/19). New prescription drugs are those that reach the market after May 11 (*AP/Detroit Free Press*, 1/19).

**Liability Provision**

FDA in a preamble to the rule on package inserts said that product liability lawsuits against pharmaceutical companies should not proceed in state courts (Kaufman, *Washington Post*, 1/19). The provision states that FDA approval of prescription drug labels "pre-empts conflicting or contrary state law." The provision included specific cases in which pre-emption would apply but said the scope could extend to other cases. According to the provision, preemption also would apply in lawsuits filed against health care providers who do not inform patients about safety risks "beyond what is included in the label" (Won Tesoriero/Wilde Matthews, *Wall Street Journal*, 1/19). FDA officials said that, although the provision does not have legal or regulatory authority, they hope that state judges accept the pre-emption. Scott Gottlieb, deputy commissioner for medical and scientific affairs at FDA, said pharmaceutical company officials convinced the agency officials that they should receive more support because the rule on package inserts will make them more vulnerable to lawsuits (*Washington Post*, 1/19). Gottlieb said, "What we are saying is that if a sponsor brings us all their evidence, everything they know about a drug, and we decide what should and should not be included in the label based on our scientific review, then that federal process should have some merit in these 'failure to warn' cases in the state

courts" (Reichard, *CQ HealthBeat*, 1/18). Gottlieb added, "We think that if your company complies with the FDA processes ... you should not be second-guessed by state courts that don't have the same scientific knowledge" (*Washington Post*, 1/19). The "real impact" of the provision "will play out case by case," and pre-emption could "change the tactics of plaintiff lawyers and drug-industry defense attorneys," the *Journal* reports (Won Tesoriero/Wilde Matthews, *Wall Street Journal*, 1/19).

**Other Implications**

FDA officials said that advertisements for prescription drugs could change "considerably" as a result of the rule on package inserts, the *New York Times* reports. The detailed pages of small print included in magazine and newspaper ads "will most likely disappear," and new print ads likely will include "shorter, clearer statements about common drug risks," according to the *New York Times*. FDA officials said that television ads also might have to change how they discuss the safety risks of medications (*New York Times*, 1/19).

**Reaction**

The rule on package inserts was "widely applauded," but the liability provision "was quickly attacked by trial lawyers and members of Congress as another effort by the Bush administration to limit the public's ability to bring and win lawsuits," the *Post* reports (*Washington Post*, 1/19). Jonathan Moss, a medical professor at the University of Chicago, said, "The streamlining of package inserts will be very useful." However, Sidney Wolfe, director of the Health Research Group at Public Citizen, said, "Revisions released Wednesday will simplify and prioritize the labeling information that doctors receive. But the vast majority of patients will not get that information unless they specifically request it" (Gorner, *Chicago Tribune*, 1/19). In reference to the liability provision, Sen. Edward Kennedy (D-Mass.) said, "It's a typical abuse by the Bush administration -- take a regulation to improve the information that doctors and patients receive about prescription drugs and turn it into a protection against liability for the drug industry." Joy Johnson Wilson, health policy director for the National Conference of State Legislatures, said, "Where is the authority to pre-empt state law?" She added, "They put in this rule to make it look like it's settled law" (Timiraos, *Los Angeles Times*, 1/19). Ken Suggs, president of the Association of Trial Lawyers of America, said that the provision is "the scariest example yet of how much control these big corporations have over our political process" (*Washington Post*, 1/19). However, Alan Goldhammer, vice president of regulatory affairs for the Pharmaceutical Research and Manufacturers of America, said, "It is important that a pharmaceutical company's efforts to provide vital information in a useful format not be undone by 50 different sets of product liability laws, particularly after a label has undergone the detailed and thorough review and approval of the FDA after years of study by its experts and access to extensive clinical data" (Baltimore *Sun*, 1/19).

