California State Board of Pharmacy
400 R Street, Suite 4070, Sacramento, CA 95814
Phone (916) 445-5014
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STATE AND CONSUMER SERVICES AGENCY
DEPARTMENT OF CONSUMER AFFAIRS
ARNOLD SCHWARZENEGGER, GOVERNOR

NOTICE OF MEETING and AGENDA
Communication and Public Education Committee

Contact Person: Virginia Herold
(916) 445-5014

Time: 2 p.m. – 5 p.m.
Date: March 22, 2005
Place: Department of Consumer Affairs
400 R Street, Suite 4080, Sacramento, CA 95814

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) 445-5014, at least five working days before the meeting. Candy Place can also 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

A. Call to Order 2 p.m.

B. Update on the Development of Consumer Fact Sheet Series with UCSF's Center for Consumer Self Care

C. Update on the Activities of the California Health Communication Partnerships

D. Update Report of *The Script*

E. Update Report of *Health Notes*

F. Redesign of the Board's Web Site

G. Center for Health Improvement: Pending Survey to Study the Impact of the Patient Consultation Mandate on Older Californians

H. White Paper Report of the Pharmaceutical Printed Literature Association

I. Initiation of the California Health Policy Forum

J. Miscellaneous Consumer Issues/Articles in the Media

K. Update on the Board's Public Outreach Activities

L. Adjournment 5 p.m.

Meeting materials will be on the board's Web site by March 16, 2005

Agenda Item B

State of California Department of Consumer Affairs

Memorandum

To: **Communication and Public Education Committee** **Date: March 14, 2005**

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

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

At the April 2004 Board Meeting, the board approved a proposal by the committee to integrate pharmacy students into public outreach activities. The project chosen was the development of a consumer fact sheet by student interns. This project is being coordinated by the UCSF Center for Consumer Self Care under the direction of R. William Soller, Ph.D.

All the fact sheets will address consumer issues involving questions to "Ask a pharmacist" about, so that consumers can make informed decisions about their medications and medications and issues in the news.

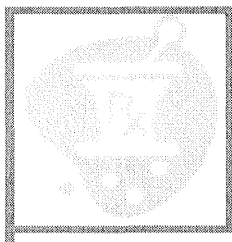
At the last meeting of the committee, a prototype format for the fact sheets was reviewed as were the first three fact sheets prepared -- "Lower Your Drug Costs to Help you Keep on Taking your Medicines," "Antibiotics – A National Treasure," and "Is Your Medicine in the News?" The fact sheets contain general information on the topic, but then contain questions consumers can discuss with their pharmacists on making wise decisions in the subject area. Copies of these fact sheets follow this page.

Dr. Soller recently provided a copy of "Generic Drugs... Real Medicines at High Quality, Low Cost" for the committee's review at this meeting.

I am also enclosing additional materials from the FDA on generics. The FDA does not promote generic drugs based on lower cost.

The goal is to develop three fact sheets per quarter. Dr. Soller plans on getting additional fact sheets to the committee in advance of the meeting. As I prepare this memorandum, I do not yet have them.

Cost estimates are being prepared for the translation of these fact sheets into different languages. After one year and 12 fact sheets, the Communication and Public Education Committee and the Center for Consumer Self Care will reevaluate the project.



Lower Your Drug Costs

To Help You 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 of us living on fixed incomes, such as Seniors.

A recent study found that 25% of Seniors reduced or stopped their medicines if they use up their yearly drug benefit 2 ½ to 6 months before the end of the year.

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

1. **Ask your pharmacist for help.** Your pharmacist can work with your doctor to safely cut your drug costs.

2. **With your pharmacist, get the answers to these questions.**
   - Can I get my medicine in generic form?
   - Is there another less costly older drug in the same class that can be used as safely for my condition?
   - Does my doctor have free samples that I can take?
   - Does my pharmacy offer mail order, so I can get a lower cost 90-day supply of my medicine?
   - Does my pharmacy offer a discount plan for Seniors?
   - Does the drug manufacturer offer discounts or coupons on my medicine?
   - Will my doctor prescribe a higher dosage, so I can use a pill cutter to cut the pill in half?
   - Do I really need the medicine? Do NOT decide this by yourself. Check with your doctor and pharmacist.

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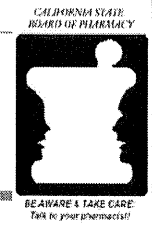

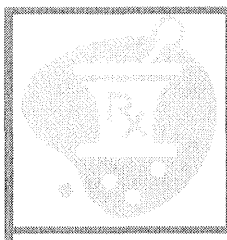

Is Your Medicine In the News?

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 medicines.

It is not a surprise that a new safety problem may arise with a medicine. When a 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 side effects found in about 1% or more of patients are 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 e-mail.
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 you 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 1-3 months to review what we've decided and see how I am doing?

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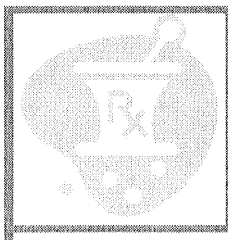

Antibiotics - *a National Treasure*

FACT: If medicines called antibiotics are not used properly or used when they are not needed, bacteria can mutate and develop resistance to the antibiotics. Then these medicines may no longer help us.

FACT: This is a big problem, and is a major public health threat within hospitals and communities — wherever antibiotics are used.

FACT: Antibiotics ***only*** work against infections caused by bacteria, ***not*** infections caused by viruses.

FACT: Illnesses that are caused by viruses are: colds, flu (or influenza). An illness caused by bacteria is strep throat.

FACT: Public health officials are asking us all to know when antibiotics work, and to know when and how to use them.

In which illness	*are antibiotics needed ?*
Cold	**No**
Flu	**No**
Chest cold (in otherwise healthy children & adults)	**No**
Sore Throats (except strep throat)	**No**
Bronchitis (in otherwise healthy children & adults)	**No**
Runny Nose (with clear discharge)*	**No**
Fluid in Middle Ear (otitis media with effusion)	**No**

(From Centers for Disease Control)

* discharge from a runny nose due to colds or flu will often turn from a clear/neutral color to yellowish as the cold is resolving. If a greenish or yellowish discharge from your nose persists, see your doctor.

What You Can Do to Help Check Antibiotic Resistance?

- Don't insist on an antibiotic when your doctor says one is not right for you. Ask how to relieve your symptoms.
- Do not take an antibiotic for a viral infection such as a cold, a cough, or the flu.
- Take medicine exactly as your health-care provider tells you. If he or she prescribes an antibiotic, take it all until it is gone, even if you're feeling better.
- Don't take leftover antibiotics, and don't take antibiotics prescribed for someone else. These antibiotics may not be right for your current symptoms. Taking the wrong medicine could delay getting the right medicine and may allow bacteria to grow.

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

...But they may cost less!

Generic drugs cost less than brand name drugs. The U.S. Food and Drug Administration (FDA) says, if people use generic drugs, they may save up to15% in drug costs.

Their quality is ensured by 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.
- A generic drug must have the same active drug ingredient and the same strength and quality as the brand name drug.
- FDA inspects the factories of generic drug companies.
- FDA decides whether generic drugs are safe and high quality before they are sold in the USA.

Ask Your Pharmacist!

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CALIFORNIA STATE BOARD OF PHARMACY

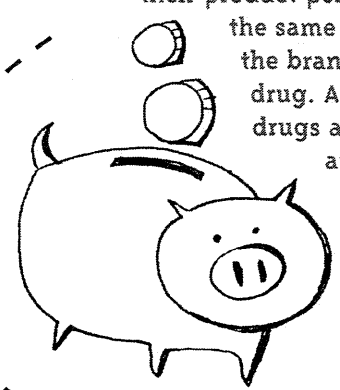
BE AWARE & TAKE CARE:
Talk to your pharmacist!

FACT DO GENERIC DRUGS TAKE LONGER TO WORK IN THE BODY?

No. Generic drugs work in the same way and in the same amount of time as brand-name drugs.

FACT WHY ARE GENERIC DRUGS LESS EXPENSIVE?

Creating a drug costs lots of money. Since generic drug makers do not develop a drug from scratch, the costs to bring the drug to market are less. But they must show that their product performs in the same way as the brand-name drug. All generic drugs are approved by FDA.



Your medication guide should be kept with you and up to date. List your prescription and over-the-counter medicines as well as your dietary supplements.

Name of my medicine	How much do I take?	When do I take it?	What do I use it for?
xxxx (Example)	1 Tablet 400 mg	Morning	Arthritis

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration FDA

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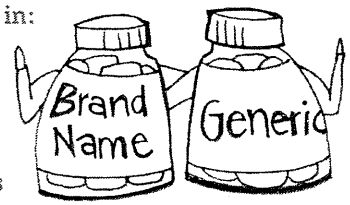
FACTS ABOUT GENERIC DRUGS

FDA FOOD AND DRUG ADMINISTRATION

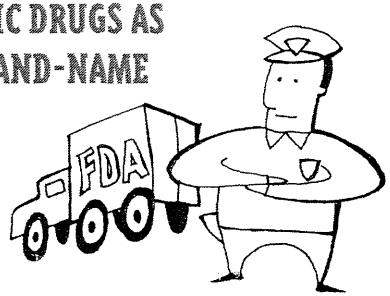
FACT WHAT ARE GENERIC DRUGS?

A generic drug is the same as a brand-name drug in:

- dosage
- safety
- strength
- quality
- the way it works
- the way it is taken
- the way it should be used

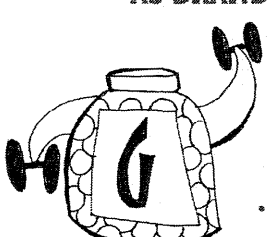


FACT ARE GENERIC DRUGS AS SAFE AS BRAND-NAME DRUGS?



Yes. The FDA says that all drugs must work well and be safe. Generic drugs use the same active ingredients as brand-name drugs and work the same way. So they have the same risks and benefits as the brand-name drugs.

FACT ARE GENERIC DRUGS AS STRONG AS BRAND-NAME DRUGS?

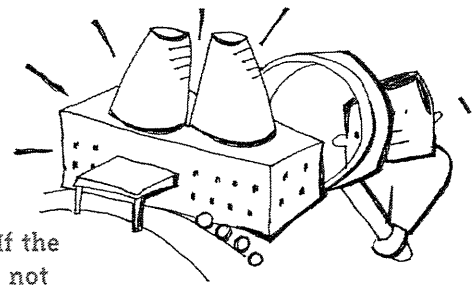


Yes. FDA requires generic drugs must be as:

- high quality
- strong
- pure, and
- stable

as brand-name drugs

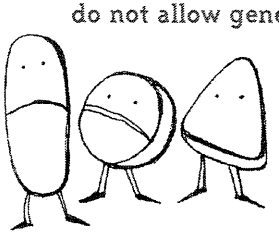
FACT ARE BRAND-NAME DRUGS MADE IN BETTER FACTORIES THAN GENERIC DRUGS?



No. All factories must meet the same high standards. If the factories do not meet certain standards, the FDA won't allow them to make drugs.

FACT IF BRAND-NAME DRUGS AND GENERIC DRUGS HAVE THE SAME ACTIVE INGREDIENTS, WHY DO THEY LOOK DIFFERENT?

In the United States, trademark laws do not allow generic drugs to look exactly like the brand-name drug. However, the generic drug must have the same active ingredients.

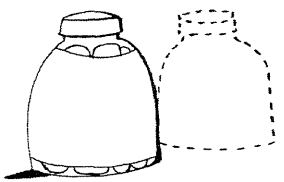


Colors, flavors, and certain other parts may be different. But these things don't affect the way the drug works and they are looked at by FDA.

Generic Drugs:
Safe. Effective. FDA Approved.

FACT DOES EVERY BRAND-NAME DRUG HAVE A GENERIC DRUG?

No. When new drugs are first made they have drug patents. Most drug patents are protected for 17 years. The patent protects the company that made the drug first. The patent doesn't allow anyone else to make and sell the drug. When the patent expires, other drug companies can start selling the generic version of the drug. But, first, they must test the drug and the FDA must approve it.



FACT WHAT IS THE BEST SOURCE OF INFORMATION ABOUT GENERIC DRUGS?

Contact your doctor, pharmacist or other healthcare worker for information on your generic drugs. For more information, you can also visit the FDA website at: http://www.fda.gov/cder and click on Consumer Education.

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

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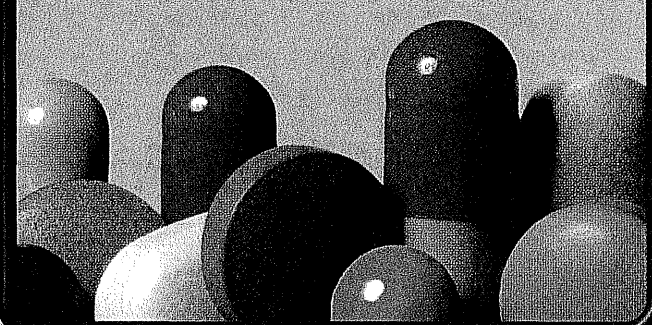
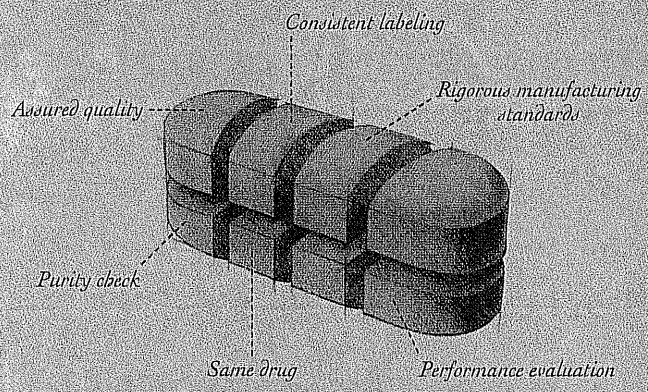
DHHS Publication No. (FDA) 02-3243

You know the questions that go through your mind when you take your generic drug?

Here are the answers.



What is a generic drug?



When a brand-name drug's patent protection expires, generic versions of the drug can be approved for sale. The generic version works like the brand-name drug in dosage, strength, performance and use, and must meet the same quality and safety standards. All generic drugs must be reviewed and approved by FDA.

How does FDA ensure that my generic drug is as safe and effective as the brand-name drug?

All generic drugs are put through a rigorous, multi-step review process that includes a review of scientific data on the generic drug's ingredients and performance. FDA also conducts periodic inspections of the manufacturing plant, and monitors drug quality—even after the generic drug has been approved.

If generic drugs and brand-name drugs have the same active ingredients, why do they look different?

Generic drugs look different because certain inactive ingredients, such as colors and flavorings, may be different. These ingredients do not affect the performance, safety or effectiveness of the generic drug. They look different because trademark laws in the U.S. do not allow a generic drug to look exactly like other drugs already on the market.

Is my generic drug made by the same company that makes the brand-name drug?

It is possible. Brand-name firms are responsible for manufacturing approximately 50 percent of generic drugs.

Are generic drugs always made in the same kind of facilities as brand-name drugs?

Yes. All generic drug manufacturing facilities must meet FDA's standards of good manufacturing practices. FDA will not permit drugs to be made in substandard facilities. FDA conducts about 3,500 inspections a year to ensure standards are met.

FDA makes it tough to become a generic drug in America so you can feel confident about taking your generic drugs. If you still want to learn more, talk with your doctor, pharmacist or other health care professional. Or call **1-888-INFO-FDA** or visit **www.fda.gov/cder** today.

U.S. Food and Drug Administration

Generic Drugs: Safe. Effective. FDA Approved.

To make sure your generic drug meets your approval, it first has to get ours.

When FDA approves your generic drugs, it ensures they are safe and effective. All generic drugs are put through a rigorous, multi-step approval process. From quality and performance to manufacturing and labeling, everything must meet FDA's high standards. We make it tough to become a generic drug in America so it's easy for you to feel confident. Visit www.fda.gov/cder/ or call 1-888-INFO-FDA to learn more.

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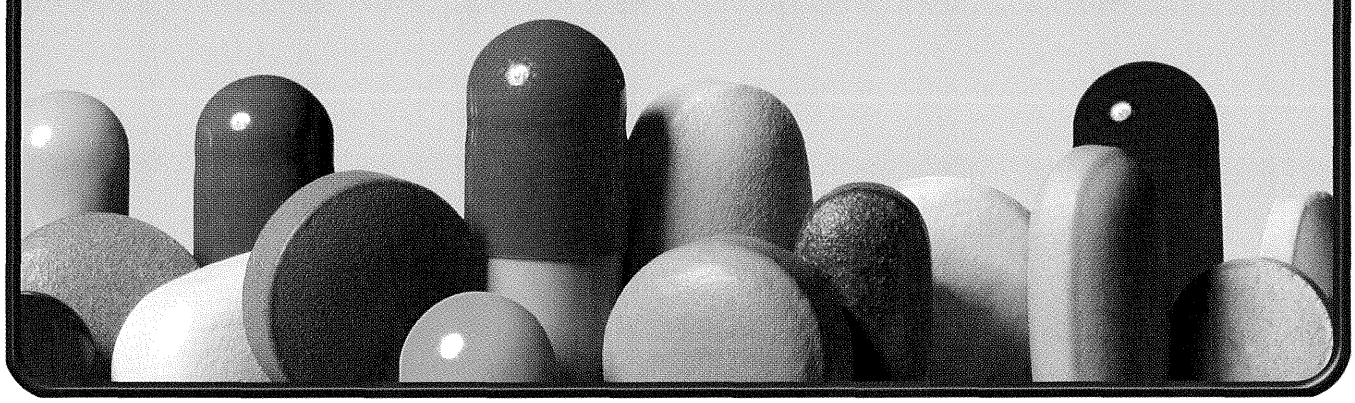
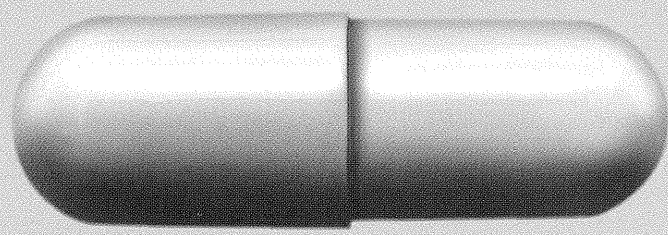
U.S. Department of Health and Human Services
Food and Drug Administration



That generic drug you're about to take had to pass many rigorous tests.



We bet you feel better already.