**Jan Perez**

02/23/2006 10:34 AM

To: joshua.room@doj.ca.gov, LaVonne Powell/EXEC/DCANotes@DCANotes, Virginia Herold/Pharmacy/DCANotes@DCANotes, Patricia Harris/Pharmacy/DCANotes@DCANotes
cc:
Subject: Press Clips - Thursday, February 23, 2006

**Program to recycle surplus medicine County to benefit from reduced drug costs**
Laura Ernde
San Mateo County Times
February 23, 2006

As much as $1 million worth of prescription drugs go to waste each year in San Mateo County because patients die or their medications are switched. But under a new program to be considered by the Board of Supervisors on Tuesday, at least some of those leftover drugs would be matched with needy patients. The San Mateo Medical Center would collect surplus drugs from patients of its 64-bed nursing home and dole them out to low-income hospital patients with valid prescriptions, said hospital spokesman Dave Hook. In crafting the program, San Mateo County would be the first county in the state to take advantage of a drug-recycling law authored by state Sen. Joe Simitian, D-Palo Alto. Santa Clara and Santa Cruz counties are considering similar programs based on the legislation, which allows any county in the state to start a drug-recycling program. ...If San Mateo County's pilot program is successful, the hospital will expand it to its Burlingame Long-term Care Center and eventually to private nursing homes in the county....Preventing people from flushing drugs down the toilet and ending up in the Bay is another issue San Mateo County officials have tried to tackle. Last year, the county collected 230 pounds of unwanted medications during a one-week voluntary drop-off program. The first regional drop-off program is being organized for the week of May 13, said Karin North, associate engineer for the City of Palo Alto. Prescription drugs are difficult to collect at hazardous waste sites because federal drug laws require police officers to handle any controlled substances. For that week, Bay Area governmental agencies will have police officers on hand to take controlled substances. All of the unused medications eventually will be incinerated, she said. North recommends that anyone who has prescription drugs to dispose of should hold onto them until the May collection.

http://www.insidebayarea.com/sanmateocountytimes/localnews/ci_3538136

**For Generics, Bumpy Road to Pharmacy**
By GARDINER HARRIS
NY Times
February 23, 2006

Public Ed

A generic version of Flonase, a popular allergy spray, was approved for sale by federal drug regulators Wednesday. The generic should be available within days, its maker said. Flonase is one of the most popular drugs in the world, with $1.14 billion in sales last year. Sales of branded drugs often tumble more than 90 percent within weeks of the introduction of a generic version. Officials at the Food and Drug Administration held a news conference to announce the generic's approval, the first such gathering for a decision about a generic drug in recent memory. The heightened attention may have been intended to rebut criticism in recent weeks that the agency is falling behind in its review of generic-drug applications. "The generic-drug program is very important to the F.D.A.," said Gary Buehler, director of the Office of Generic Drugs at the agency. The Bush administration has proposed no increase in the office's budget of $28 million for 2007, even though the number of generic drug applications more than doubled in the past five years, to 777 last year from 320 in 2001.....