When FDA approves your generic drugs, it ensures they are safe and effective. All generic drugs are put through a rigorous, multi-step approval process. From quality and performance to manufacturing and labeling, everything must meet FDA's high standards. We make it tough to become a generic drug in America so it's easy for you to feel confident. Visit www.fda.gov/cder/ or call 1-888-INFO-FDA to learn more.

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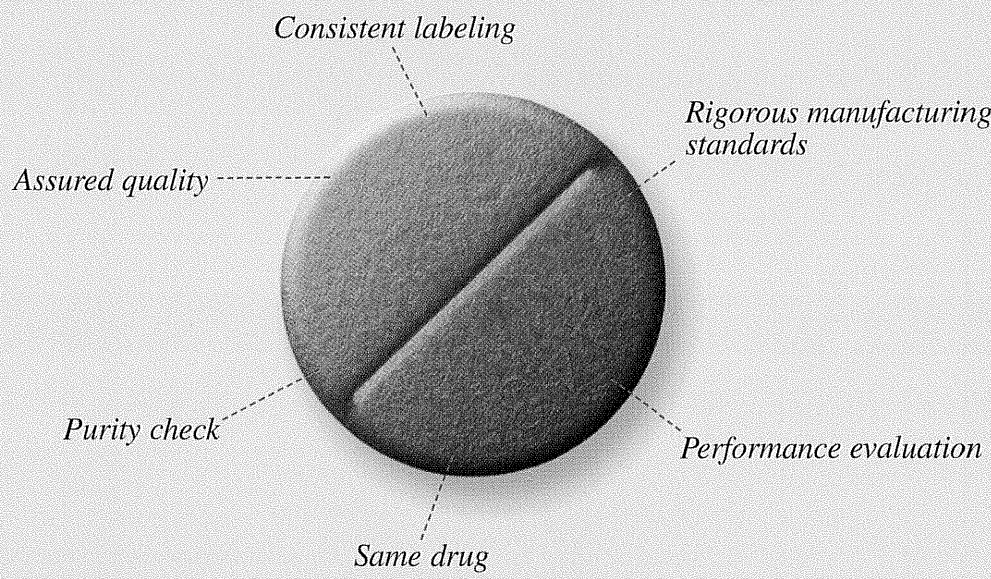
U.S. Department of Health and Human Services
Food and Drug Administration

Your generic drug is safe and effective.

And we've got the results to prove it.



When FDA approves your generic drugs, it ensures they are safe and effective. All generic drugs are put through a rigorous, multi-step approval process. From quality and performance to manufacturing and labeling, everything must meet FDA's high standards. We make it tough to become a generic drug in America so it's easy for you to feel confident. Visit www.fda.gov/cder/ or call 1-888-INFO-FDA to learn more.

Generic Drugs: Safe. Effective. FDA Approved.

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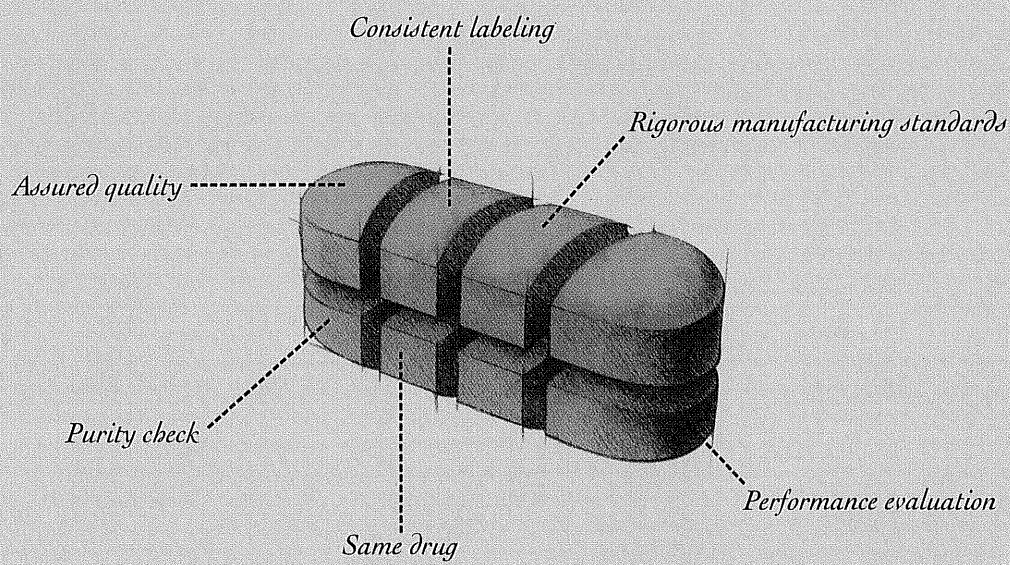
U.S. Department of Health and Human Services
Food and Drug Administration

Think it's easy becoming a generic drug in America?

Think again.



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Generic Drugs: Safe. Effective. FDA Approved.

FDA
U.S. Food and Drug Administration
U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

If you're experiencing anxiety about taking your generic drug, read this ad and repeat as needed.

FDA ensures that your generic drug is safe and effective. All generic drugs are put through a rigorous, multi-step approval process. From quality and performance to manufacturing and labeling, everything must meet FDA's high standards. We make it tough to become a generic drug in America so it's easy for you to rest assured. Visit www.fda.gov/cder/ or call 1-888-INFO-FDA to learn more.

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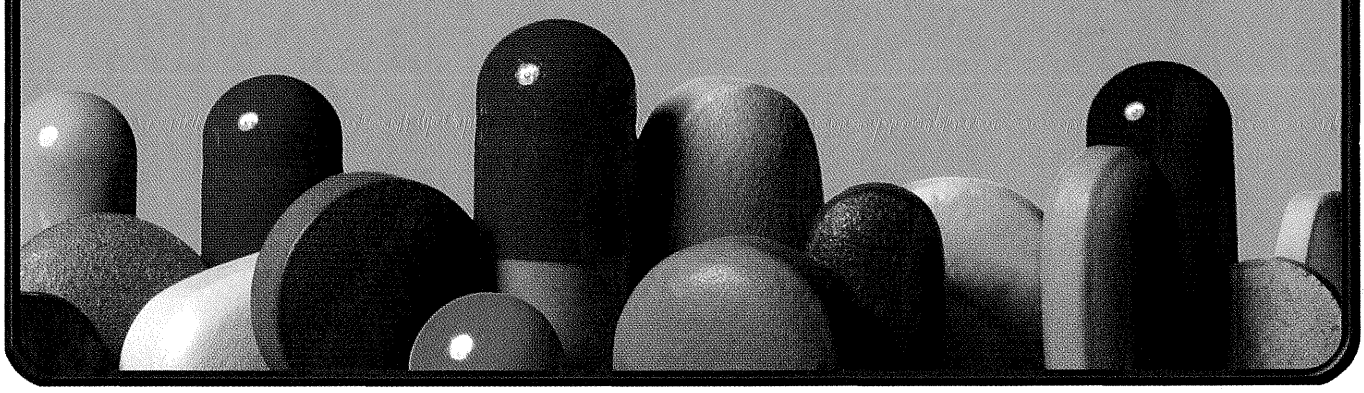

You know that question that goes through your mind when you take your generic drug? Here's the answer.

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Visit www.fda.gov/cder/ or call 1-888-INFO-FDA to learn more.

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FDA
U.S. Food and Drug Administration
U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

Agenda Item C

Memorandum

To: **Communication and Public Education Committee** **Date: March 15, 2005**

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

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

At the July board meeting, the board voted to become 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. Bill Soller, PhD, is the director of the Center for Consumer Self Care.

There have been monthly meetings since September 2004. Membership on the committee includes representation from the CSHP, CMA, Medical Board of California, UCSF, FDA, CPhA, Board of Registered Nursing, and the Department of Consumer Affairs.

The function of the group is to develop or disseminate integrated public information campaigns on priority health topics identified by the partnership members.

The first integrated project was an education campaign for practitioners and patients on antibiotic use, misuse and overuse. Between November 2004 and February 2005, the partnership agencies promoted these materials in their quarterly newsletters to licensees and on their Web sites. Consumer materials were distributed at public education fairs, and could be distributed by practitioners in their offices or pharmacies (via download of material from the Internet). Both the Medical Board and our board published the announcement in our winter newsletters.

The next integrated campaign is planned for May 2005, which is seniors' month. Generic drugs will be the focus of this effort. In this regard, various materials from the FDA and the board's new consumer fact sheet will be among the materials promoted.

In the future (October or November) the partnership is considering continued emphasis on generic drugs or early detection tests for cancer. October is Talk About Prescriptions Month.

Dr. Soller is preparing an assessment of the partnership's efforts to date, but at the time of this writing, this assessment is not yet ready.

Agenda Item D

State of California Department of Consumer Affairs

Memorandum

To: Communication and Public Education Committee

Date: March 13, 2005

From: Virginia Herold

Subject: Update on *The Script*

The board's newsletter, *The Script,* was printed and mailed to California pharmacies in early February.

The Pharmacy Foundation of California will again mail this issue to California pharmacists in the next few weeks.

In March, the board will begin development of the next issue. Publication is planned for July 2005.

Agenda Item E

State of California Department of Consumer Affairs

Memorandum

To: Communication and Public Education Committee

Date: March 14, 2005

From: Virginia Herold

Subject: Update on *Health Notes*

Health Notes is a monograph, produced by the board, that contains up-to-date drug therapy guidelines for a specific subject area. Because *Health Notes* is produced by the board, it conveys what the board believes is current drug treatment in a particular area. Pharmacists can earn continuing education credit by completing a test published at the back of the monograph. Thus the board provides information and actually is sponsoring CE in an area of importance to the board. Seven issues have been produced since 1996.