http://www.nytimes.com/2006/02/23/health/23drug.html

**Medicare Enrolls 5.4 Million People For Drug Benefit**
WSJ - AP

**Purdue students track patient interventions**
Carol Ukens
Drug Topics
Feb 6, 2006

A quartet of Pharm.D. candidates from the Purdue University School of Pharmacy and Pharmaceutical Sciences is tracking interventions during clerkship rotations, with an eye to gauging the impact of student recommendations in reducing medication errors and improving patient care. Using their computers or PDAs, students in clerkships are encouraged to input the details of their patient interventions to a central database in the medication intervention tracking program that began last July and will continue through the end of this month. Seniors Tia Cooper, Karishma Deodhar, Emily Hutchinson, and Todd Walroth are overseeing the project under the direction of Brian Shepler, Pharm.D., clinical assistant professor of pharmacy practice and director of experiential learning. The 170 Purdue students in rotations this year are asked to fill out an on-line form asking the age of the patient, the types of drugs involved, and whether the intervention prevented or corrected an error. When an error is suspected, the student contacts the physician to see whether the order can be modified. The form also asks if the physician accepted the recommendation, accepted it with modifications, accepted but delayed it, or rejected it. As of last November, 560 student interventions, including those from a clerkship site in Kenya, had been logged into the database, according to Shepler, who came up with the idea. Student recommendations were accepted by physicians 70% of the time. The most frequent interventions included changing the drug dose, initiating drug therapy, discontinuing the drug, or changing the frequency of administration. "The reason this project is so important is that the public thinks the pharmacist behind the counter is only dispensing medications," said Shepler. "We're hoping we can show that pharmacy students are making interventions, making a difference, and saving money. It will also help us recruit more clerkship sites to take future students." The intervention tracking program took the four students to Las Vegas last December for a poster presentation at ASHP's annual Midyear Clinical Meeting. "We spoke with many pharmacists who were interested in the results of our program as well as the methods used to obtain the data," they said in a joint statement. "This has been a great learning experience for us. It's been interesting to see the positive response clinicians are having to student interventions. Our aim is to pave the way for future pharmacy students, fostering an interprofessional commitment to patient care."

Public ed

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**Take Your Pills, All Your Pills**
ANDREW POLLACK
NY Times
March 11, 2006

Joseph A. Brocato's weekly self-injections of a drug to treat hepatitis C left him so feverish and fatigued, he said, he often thought of quitting. He didn't, thanks to a nurse who urged him by phone to stay the course. The nurse, Colleen Dinsdale, did not work for Mr. Brocato's doctor. Rather, Ms. Dinsdale was paid by the drug's maker, Roche, and its distributor, McKesson. Each month that Mr. Brocato took the drug, Pegasys, and its companion pill, ribavirin, meant $3,000 in sales — most of it paid by his insurance company. His share was a $50 co-payment. The take-your-medicine program is part of a sales and marketing strategy that is gaining urgency for drug makers experiencing slowing sales. As it turns out, the industry leaves billions of dollars on the table — or the pharmacy shelves — annually because people do not take their drugs as often or as long as prescribed. ...Stimulating sales this way is the focus of other industry initiatives, including television advertisements like one by AstraZeneca in which a doctor asks a series of patients if they are taking their Toprol-XL hypertension pills daily. "You can't forget," the doctor gently scolds. "High blood pressure can make your heart work harder than it should, every day." Lending credence to such efforts are many studies showing that failure to take medicines as prescribed can cause patients to develop more serious and costly complications later. So as industry tactics like wining and dining doctors draw scrutiny, spurring people to take their pills is a less controversial way to increase sales, one that the industry says is in the best interests of patients and insurers. Still, the efforts are not without detractors. Some medical experts worry about consumers' privacy or the possibility of undermining doctor-patient relations. There are also questions about the industry's motives. "They're about brand loyalty and not about public health," said Dr. Jerry Avorn, a professor at Harvard Medical School and the author of "Powerful Medicines," a book critical of pharmaceutical marketing and regulation. ...The World Health Organization, in a report in 2003, called noncompliance a "worldwide problem of striking magnitude." It estimated that in developed nations, half of patients did not take medicines for chronic diseases in the prescribed manner. Insurance companies have their own programs to get customers to take their medicine. But it is the drug companies that feel the most direct impact when patients fail to finish or renew prescriptions....

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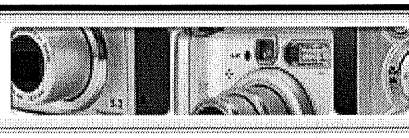
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# Is Business Ready for a Flu Pandemic?

By ELISABETH ROSENTHAL and KEITH BRADSHER
Published: March 16, 2006

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ROME — Governments worldwide have spent billions planning for a potential influenza pandemic: buying medicines, running disaster drills, developing strategies for tighter border controls. But one piece of the plan may be missing: the ability of corporations to continue to provide vital services.