Under development are two issues:

1. Pain Management Issue:

The board's staff still is working to complete this new issue on pain management. The new issue will contain new pain management therapies and the new prescribing and dispensing requirements for controlled substances. It will be an interdisciplinary issue for pharmacists as well as physicians, dentists and nurse practitioners.

Prominent pain management authors have written the articles, Board Member Schell has edited the articles. The CSHP is seeking funding for production and mailing costs. Depending on how many grants the CSHP obtains for this issue, the board hopes to spend $0 on this issue.

Work on the manuscript for this issue will be completed this summer.

2. Pharmacy Emergency Response to Patients in a Declared Disaster Area

At the January 2005 Board Meeting, the board approved the development of a pharmacist emergency response *Health Notes* for the board.

RoseAnn Jankowski, former chair of the board's Competency Committee is coordinating this issue. A list of articles is provided as is a outline and educational objectives for this issue prepared by Dr. Jankowski. Completion of this issue is scheduled for mid summer 2005.

3. Smoking Cessation – inactive

4. UCSF Monograph on Atrial Fibrilation *(will not be called a Health Notes)* -- inactive

Outline of CABOP Presentation on January 19, 2005

"Proposed Health Notes Outline and Educational Objectives:
Disaster Preparedness for the California Pharmacist"

1. Purpose: Statement of purpose for the publication.
2. Background: Context for the publication – natural and man-made/urban disasters... suggestions for preparedness...interpretation of emergency statutes for Pharmacy practice.
3. Educational Objectives: Objectives for the publication as well as for each content article. Bloom's Taxonomy to be utilized in order to qualify for CEU credit award.
4. Proposed content articles, suggested authors by expertise.
5. Proposal for CEU credit award
6. Suggestions for funding support
7. Request for authorization to proceed, timeline and due dates

Proposed *Health Notes* Outline and Educational Objectives:

Disaster Preparedness for the California Pharmacist

Presentation to the California State Board of Pharmacy

January 19, 2005

UPDATED OUTLINE
MARCH 9, 2005

Purpose

Consistent with the mission of the California State Board of Pharmacy, the purpose of a *Health Notes* issue focusing on disaster preparedness is to communicate information to pharmacists that will contribute to maintaining the health of Californians during times of emergency.

Background

The topography and natural history of California have always contributed to the potential for natural disasters to occur. Aware of potential natural disasters, the possibilities of large-scale accidents relating to urban development, and the heightened awareness of global terrorism, California State Government has been very active in the continued development and implementation of regulations and strategies for responding to both natural and man-made emergencies. Outlining recommendations for prudent disaster preparation, the current plans for deployment of resources to aid in the management of disasters and large scale emergencies, and regulatory interpretation of emergency response statutes in the context of Pharmacy practice will enable pharmacists to better respond to patient needs, maintain community wellness, and minimize loss.

Educational Objectives for *Health Notes* Edition

After concluding this educational activity, the pharmacist should be able to:

- List at least three recommendations to assist in preparing for potential natural disasters.
- Outline current state plans for activating emergency response systems and potential deployment of aid resources.
- Describe the potential roles for community and institutional pharmacists during large-scale emergencies.
- Discuss practical compliance with statutes relating to dispensing of drugs and devices during emergency situations.
- Make practical recommendations for adjusting routine patient-related services to accommodate emergency situations and support community health maintenance.

Notation on Educational Objectives:

Drafted objectives are consistent with Adult Professional Learner Cognitive Level Two (Comprehension/Application) standards in order to qualify for ACPE CEU credit award.

Proposed *Health Notes* Content

1. Introduction: President of the California Board of Pharmacy

Outline: Introduction of publication intent and outlining content. (Non-CEU eligible)

2. The Northridge Earthquake: Learning From Experience. Pending alternate author confirmation

Outline: Summary of the immediate impact of the Northridge earthquake on routine operations and pharmaceutical care delivery. Specifics to include determination of immediate needs, communication, and operational decisions. Article will also include summary recommendations for pharmacists and pharmacies based on lessons learned. (CEU eligible)

Educational Objectives: At the conclusion of this educational activity, the pharmacist should be able to describe at least three general recommendations for preparing to meet immediate operational needs in the event of natural or declared disaster.

3. How Does it All Fit Together? Part I: State and Local Responses to Emergencies. Invited author: Mary Massey, R.N., BSN, USDOJWMD Instructor, DMAT CA-1, EMS Facilitator

Outline: Overview of how local and state-based emergencies are declared, and how disaster plans are activated. Summary of state-based plans, and examples of how counties can work proactively with pharmacists both in community and institutional settings to support patient screening and the timely deployment of disaster management resources. Listing of additional information resources will be included.(CEU eligible)

Educational Objectives: At the conclusion of this educational activity, the pharmacist should be able to describe how plans for managing disasters and large scale emergencies are activated on the state and local level, to identify at least two sources of information relating to emergency response planning, and to discuss ways in which pharmacists can seek active involvement in disaster planning and response.

Proposed *Health Notes* Content

4. How Does it All Fit Together? Part II: National Response to Emergencies. Invited author: Fadi Essmaeel M.D., CEM, Homeland Security Director -U.S. House of Representatives

Outline: Overview of how federal responses to state-based disasters/emergencies are declared, and how these plans are activated in California. Presentation of the Strategic National Stockpile (SNS), including summary of content, logistics and deployment. Description of latest plans for SNS segment caches in participating California hospitals. Summary example of FEMA and SNS resource deployment in response to a major natural disaster will be provided, along with potential expectations for institutional and community pharmacies. (CEU eligible)

Educational Objectives: At the conclusion of this educational activity, the pharmacist should be able to describe the intent of the SNS, and the principles involved in its deployment. Pharmacists should also be able to discuss the potential implications of SNS deployment from both the community and institutional practice perspective.

5. Preparing Your Pharmacy and Patients for Emergencies. Author: RoseAnn L. Jankowski, Pharm.D., Clinical Resource Specialist, Anaheim Memorial Medical Center. Assoc. Clinical Professor of Pharmacy, University of the Pacific. DEAG and CPAC Advisor, County of Orange

Outline: Presentation of specific recommendations for community, hospital, and SNF/ICF pharmacies and pharmacy staff in preparing for emergency or disaster situations. Summary of recommendations for community pharmacists to use in educating the public on home disaster preparedness, and health maintenance during emergency situations. Recommendations for public information resources will be included. (CEU eligible)

Educational Objectives: At the conclusion of this educational activity, the pharmacist should be able to discuss practical disaster preparedness suggestions appropriate to the pharmacy practice setting, and outline recommendations for educating the public on disaster planning and wellness during emergency situations.

Proposed *Health Notes* Content

6. Coping with Disaster: Special Considerations for Structural Safety and Security Invited author: Ken Miller, M.D., Medical Director, County of Orange Fire Authority. Assistant Medical Director, OCEMS.

Outline: Short summary of recommendations and considerations relating to structural safety, and security of staff and resources during emergencies and disasters. (CEU eligible)

Educational Objectives: At the conclusion of this educational activity, the pharmacist should be able to identify potential disaster-related security and structural issues in his/her workplace, and to discuss measures to minimize damage or loss.

7. Coping with Disaster: Special Considerations for Unseen Risks Invited authors: Ramon E. Perez, M.D.(Infectious Disease Specialist), Robert Woodhouse, M.D. (Radiation Oncology Specialist), and RoseAnn L. Jankowski, Pharm.D. Editorial overview of toxicology portions to be requested of California Poison Control System.

Outline: Summary of recommendations for minimizing risks and current recommendations for prophylaxis/medical treatment of toxic gas/chemical exposure, infectious agents, and radioactive emergencies resulting from natural or man-made disasters. Short explanation of requirements of H & S Code 115340 will be included, along with recommendations for additional sources of information for pharmacists and the public. (CEU eligible)

Educational Objectives: At the conclusion of this educational activity, the pharmacist should be be able to list a drug of choice for prophylaxis and treatment of 5 potential bacteriologic and viral pathogens that could affect the public as a result of disaster, discuss the intent and use of potassium iodide in the event of nuclear accident, and potential use of antidotes in accidental toxic gas/chemical exposures.

Proposed *Health Notes* Content

8. Dispensing During Emergencies: Practical Implications of B & P Codes 4062 and 4064 Author: RoseAnn L. Jankowski, Pharm.D., with editorial overview by CABOP staff/inspectors.

Outline: Practical explanation of statues concerning dispensing of drugs and medical devices during times of emergency. Suggestions for prescription processing and dispensing operations during emergency situations that will enable pharmacists to more easily comply with the intent of these statutes, while meeting patient need. (CEU eligible)

Educational Objectives: At the conclusion of this educational activity, the pharmacist should be able to describe the intent of B & P Codes 4062 and 4064, and to discuss operational changes that would facilitate continued medication dispensing in the interests of patient care during emergency situations.

Planning Committee

(To date) CABOP Staff, R. Jankowski, Pharm.D., R. Perez M.D., L. Norton, Pharm.D., P. Oppenheimer, Pharm.D.

Editorial and Expert Review

CABOP Staff and Inspectors, R. Jankowski, Pharm.D., P. Oppenheimer, Pharm.D., L. Norton, Pharm.D., K. Miller, M.D., others in process of confirmation.

Continuing Education Unit Provider Status

As an ACPE-accredited provider of continuing education activities for pharmacists, the T.J. Long School of Pharmacy and Health Sciences at the University of the Pacific has given approval to working the California Board of Pharmacy to provide continuing education contact hours to pharmacists successfully completing the test questions that will be included in this proposed edition of *Health Notes.*

The content outline and suggested educational objectives have been submitted to the T.J. Long School of Pharmacy and Health Sciences for review and approval. In accordance with precedent, the school will determine, issue, and collect a nominal fee to cover expenses of providing CEU credit, and maintaining records for pharmacists who choose to apply for CEU credit.

Milestones

Milestone	Target Date	Current Issues	Completion Date
CABOP approval	January, 2005	None	January 19, 2005
CEU accreditation approved	June 1, 2005	Proposal and outline accepted by UOP in January 2005, approval process is ongoing. Currently working on author credentials and educational assessment elements.	Pending
Author notification and confirmation completed	March 31, 2005	One contributing author needs to be replaced, alternate being contacted.	Pending
Graphic design	May 1, 2005	Cover/cover page completed, font and lay out styles completed. Article break page and graphics are in process.	Pending
Authors submit article drafts	June 1, 2005	None	Pending
Editorial review of drafts	June 15, 2005	None	Pending
Submission of final approved drafts	June 30, 2005	None	Pending
Approved draft paste-up	July 11, 2005	None	Pending
Final accreditation confirmation and segment paste-up	July 15, 2005	None	Pending
Final CABOP approval	TBD	None	Pending
Submission to CABOP for electronic posting	TBD	None	Pending

State of California | Department of Consumer Affairs

Memorandum

To: Communication and Public Education Committee

Date: March 14, 2005

From: Virginia Herold

Subject: Miscellaneous Consumer Issues and Articles in the News

In this section, I have gathered several items 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 they wish to propose future action at the next committee meeting.

Agenda Item F

State of California | Department of Consumer Affairs

Memorandum

To: Communication and Public Education Committee

Date: March 15, 2005

From: Virginia Herold

Subject: Redesign of the Board's Web Site

The board's Web site has been reconfigured into the mandated style designated by the Governor's Office. The goal is to have all state Web sites look similar.

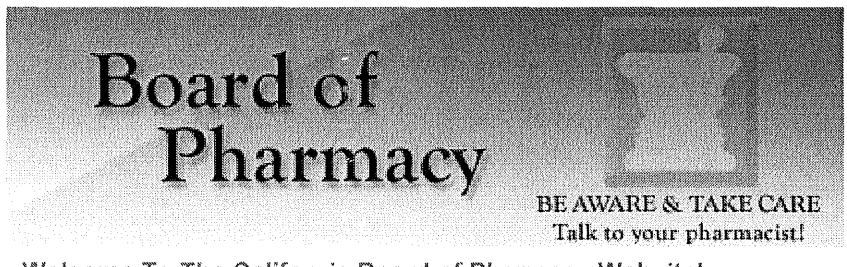
Four board staff have worked on this project as a portion of their assigned workload. The department also has provided staff to implement the new design.

A copy of the new Web page follows.

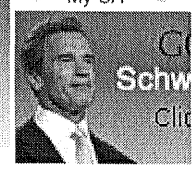
However, several additional changes will be made to the Web site in the next few weeks as the new configuration is a little more difficult for some of us (who were very familiar with the old Web site) to use.

California Home Tuesday,

- About the Board
- Apply For a License
- Archive
- Consumer Services
- Controlled Substance Rx
- Important Links
- Information for Licensees
- Laws & Regulations
- Online Services
- What's New
- Written Information & Research Tools



My CA



Welcome To The California Board of Pharmacy Website!

Consumer Services
- File a Complaint
- Complaint Process
- Information for Consumers

more...

About the Board
- Board & Committee Meetings (Open to the Public)
- Meeting Materials
- Board Members
- Strategic Plan *(PDF)*

more...

Apply for a License
- Personal License
- Site License

Information for Licensees
- Pharmacist
- Interm Pharmacist
- Pharmacy Technician
- Site License

Written Information & Research Tools
- Applications and Forms
- Publications & Newsletters
- Pharmacy Law & Regulation
- Frequently Asked Questions
- Important Links

Laws & Regulations
- Pharmacy Law & Regulation *(PDF)*
- Pending Regulation Changes
- Pending California Legislation

Controlled Substance Rx Forms
- Prescribing & Dispensing
- Security Printers

Online Services
- Verify a License
- File a Complaint
- Join our E-mail List
- Take our Survey
- Request a Publication

Quick
- Verify a Lic
- Change of A
- License Re
- File a Comp
- Join Our E-
- Security Pri
- Newsletter
- Self-Assess

Contact Us:

Board of Pharmacy
400 R Street, Suite 4070
Sacramento, CA 95814
Phone: (916) 445-5014
Fax: (916) 327-6308

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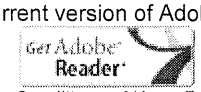

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Agenda Item G

State of California | Department of Consumer Affairs

Memorandum

To: Communication and Public Education Committee

Date: March 15, 2005

From: Virginia Herold

Subject: Survey to Study the Impact of the Patient Consultation Mandate on Older Americans

The board has been a strong supporter of pharmacist to patient consultation over the years, and this is a key area reviewed by board inspectors during all compliance inspections.

Early in 2004, the board was contacted about a study being done by the Center for Health Improvement assessing patient consultation requirements and their impact on older Californians aged 65 or older. The CHI describes itself as "a nationally known health policy nonprofit based in California." The California Pharmacist Association's Pharmacy Foundation of California and the AARP are also collaborators of this project.

The two-year study's goal is to inform and improve the pharmacist to patients aged 65 and over consultation process:

- To assess the impact of the pharmacist consultation for persons 65+ through quantitative and qualitative methods.
- To educate Californians, especially pharmacists about findings and recommendations through development and distribution of a policy brief.
- To begin discussions with policymakers and stakeholders about options for future action.

A summary of the plan is provided.

At the October committee meeting, the committee asked that a representative of the Center for Health Improvement attend the October Board Meeting to discuss the objectives of this study. Unfortunately, this was not possible. A representative planned to attend the January Board Meeting, but due to their limited budget would prefer to attend the Sacramento Board Meeting in April where there would be no travel expense.

Since October, the Center for Health Improvement has mailed a survey to 3,000 pharmacies, and 1,000 pharmacists responded to the questions about patient consultation. The preliminary results of this survey will be discussed in focus groups.

By the April Board Meeting, the Center for Health Improvement may have some results to discuss.

I. Executive Summary

The Center for Health Improvement (CHI) is proposing a two year project to examine and improve the pharmacist-patient consult process for persons 65 or older (65+) required by California regulation. The study design will achieve this goal by:

1. Gathering quantitative and qualitative information to assess the implementation of the regulation,
2. Educating policymakers and key stakeholders through the creation and dissemination of a policy issue brief, and
3. Conducting a policy roundtable to present the study's findings, recommendations, and to discuss potential next steps.

This proposed study is especially timely given recent national attention to the issue of medical errors and the link between drug-related errors and failure to consult. Furthermore, it will be the first study of its kind to incorporate data from the California State Board of Pharmacy's recently implemented inspection process of mandated pharmacy quality assurance programs, which includes observations of consultations. The study focuses on persons 65+ as they consume and spend significantly more on prescription drugs than persons under age 65. Moreover, persons in this age group are more likely to complain about a failure to consult.

CHI is a nationally known health policy non-profit based in Sacramento. CHI serves as a catalyst to ensure that prevention remains at the forefront of health policy and health care services. Policymakers and others respect our policy issue briefs, convenings, and other products and services for their objectivity and nonpartisanship. This proposal also includes collaborators from three established organizations that represent targeted stakeholders. These include the California State Board of Pharmacy, which provides oversight to the State's 6,000 pharmacies and all licensed California pharmacists; AARP, which represents 3.2 million older Californians; and the California Pharmacist Association Educational Foundation, which maintains a database of 26,000 pharmacists and conducts research on salient issues for this constituency.

II. Proposed Scope of Work

The Center for Health Improvement (CHI) in collaboration with the California Pharmacists Association Educational Foundation (CPhA-EF), AARP, and the California State Board of Pharmacy (Board)[1], proposes to conduct an assessment of the outpatient pharmacist consultation process that is required when any new or changed prescription is dispensed[2]. Based upon the findings of this assessment, we will educate California policymakers and select stakeholders by disseminating a policy issue brief and hosting a roundtable discussion. The assessment will target California's older population (65+), focusing on the value of pharmacist care and how this process may be improved. We are targeting this population for several reasons. First, persons 65+ are prescribed twice as many medications as persons under the age of 65[3]; second, older

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[1] See letters of support, attachment 1.
[2] Inpatient, PBM prescriptions, and certain other settings are excluded.
[3] Stagnitti, M. (2003, July). Statistical Brief #21: Trends in Outpatient Prescription Drug Utilization and Expenditures: 1997-2000. Rockville, MD: Agency for Healthcare Research and Quality.

adults have more chronic diseases and multiple conditions[4], thus the consultation is more relevant, important, and complex; and third, persons 65+ are a more vulnerable population[5].