Airlines, for instance, would have to fly health experts around the world and overnight couriers would have to rush medical supplies to the front lines. Banks would need to ensure that computer systems continued to move money internationally and that local customers could get cash. News outlets would have to keep broadcasting so people could get information that might mean the difference between life and death.

"I tell companies to use their imagination to think of all the unintended consequences," said Mark Layton, global leader for enterprise risk services at Deloitte & Touche in New York. "Will suppliers be able to deliver goods? How about services they've outsourced — are they still reliable?"

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Experts say that many essential functions would have to continue despite the likelihood of a depleted work force and more limited transportation. Up to 40 percent of employees could be sick at one time.

Indeed, the return of the bird migration season has touched off new worries over how a serious outbreak could interrupt business in many parts of the world simultaneously, perhaps for months on end.

The World Health Organization has confirmed 173 cases of the avian flu virus in humans, most of whom had close contact with diseased birds. Of those, 93 people died, almost all of them in Asia. Vietnam has been particularly hard hit. In January, though, the first human cases were confirmed in Turkey — far from the origin of the virus in central China.

And in recent weeks, officials in several European and African countries have confirmed the virus in wild or domestic flocks of birds. While avian influenza does not now readily infect humans or spread among them, scientists are worried that the virus could soon acquire that ability through normal biological mixing, setting off a human pandemic.

Yet despite this threat, many companies have only rudimentary contingency plans in place. In a survey of more than 100 executives in the United States by Deloitte & Touche, released this January, two-thirds said their companies had not yet prepared adequately for avian flu, and most had no one specifically in charge of such a plan.

"Business is not prepared for even a moderate avian flu epidemic," the report concluded.

In contrast, corporations in Southeast Asia have made more headway, in part because the avian influenza virus has been circulating in birds in Asia for years. Also, Asian companies learned in the 2003 outbreak of Sudden Acute Respiratory Syndrome, or SARS, that even a small infectious outbreak could have devastating consequences,

**What transpired between George Clooney and Post?**

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bringing commerce in Hong Kong, Singapore and Beijing to a near standstill.

A recent survey of 80 corporate officials at an avian flu seminar held by the American Chamber of Commerce in Hong Kong found that nearly every company had someone in charge of avian flu policy, and 60 percent had clearly stated plans that could be put in place immediately. These included provisions for employees to work at home to prevent the spread of disease in the office, and for relaying warnings to workers by text messages to mobile phones.

The lack of corporate preparedness elsewhere has "enormous implications," the Deloitte report said.

"A pandemic flu outbreak in any part of the world would potentially cripple supply chains, dramatically reduce available labor pools," the report said. "In a world where the global supply chain and real-time inventories determine most everything we do, down to the food available for purchase in our grocery stores, one begins to understand the importance of advanced planning."

Among the prepared, HSBC, a global bank that started as the Hongkong and Shanghai Bank and remains the dominant bank in Hong Kong, has an especially detailed plan for avian flu, drawing on its experience with SARS. The company has been making preparations for employees to work from home, but is also preparing to divide work among multiple sites, an approach that appeared in only 37 percent of the plans in the American Chamber survey.

The hope is that if the flu races through the staff at one site, another site may be spared. During SARS, the bank activated an emergency center at the opposite end of Hong Kong's harbor and sent 50 bond traders there with instructions that they were not to see anyone from the head office even at social occasions.

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*Elisabeth Rosenthal reported from Rome for this article, and Keith Bradsher from Hong Kong.*

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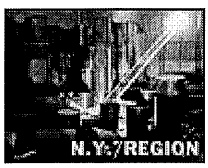


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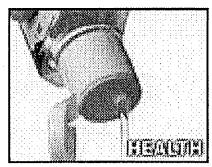


Hand Sanitizers, Good or Bad?

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Public Ed

**This Site Knows a Cold Isn't a Rock Band**
By BOB TEDESCHI
NY times
January 23, 2006

HYPOCHONDRIACS of the world, rejoice: a new Web site, Healthline.com, could make it easier to identify whatever doesn't ail you. The core mission of the Web site, which is owned by Healthline Networks, is to act as a medical search engine, finding articles on ailments and remedies from some 66,000 Web sites it has identified as providing medical content. In doing so, Healthline says it offers consumers a broader choice of information than WebMD, which is by far the most popular single medical resource online, and a more refined choice than general search engines like Google. For consumers, looking for health and medical information is one of the most common - and frustrating - searches on the Web, as they must navigate through pages of miracle cures, dubious claims and offshore pharmaceuticals. According to a study last year by the Pew Internet and American Life Project, a nonprofit research group, 80 percent of Internet users in the United States have surfed the Web for health-related information. Healthline.com hopes to narrow their searching. Type "cold" into Google, for instance, and the site displays links to information on everything from nasal maladies to Cold, the rock band. Do the same thing on WebMD, and the site will post many links, but only to its own content. Type "cold" into Healthline's search box, by contrast, and the site presents you with a map of different respiratory diseases and disorders, along with a list of links to Web sites with information - but not commercial products - related to those disorders. (The site runs advertising for commercial products and services only in its own space.) ....Healthline is also hoping for good word-of-mouth marketing. Mr. Shell noted that many people search for medical articles or advice on behalf of a friend or a family member, and end up passing that information along. "People want to leave breadcrumbs for those behind them," he said. "Health is a viral category."

http://www.nytimes.com/2006/01/23/technology/23ecom.html?pagewanted=print

**Studies Identify Why Avian Flu Not Spreading Among Humans**
CA Healthline
March 24, 2006

Studies conducted by two separate groups of researchers have found that the avian flu virus attaches deep within the human respiratory tract, which prevents the spread of the virus through coughs and sneezes and indicates "why the bird flu is not spreading easily from person to person," the Washington Times reports (Howard Price, Washington Times, 3/23). The studies "suggest that the virus could acquire" the ability to spread among humans by "switching its preference from the cell receptor found in the lower lung, known as alpha 2-3, to the receptor found on cells in the upper airways, known as alpha 2-6," the New York Times reports. According to Yoshihiro Kawaoka -- a virologist at the University of Wisconsin at Madison and lead author of one of the studies, which was published on Thursday in the journal Nature -- the avian flu virus would have to undergo many mutations before the virus could cause a pandemic. The second study, which was led by Thijs Kuiken at the Erasmus Medical Center in the Netherlands and appears this week in the journal Science, found similar results. (Wade, New York Times, 3/23). Kawaoka said the studies do not eliminate the possibility of an avian flu pandemic. He said, "Flu viruses constantly change. Certainly, multiple mutations need to be accumulated for the H5N1 virus to become a pandemic strain" (Washington Times, 3/23). Nikki Shindo, an influenza expert at the World Health Organization, questioned the conclusions of the studies. Shindo said, "I don't think it directly affects the transmissibility just because it's in the lower respiratory tract" (Regalado, Wall Street Journal, 3/23). An abstract of the Nature study is available online.

http://www.californiahealthline.org/track/url.cfm?u=35561&rurl=www%2Ecaliforniahealthline%2Eorg%2Findex%2Ecfm%3FAction%3DdspItem%26itemID%3D119631%26classCD%3DCL351

**Jan Perez**

03/14/2006 10:28 AM

To: joshua.room@doj.ca.gov, LaVonne Powell/EXEC/DCANotes@DCANotes, Virginia Herold/Pharmacy/DCANotes@DCANotes, Patricia Harris/Pharmacy/DCANotes@DCANotes
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**Suspicious Death Illegal Prescription Drugs**
San Diego Headline News
3-12-06