Originally filed in August of 1990, California's Board of Pharmacy California Code of Regulations number 1707.2.b.1 mandated pharmacist consultation to every patient who receives a new or changed prescription. The regulation was enacted to ensure that necessary dialogue occurs between patients and medication experts to promote safe and effective medication use[6]. Following these requirements, recent attention by the Institute of Medicine[7] and others has significantly raised the visibility of medical errors overall. Evidence suggests, however, that despite this attention, more needs to be done to prevent medication-related adverse events. For example, an analysis of adverse drug events occurring in a population of older adults in an ambulatory setting,[8] found that overall, 27.6% of the documented adverse drug events was deemed by the investigators as *preventable*. Inadequate patient education concerning medication use and prescription of a drug for which there was a well-established, clinically important interaction with another drug were cited as common errors (18.0% and 13.3% of the preventable prescribing stage errors). Recent discussions with staff of the Board[9] also revealed that through its inspection process, a majority of medication errors involve a "failure to consult."

Methods

As described in our May 19, 2003 letter of interest, CHI addressed the goal of assessing the pharmacist-patient 65+ consult process through a methodology that involved conducting three focus groups – two of pharmacists and one of older Californians – to obtain qualitative data; compiling the focus group interpretations into a policy brief to be disseminated to policymakers and stakeholders; and coordinating a statewide convening to discuss this issue and consider opportunities for action.

Through research and discussion with our collaborative partners, we have revised the proposed methodology to include a more robust and objective approach. This methodology includes:

1. Gathering data from a review of the literature and from the Board and other sources,
2. Conducting a written survey of pharmacists,
3. Conducting four focus groups, including two composed of pharmacists, one of persons 65+, and one of physicians,
4. Developing a policy brief, and
5. Hosting a statewide roundtable for policymakers and select stakeholders.

Each of these activities is described below.

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[4] American Society of Consultant Pharmacists. (2002, March). *Seniors at Risk: Designing the System to Protect America's Most Vulnerable Citizens From Medication-Related Problems.* Alexandria, VA: Author.
[5] Ibid.
[6] A similar federal law—the Omnibus Budget Reconciliation Act of 1990—applies to the Medicaid population.
[7] See Kohn, L., et al. *To Err is Human: Building a Safer Health System*, 2000. National Academy Press.
[8] Gurwitz, J.H., et al. (2003, March 5). Incidence and preventability of adverse drug events among older persons in the ambulatory setting. *Journal of the American Medical Association, 289*(9), 1107-1116.
[9] Riches, P. (2003, August 7). Personal communication with Center for Health Improvement.

1. Conduct a Literature Review and Analyze State Board of Pharmacy and Other Data

CHI will conduct a literature review to ascertain whether other states have assessed the implementation of the pharmacist consultation process, notably with persons 65+. The literature review will include web-based research, as well as contacts with several state-focused health policy organizations in Washington, D.C., such as the National Governor's Association. We will also contact at least one insurance company that may be able to provide aggregate figures on malpractice claims involving failure to consult for the target population.

Effective January 2002, the Board began a quality assurance program that includes random observations of California's 6000 pharmacies. The desired outcome of the program is a reduction of medication errors.[10] Every pharmacy is inspected at a rate of once every two and a half years. Citations/fines are issued in instances where pharmacists fail to consult. Although patients may legally waive the right to consultation, according to the Board, the pharmacy must document that the pharmacist—not another staff member—attempted to consult and the patient refused. The Board has agreed to share aggregate findings on citations related to failure to consult; if feasible, information specific to our target population will be pulled. The Board also agreed to share information on consumer complaints, many of which relate to failure to consult. (NOTE: While the Board staff stated that the majority of errors detected through the inspection process or complaints involved a "failure to consult," it is not known whether an error would have been prevented had a consultation occurred.) A public analysis of this data in California will be the first of its kind. Placed within the context of this study, the analysis will add valuable information to be compared with that gathered from pharmacists, patients, and physicians.

2. Conduct Written Survey of 3,000 Pharmacists

CPhA-EF maintains a database of the state's more than 26,000 pharmacists. A stratified sample of roughly 3,000 pharmacists will be drawn in order to survey their perceptions of how the consult process is working for patients 65+. We will query pharmacists on their perceived barriers to consult (e.g., time pressures, setting, privacy, etc.) and solicit opportunities for improvements. A letter from the CPhA president or their board chair will accompany the brief survey. This letter, along with the salient nature of the issue, should encourage a high response rate. Following the first wave, a reminder post card will be mailed followed by a second survey mailing to non-respondents. Based on surveys conducted for similar professions, such as doctors, a 33% response rate is anticipated. A non-respondent bias test will be conducted in an attempt to discern whether this population varies significantly from survey respondents. The roughly two-page survey will query pharmacists on their perceptions of the consult process, asking them to identify barriers, as well as potential solutions.

3. Conduct Four Focus Groups

Following the pharmacist survey we will conduct four focus groups: two with pharmacists, one with persons 65+, and one with physicians. The purpose of the focus groups is to elicit participant opinions about the consult process, as well as identify opportunities to ensure a safer and smoother consultation. The survey findings will be used to establish questions for the focus group facilitator. Each focus group will include approximately 15 participants.

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[10] Jones, J.D. (2003, March). President's message. *The Script*, 2.

CPhA-EF will help to recruit pharmacists for participation. AARP will assist in identifying persons 65+ who have picked up a new or changed prescription within the past year. CHI will approach a major medical group that includes at least 15 physicians with a sizeable Medicare patient mix. We will request 45 minutes to an hour at an already-scheduled physician meeting to conduct a focus group session. Given their schedules and priorities, it would be extremely improbable that physicians would attend a separate meeting on this topic. However, because doctors write prescriptions and likely receive patient and/or pharmacy feedback on medical errors, as well as the consult process, it is important to gain their perspective on this issue.

4. Create and Disseminate Policy Issue Brief

Based on the preceding quantitative and qualitative information, CHI will draft a policy brief on this issue[11]. The brief will contain background information on the California regulation and federal legislation mandating pharmacist consults, as well as additional California interpretations related to compliance and the inspection process. For example, California law does not allow inspection evidence to be admitted as discovery material for litigation purposes. In addition, background information will include a summary of the literature review and Board data analysis. Information from the pharmacist survey, along with focus group key findings will also be tallied and presented in a readable format. Policy recommendations stemming from these sources will be presented.

The draft policy brief will be reviewed by the collaborating organizations on this project, including CHI, CPhA-EF, AARP, the Board, and TCWF, as well as other select individuals (e.g., Chairman of State Board of Pharmacy). We will disseminate it to our database of approximately 2,000 policymakers, targeting those with a strong interest in aging and health care. Our partner organizations will also assist in disseminating the policy brief to their respective constituents.

5. Host Policy Roundtable

CHI will coordinate a statewide roundtable of California legislators, their staff, and select stakeholders. The purpose of this meeting is to bring together appropriate participants to discuss our research findings and recommendations, and to begin the discussion of future next steps. Our study rests on the assumption that there is room for improvement in the pharmacist-65+ patient consult. The preceding methodology will shed light on how the process can be improved by identifying current barriers, gathering solutions for improvement directly from participants in the process (i.e., pharmacists, persons 65+, and physicians, and the Board), and developing recommendations for policymakers and relevant industry parties. A secondary intent of this study is to increase attention paid to this issue as an important component to reducing medical errors.

Sharing Lessons Learned with TCWF

Through semi-annual reports to The California Wellness Foundation, CHI will share lessons learned from the project. Such reports will include copies of important written materials (e.g., survey instruments, draft policy issue brief). We will also address any difficulties faced during

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[11] See sample policy briefs, attachment 2.

the project and how these are handled. CHI is willing to share our lessons learned and key findings through an article in TCWF's *Portfolio* newsletter.

III. Grant Objectives

The overarching goal of this study is to inform and improve the pharmacist-65+ patient consult process required by California regulation. In order to achieve this goal, specific objectives for conducting the study are threefold:

1. To assess the impact of the pharmacist consultation for persons 65+ through quantitative and qualitative methods.
2. To educate Californians, especially pharmacists, about our findings and recommendations through the development and dissemination of a policy brief.
3. To begin a conversation with targeted policymakers and select stakeholders about options for future action.

IV. Applicant Organization

Established in 1995, the CHI is a non-partisan, objective, prevention-focused health policy center based in Sacramento, California. CHI is known for its ability to synthesize complex data and research and present it in a useful format for policymakers and others. We have extensive experience in all of the tasks mentioned here, including reviewing literature, analyzing data, conducting surveys and focus groups, and writing policy issue briefs. Moreover, CHI has a successful history of organizing and facilitating convenings for relevant stakeholders around emerging health issues (see www.centerforhealthimprovement.org). CHI's operating budget is nearly $1 million[12].

CHI president and CEO, Patricia E. Powers[13], will serve as the lead on this effort. Ms. Powers possesses more than 20 years of experience in health care, including leadership of large-scale technical research studies related to quality of care and preventive services. Her previous consulting clients include pharmaceutical firms, generic drug manufacturers, and physician organizations. As the former CEO of the Pacific Business Group on Health, Ms. Powers worked with employers to negotiate costs and benefits for their commercial and Medicare populations. She previously served on the Federal Physician Payment Review Commission, which provided policy information for the Medicare program. In addition to Ms. Powers, Gregg Y. Shibata[14], will serve as project manager. Mr. Shibata leads several initiatives at CHI, including developing a statewide collaborative to improve early diagnosis and intervention for children suspected of having an autistic spectrum disorder. His work for the past two years involved data gathering and analysis, writing, direct technical assistance, and managing convenings and group-learning opportunities (e.g., workshops, teleconferences, internet-based teleconferences) for California Prop. 10 Commissions, California Local Planning Councils, and community-based organizations. CHI will work with a reputable survey research firm to conduct the pharmacist survey.

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[12] See current organizational budget, attachment 3.
[13] See resume, attachment 4.
[14] See resume, attachment 4.

V. Evaluation Plan

Overall, this project will be viewed as a success if we obtain reliable information about barriers to effective implementation to the pharmacist consultation for persons 65+, as well as identify solutions for improvement. Policymakers' and other relevant stakeholders' receptivity to this information as evidenced by interest level and any follow-up activity will be another gauge of its success. Sample specific measures of success tied to each of our three objectives are as follows:

1. To assess the impact of the pharmacist consultation process: results from research, including any findings from a literature review and data analyses; statistical significance, reliability and response rate for the survey; level of participation and number of identified solutions from focus group sessions.

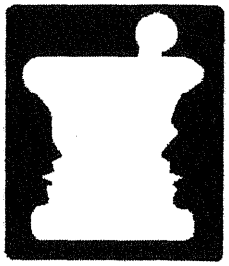
2. To educate policymakers and others: number of pharmacists, policymakers, and others who receive the policy brief and qualitative feedback from them.

3. To begin a conversation with policymakers and others: number and level of attendees at roundtable; level of agreement on "next steps;" and any actions taken by key decision-makers as indicated by responses to a one-page evaluation administered during the close of the roundtable.

Center for
Health Improvement

Pharmacy Foundation
of California

CALIFORNIA STATE
BOARD OF PHARMACY



BE AWARE & TAKE CARE:
Talk to your pharmacist!

Monday, August 30, 2004

Dear Pharmacy Manager,

The Center for Health Improvement, with support from the Pharmacy Foundation of California and the California State Board of Pharmacy, is conducting a statewide survey of pharmacists who work in a community-based setting. This survey is part of a larger study to examine and assess the pharmacist-patient consultation that occurs for new or changed prescriptions and its impact on older Californians (persons 65 and above).

Your feedback is extremely important and will help shape future policy recommendations. For your convenience, a self-addressed, postage-paid envelope is included. We anticipate this survey taking no more than a few minutes of your time. **Your responses will be kept completely confidential.** All surveys will go directly to a third-party survey firm. Only aggregated results will be presented. We thank you for your time and would appreciate your **response by September 13, 2004**.

Please accept the attached Golden Eagle coin as a token of our appreciation.

Thank you for your assistance!

Patricia G. Powers

Patricia G. Powers

President & CEO
Center for Health Improvement

Center for Health Improvement

Pharmacy Foundation of California

BOARD OF PHARMACY

BE AWARE & TAKE CARE: Talk to your pharmacist!

PHARMACIST CONSULT SURVEY

1. **Which one of the following best describes your primary practice setting?**
   - ❑1 Community – independent pharmacy
   - ❑2 Community – small chain pharmacy (e.g., local, four or more outlets)
   - ❑3 Community – grocery chain pharmacy (e.g., Raley's, Safeway, Von's)
   - ❑4 Community – mass merchandise chain pharmacy (e.g., CostCo, Walgreen's)

2. **Please indicate the number of years you have been in practice.**
   - ❑1 Less than three
   - ❑2 Four to ten
   - ❑3 Eleven to twenty
   - ❑4 Twenty-one to thirty
   - ❑5 Thirty-one or more

Please select the title(s) or position(s) that best describes you (select all that apply):
   - ❑1 Pharmacist in charge/Pharmacy manager
   - ❑2 Full time, staff pharmacist
   - ❑3 Part time, staff pharmacist
   - ❑4 Owner

4. **Please approximate how much time you spend on each activity during an average eight-hour period:**

	0%	5%	10%	25%	50%	75%	100%
A. Dispensing prescriptions							
B. Consulting with physicians about medication and diagnosis							
C. Consulting with patients about medication							
D. Explaining benefit coverage to patients							
E. Formulary/3rd party management matters							
F. Administrative/pharmacy management activities							
G. Teaching/precepting student interns							
H. Other							

Your Response Will Be Kept Confidential

Center for Health Improvement, 2004

5. **Based on your experience with patients aged 65 or older, how often do you perform the following during an average patient consultation?**

	Rarely Ever	Occasionally	Sometimes	Often	Always
A. Verify the patient's name					
B. Verify the patient's date of birth					
C. Verify the patient's address					
D. Verify the name and description of the medication					
E. Provide directions for use and storage of the medication					
F. Discuss any precautions for preparation and administration of the medication by the patient, including self-monitoring drug therapy (where applicable)					
G. Describe the importance of compliance with the medication directions					
H. Discuss therapeutic contraindications					
I. Discuss serious potential interactions with known *nonprescription* medications (where applicable)					
J. Discuss precautions and relevant warnings, including common severe side or adverse effects or interactions that may be encountered					
K. Discuss action to be taken in the event of a missed dose					
L. Discuss prescription refill information (where applicable)					
M. Discuss the prescribing doctor's comments regarding the medication					

6. **Over an average eight-hour period, how many patient consultations do you perform?**

	less than 5	6-10	11-15	16-20	more than 21
A. For patients aged 65 or older					
B. For patients under 65					

7. **Based on your experience, how long does it take to conduct an average patient consultation?**

	less than 1 minute	1-2 minutes	2-3 minutes	3-4 minutes	more than 4 minutes
A. For patients aged 65 or older					
B. For patients under 65					
C. For patients with a chronic condition (e.g., diabetes)					
D. For patients taking multiple medications					

Your Response Will Be Kept Confidential

8. **Based on your experience, how often are the patient consultations waived by**

	Rarely Ever	Occasionally	Sometimes	Often	Always
A. Patients aged 65 or older					
B. Patients under 65					
C. Patients with a chronic condition (e.g., diabetes)					
D. Patients taking multiple medications					

9. **Based on your experience, how often:**

	Rarely Ever	Occasionally	Sometimes	Often	Always
A. Do patients ask questions of you during the pharmacist-patient consultation for new or changed prescriptions					
B. Do patients with a chronic condition (e.g. diabetes) ask questions of you regarding their disease, self-management strategies or other clinical services available					
C. Do you provide verbal information to patients with a chronic condition about their disease, self-management strategies or other clinical services available					
D. Do you provide self-management counseling or other advice on other clinical services for patients with a chronic condition (e.g., diabetes)					
E. Do you work with disease management vendors who address chronic conditions (e.g., diabetes)					
F. Do you have difficulty performing consultations due to a language or cultural barrier					

10. **Please rank the following barriers to the patient consultation process (with 1 being "not very significant" to 5 being "very significant").**

	1	2	3	4	5
A. Pharmacist's lack of time					
B. Insufficient compensation specific to the consultation					
C. Lack of pharmacist-patient privacy					
D. Language barriers					
E. Cultural barriers					
F. Unavailability of general clinical/diagnostic data (e.g., lab values, other medications)					
G. Patient's refusal to participate in the consultation					
H. Aside from language or cultural barriers, lack of patient's understanding during the consultation					

Your Response Will Be Kept Confidential

11. **Based on your experience, of the errors you have noticed during the patient consultation, how frequently do the errors relate to:**

	Rarely Ever	Occasionally	Sometimes	Often	Always
A. Fill errors					
B. Incorrect medication for patient's diagnosis					
C. Therapeutic errors (drug allergy, incorrect dosage)					

12. **Based on your experience, approximately what percentage of pharmacist-patient consultations for new or changed prescriptions result in each of the following:**

	less than 1%	2-3%	4-6%	7-10%	more than 10%
A. A call to the patient's physician to address a therapeutic problem (e.g., drug allergy, therapeutic duplication, drug interaction)					
B. A call to the patient's physician or insurance company to address coverage issues (e.g., formulary compliance, prior authorization)					
C. A recommendation that the patient contact their physician to resolve any questions or issues					

How effective is the patient consultation process in improving the quality of care (with 1 being "not very significant" to 5 being "very significant")?

1	2	3	4	5

14. **If you could change one part of the patient consultation process, what would it be?**

_____

_____

Your Response Will Be Kept Confidential

Center for Health Improvement, 2004

Agenda Item H

State of California | Department of Consumer Affairs

Memorandum

To: Communications & Public Education Committee

Date: March 14, 2005

From: Virginia Herold

Subject: Report by the Pharmaceutical Printed Literature Association on Patient Package Inserts

The board recently received the following White Paper titled: The Void in Useful Consumer Rx Information: Past, Present and Future. It was prepared by the Pharmaceutical Printed Literature Association. The committee may or may not wish to review and comment on this report.

So who is the Pharmaceutical Printed Literature Association? I am enclosing a brochure about this association (after their White Paper), which according to its Web site is:

> ...the sole trade association exclusively serving printers of pharmaceutical inserts, labels and cartons. Representing the majority of the North American pharmaceutical printed-insert industry, the not-for-profit trade group was chartered in 2001 to serve as the voice of manufacturers, and to provide a forum for members to advance patient safety and risk communication. The PPLA supports health care professionals, and advocates use of printed literature to legislative, regulatory and other decision-making bodies. In addition, the PPLA is an educational resource for strategic partners and the public.
>
> As a young association, the PPLA's core initial goal is to help the pharmaceutical industry help consumers benefit from existing and new drugs - a return on investment of billions of research and development dollars - by taking those drugs as prescribed, with instructions, precautions and risk data clearly understood. The desired outcome is a win-win-win situation: consumers enjoy better health, the healthcare system operates at a lower total cost, and drug manufacturers report higher sales.