SAN DIEGO, CA A twenty-one year old woman is dead and police are looking into the sale of illegal prescription drugs as the possible cause. The woman was apparently suffering from flu-like symptoms. Her family reportedly went to a produce market on the 1000 block of 25th Street that they say told investigators they knew sold prescription drugs without a prescription. Shortly after being injected with the medication the woman went into medical distress then died. In an undercover operation, officials purchased drugs from the store. Authorities are continuing to investigate the circumstances surrounding the woman's death.

http://www.primenews.com/sdhn_031206_suspicious.html

**Customs Apology on Drug Seizures, The agency should have warned of a crackdown on importing medicines, an administrator says.**
Lisa Girion
LA Times
March 14, 2006

A customs administrator apologized Monday for not warning consumers that the agency was cracking down on the shipping of prescription drugs from foreign discount pharmacies. "I'm sorry that we didn't do a better job maybe announcing that we were implementing this," said Vera Adams, executive director of trade enforcement for U.S. Customs and Border Protection. But, she added, "I will never apologize for trying to protect the American public."...Drawing an estimated 2 million customers seeking relief from soaring U.S. pharmaceutical prices, the mail-order drug business, based largely in Canada, has grown into $1-billion market. Since the crackdown began, the agency has notified 12,735 consumers that their packages were stopped — medications in most cases for seniors with heart and other chronic conditions....Canadian pharmacies have said that as many as 5% of all shipments are being stopped, an increase from less than 1% in the past.

http://www.latimes.com/business/la-fi-seize14mar14,1,5247407.story?coll=la-headlines-business

**FDA joins e-mail counterfeit drug alert service**
Pharmatechnologist.com
13/03/2006

The US Food and Drug Administration (FDA) has linked its Counterfeit Alert Network (CAN) to SafeMeds Alert System, an electronic mailing list backed by pharmaceutical manufacturers that sends warnings about fake drugs to anyone who signs up, significantly increasing public awareness and cracking down on fraud. Previously the CAN was only available to key stakeholders, like health care providers and big pharma, so this partnership will make an important difference in the dissemination of information on counterfeit drugs. Around 10 per cent of all prescription drugs are forgeries according to the World Health Organisation (WHO), and the FDA estimates that 1 per cent of the drugs in the US are counterfeit, leading to 35 million prescriptions filled with something else other than the supposed drug. Liability issues, consumer confidence, and brand erosion costs are driving pharmaceutical manufacturers to seek new approaches to combat this growing global problem. To tackle the issue, which not just jeopardises the health of patients but also damages manufacturers financially, many US pharma and biotech companies

are supporting, through their trade organisations, the Partnership for Safe Medicines, a coalition of patient, physician, pharmacist, university, industry and other professional agencies determined to consumers against unapproved, counterfeit, substandard, mishandled or otherwise unsafe medicines. The Partnership has now secured the FDA's collaboration to its electronic alert service so that anyone who signs up with just their name and e-mail address will receive alerts as soon as the FDA or other health agencies announce them. The free counterfeit electronic alert service is available at http://www.safemedicines.org

http://www.in-pharmatechnologist.com/news/ng.asp?n=66396-fda-partnership-for-safe-medi-counterfeit-drugs-who-counterfeit-alert-network

**Medical School Addresses Disparities in Pain Treatment**
CA Healthline
March 14, 2006

Professors at the University of California-Davis School of Medicine are trying to get their third-year students to think differently about pain management through role-playing exercises in response to studies that have found racial disparities in care, the Sacramento Bee reports. According to UC-Los Angeles studies, white patients with broken arms or legs, on average, receive pain medication more often than Latinos or blacks with the same injuries. The Bee reports that UC-Davis faculty want to redress "the influence of the 'medical culture' on attitudes about patients" by "allowing students to explore their role in perpetuating those attitudes" (Griffith, Sacramento Bee, 3/12).

http://www.sacbee.com/content/news/medical/story/14229399p-15052529c.html

**Drug Ads Focus More on Diseases, Less on Brands**
WSJ - Associated Press
March 14, 2006

NEW YORK -- Facing a furor over its advertising practices and the potential of more government regulation, the pharmaceutical industry adopted voluntary guidelines in January to improve the accuracy and balance of ads so the severity of diseases and the side effects of drugs aren't whitewashed. The guidelines, announced last summer, have already sparked changes: Spending on brand advertising is flat while disease awareness campaigns are flourishing. The look of the ads are more straightforward; doctors bluntly describing products is becoming de rigueur. The possibility of more government regulation looms. Late last year, the Food and Drug Administration held two days of public hearings on drug advertising and is now reviewing comments on the subject. The FDA said it is too early to say whether any new rules will be instituted, but some say it is likely. "Whenever there is a public hearing, it is a sign that change is coming," said Gary Messplay, a lawyer who represents drug companies. While Mr. Messplay praised the guidelines, he said they were "a little too little, a little too late." Only 18% of consumers believe pharmaceutical ads can be trusted "most of the time," according to a study released last year by the Kaiser Family Foundation. That is down by almost half since 1997, when one-third of people surveyed said you could trust ads most of the time.

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## How We Pay for Health Care
## Keeping the right drugs in seniors' hands

- Spyros Andreopoulos
Tuesday, November 29, 2005

Medicare's new prescription drug insurance coverage will start next month. The program, offered through private insurance companies rather than by the government directly, has been received with complaints about its confusing provisions.

But the new benefit brings into focus two unpublicized issues: inappropriate prescribing for seniors and importation of counterfeit drugs. The first must be addressed by the medical profession. The second must be tackled by government and the pharmaceutical industry, because under the new law's puzzling provisions, counterfeits could easily slip into seniors' medicine cabinets.

Prescribing for seniors is problematic because older people often suffer from multiple chronic conditions and confront age-related physiological changes. Doctors also face challenges in prescribing, because many drugs are not tested in older adults and no concise guidelines exist for the effective, safe use of pharmaceuticals in elderly patients, in spite of evidence that seniors are receiving too many medicines or the wrong drugs.

For example, the medical journal Annals of Internal Medicine published criteria in 1991 for identifying drugs that should be avoided in the elderly. The criteria were updated by an expert panel in 2003 and used to study prescribing in elderly patients in nursing homes, hospitals and doctors' offices. The prevalence of inappropriate prescribing, the researchers found, was in the range of 21 percent and 40 percent in outpatient clinics and doctors' offices and in nursing homes, respectively.

A 2003 study by Medco Health Solutions, a pharmacy services company, found 7.9 million prescription errors, based on an analysis of 6.3 million seniors. The error rate had more than doubled since Medco's earlier study in 1999. Mistakes included excessive dosages, prescriptions that would interact badly with other drugs and improper treatments.

A number of measures could improve prescribing for seniors. They include more research on elderly populations by pharmaceutical companies during clinical trials, making hospitals and medical organizations more responsible for defining appropriate prescribing criteria for seniors as a requirement of accreditation and prevailing on medical schools to encourage more training in geriatric medicine.

The second problem -- importation of counterfeit drugs -- presents a different challenge. According to estimates from federal officials, some 20 million packages of pharmaceutical products enter the United States each year. Of these, 14 percent are fake. The United States is a prime target for the sale of fake pharmaceuticals because of the potential for huge profits.

Counterfeiters can obtain raw materials easily and keep their production costs low. According to a 2003 article in the Journal of Law and Medicine, counterfeiters may make as much as 2,000 percent profit by taking advantage of lax drug re-importation laws and selling the fake drug at the brand name's price. The fakes include generics, drugs whose patents have expired and serve as a cheaper alternative to brand-name drugs. Fake drugs generally look like legitimate drugs and are hard to detect. The Food and Drug Administration has found counterfeit medicines with inactive, subpotent or superpotent ingredients or impurities harmful to patients. Some fakes have involved high-volume statins prescribed to reduce high cholesterol, drugs for AIDS and antidepressants. Pfizer, for example, recently warned pharmacists of a widespread distribution of unauthorized Lipitor, its cholesterol-lowering drug. The World Health Organization has identified China, India and South Asian countries as at the center of the counterfeit pharmaceutical trade. But the synthesis, packaging and sale of these drugs involve other countries, including Italy, Argentina, Mexico, Nigeria and Greece.

The rise of smaller wholesalers in the distribution chain and Internet pharmacies add to the problem. In 2002, authorities uncovered a fake-Viagra distribution ring, which linked Chinese factories to Internet vendors in Nevada and Colorado. Three years ago, the United States and Canada, working with authorities in Thailand, closed several Thai Web sites selling fake steroids, tranquilizers and other drugs to American consumers.

The FDA is looking at strategies for countering illegal imports. But critics say the agency is too underfunded to stem the tide of fake pharmaceuticals. Congress has tried to combat fakes by addressing issues of intellectual property rights and patent infringement. But such measures have proved unenforceable.

Many had hoped Congress would pass a drug bill that strengthened Medicare and added affordable drug coverage by containing costs. But rather than making enrollment simple through existing Medicare and giving the program authority to negotiate prices, Congress created a complex system that ensures that the estimated $700 billion to be spent on the program over the next 10 years goes to the insurance industry. This guarantees continued high drug prices, which tempt private-plan operators -- eyeing profit margins -- to shift from brand-name drugs to cheaper alternatives, paving the way for counterfeits to slip through the system.

Counterfeiting, some experts believe, is on the rise because brand-name pharmaceuticals in the United States are too expensive. The problem stems from industry pricing practices of overcharging Americans in order to support worldwide markets with lower prices. Unless pharmaceutical companies stop forcing on American consumers an unfair system, the counterfeit imports will continue to fill the price gap and thrive -- even more so when the government foots the bill.

*Spyros Andreopoulos is director emeritus of the Office of Communication and Public Affairs at Stanford University School of Medicine. This article reflects his opinion alone.*

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# Agenda Item J

State of California | Department of Consumer Affairs

# Memorandum

To: Communication and Public Education Committee

Date: March 28, 2006

From: Virginia Herold

Subject: Public Outreach Activities

The board strives to provide information to licensees and the public. To this end, it 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.

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 February 2006 report to the board that have been reported:

- Executive Officer Harris participated as a speaker during the Federation of Associations of Regulatory Boards annual meeting in early February, as part of a panel discussion on "Board Governance: A Panel Discussion on the Pros and Cons of Different Board Structures" on February 3. She also participated in a panel discussion on February 5 on alternative enforcement models.
- Executive Officer Harris and Analyst Sue Durst staffed an information booth at the San Diego Consumer Protection Day fair on February 3; approximately 1,500 people attended.
- Supervising Inspector Nurse provided a PowerPoint presentation via teleconference to an FDA Counterfeiting Task Force in Bethesda, MD, on February 9.
- The board staffed an information booth at the CPhA Outlook Meeting on February 17 and 18.
- Supervising Inspector Ming and Exam Analyst Debbie Anderson provided law and examination information to 80 Western Pharmacy School students on February 24.
- Supervising Inspector Ratcliff provided information about pharmacy law to 125 students at UCSF on February 28.

Future Presentations:

- Board Member Ruth Conroy will speak to 50 Touro University pharmacy students on board legislative issues on March 31, as preparation for their Legislative Day in April.
- Supervising Inspector Ming will present law review information to UCSF's 4th year students on April 7.
- Executive Officer Harris will be a speaker at the Department of Consumer Affairs Senior Summit on May 12 in Sacramento. Her topic is "Protecting and Serving California's Aging Population.
- Exam Analyst Debbie Anderson will provide information about examination application to Loma Linda University's pharmacy students in mid May.