PPLA

PHARMACEUTICAL PRINTED LITERATURE ASSOCIATION

131 E. BROAD STREET, SUITE 206 • FALLS CHURCH, VIRGINIA 22046
PHONE: 703-538-5799 • FAX: 703-538-6305 • EMAIL: info@pplaonline.com

RECEIVED BY DALLAS BOARD OF PHARMACY
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January 3, 2005

Dear Colleague:

The Pharmaceutical Printed Literature Association is a trade group whose mission is to promote the importance of useful printed information for all prescription drugs so they can be used properly by consumers and healthcare providers. To that end, the PPLA recently published the enclosed White Paper entitled, "The Void in Useful Consumer Rx Information: Past, Present and Future," which examines the state of useful prescribing information. This White Paper also looks ahead to 2006 when Congress has mandated that prescribing information which is useful, complete, accurate, consistent, comprehensible and legible be provided with 95 percent of all Rx medications dispensed.

The PPLA White Paper outlines the organization's contention that the Congressional deadline for action may be unreachable with the current strategy in place. Our group is urging FDA to require approved patient prescription drug information in the form of patient package inserts (PPIs) or MedGuides. It is our belief that this requirement will ensure that Congressional directives included in Public Law 104-180 for 2006 are attained.

Enclosed with the PPLA White Paper are a press release announcing its publication, and a summary sheet chronicling the status of useful prescription drug information since 1996 when FDA's MedGuide proposal was put on hold by Congress.

As an advocate for useful medication information and education, we urge you to read through the PPLA White Paper. If you would like to discuss the issue further or receive more information, please do not hesitate to contact our offices. We plan a strong effort as the 2006 Congressional deadline approaches toward calling on FDA to require that useful consumer information, prepared by pharmaceutical manufacturers and approved by government officials, is made readily available with all prescription drugs.

Sincerely,

Peter G. Mayberry
Executive Director

Enclosures

PPLA
PHARMACEUTICAL PRINTED LITERATURE ASSOCIATION

FOR IMMEDIATE RELEASE

Contact: Peter Mayberry
703/538-5799

NEW REPORT SHOWS INHERENT DEFICIENCIES IN PATIENT Rx INFORMATION PROVIDED BY PHARMACIES

After Decades of Failure, Industry Association Urges Action

Falls Church, VA, October 11, 2004 – The Pharmaceutical Printed Literature Association (PPLA) today issued a White Paper entitled "The Void in Useful Consumer Rx Information: Past, Present and Future." The White Paper details the failure of pharmacies to provide uniform consumer-oriented information that is comprehensive, FDA-approved, and useful when dispensing Rx drugs to consumers. The PPLA White Paper also calls on government officials to address the issue immediately. "Consumers need reliable information to ensure that they take their prescription medications properly," notes PPLA Executive Director Peter G. Mayberry. "Unfortunately, as our White Paper details, consumers are not getting that information from their pharmacies."

As the PPLA report spells out, there is a long history behind this issue. "Going back to the early 1970's," Mayberry explains, "the U.S. Food and Drug Administration (FDA) has repeatedly attempted to require that pharmaceutical manufacturers include patient-oriented inserts with the drugs they distribute. Over and over again, however, FDA has been stymied, most recently by an act of Congress that was passed almost ten years ago." Indeed, FDA had developed proposed rules in the early1990's which would have required that pharmaceutical manufacturers include FDA-approved leaflets known as MedGuides with most Rx drug products, but Congress stepped in with legislation (Public Law 104-180) that placed a moratorium on FDA action until 2006. "The law basically gave the pharmacy industry ten years to demonstrate that they could print useful, patient-oriented literature inside the pharmacy," says Mayberry.

Congressional action came largely in response to pharmacy industry concerns that the FDA rules would swamp pharmacies with filing cabinets full of leaflets from pharmaceutical manufacturers, many of which would be obsolete before they even reached the pharmacy. But changes in printing technology, along with the advent of scanning technologies and other electronic advances have since rendered these concerns moot.

And recent research conducted by the University of Wisconsin demonstrates the shortcomings of the pharmacy industry efforts to reach Congressional goals contained under Public Law 104-180. According to these findings, in fact, pharmacies are failing to meet nearly 50 percent of the criteria established by independent experts to gauge the usefulness of pharmaceutical information to consumers. Moreover, in testimony delivered during a July, 2003, FDA hearing on the issues, the inherent weaknesses in pharmacy-based printing systems were documented.

"What we learned from the University of Wisconsin study and the FDA public meeting is that pharmacies simply do not have the same abilities as pharmaceutical manufacturers to prepare and distribute useful patient information," Mayberry explained. "Pharmacies rely on unregulated, third-party vendors to provide the information that they print, and generally have no idea where that information comes from. In addition, pharmacies typically utilize equipment that can only print on one side of one piece of paper. No matter how much critical information is required for a particular drug, therefore, there is only so much space available to the pharmacist. Lastly, we learned that one out of ten pharmacies distributed no written information whatsoever when filling prescriptions."

* * * * * MORE * * * * *

USEFUL PRESCRIPTION DRUG INFORMATION: A PATIENT'S ELUSIVE RIGHT

What does a consumer have to do to get accurate, complete, consistent and comprehensible information when filling a prescription? In theory, nothing. Drug information that is legible and useful to consumers is a goal contained in Federal law for no fewer than 75 percent of new prescriptions filled. Seeking a higher standard still, the same law establishes a goal that 95 percent of all new prescriptions be accompanied with printed literature that is useful to consumers by 2006. The reality, however, is that barely 50 percent of the information contained in prescription drug leaflets analyzed by the University of Wisconsin in 2002-2003 was useful to consumers.

This lamentable performance record, revealed by studies sponsored by Health and Human Services and the U.S. Food and Drug Administration, has persisted since the early 1970's, and most recently came to a head in 1996 when Congress passed Public Law 104-180. Over the past three decades, in fact, FDA has issued guidelines and rules that the Agency later reversed, failed to implement, or saw thwarted by Congress – all in a consistently unsuccessful bid to ensure that consumers get adequate information regarding drugs they have been prescribed.

At the heart of the matter is a debate that has taken several different forms over the years but currently centers on which entity – the pharmaceutical manufacturer or the dispensing pharmacy – should have responsibility for producing and distributing consumer-oriented information about prescription drugs at the time they are dispensed to consumers. While Federal regulations have been in place for decades requiring that FDA-approved printed literature be dispensed by pharmaceutical manufacturers to physicians and pharmacists, the same is not true for consumer-oriented information.

Up until the "Republican Revolution" of 1995 and Newt Gingrich's conquest to eliminate "silly" Federal regulations, in fact, FDA had repeatedly attempted to create rules that would have required pharmaceutical manufacturers to prepare consumer-oriented leaflets for the drugs they put on the market. Indeed, at the time Congress passed PL 104-180, FDA was in the process of finalizing regulations that would have required the preparation and distribution of leaflets known as MedGuides for the vast majority of prescription drugs. MedGuides are leaflets written for consumers by pharmaceutical manufacturers in language that is approved by FDA, and are based on criteria established by FDA to ensure that the drugs are taken properly.

But FDA's MedGuide proposal was put on hold by Congress for 10 years in 1996 based on arguments from various stakeholder groups that patient-oriented leaflets could more efficiently be prepared and dispensed by pharmacies. Among the leading advocates for this approach were representatives of the pharmacy industry who argued, among other things, that pharmacists would be inundated with mountains of leaflets from manufacturers if FDA's MedGuide proposal were finalized. This concern was articulated as recently as July, 2003, by Dr. John Coster, Vice President, Policy and Programs, for the National Association of Chain Drugstores during an FDA public meeting. Coster basically told FDA officials that pharmacists fear they do not have enough space behind the counter to store leaflets provided by manufacturers when he said "I can't imagine where we'd put all that stuff." The pharmacy industry urged, therefore, that its members should be allowed to take responsibility for preparing and distributing consumer-oriented literature.

In response to these concerns and others, Congress placed a moratorium on FDA action for a full decade. If it could be demonstrated that 95 percent of all new prescriptions filled were accompanied by printed information that is useful to consumers by 2006, Congress directed, then there would be no need for FDA intervention. The end result being that, currently, if any printed literature is provided when a consumer fills a prescription, that literature has most likely been printed inside the pharmacy based on information provided to the pharmacy by a third-party vendor without any regulatory review or approval of content and format.

About five years after Congress passed Public Law 104-180, FDA sponsored a study to see how well the pharmacy industry was meeting its obligations. The study, which was conducted by the University of Wisconsin and the National Association of Boards of Pharmacy (NABP) involved "secret shoppers" who were given the same three prescriptions to fill in various locations throughout the country. These shoppers were instructed not to request printed information regarding their prescriptions, but to take anything that was

virtually all prescription medications dispensed in the United States. The pharmacy industry has failed to meet the challenge laid out by Congress almost a decade ago, and the time for action has come.

####

Supplemental Information

The PPLA cites the following benefit-and-efficacy points relative to mandatory, approved, manufacturer produced information for all prescription drugs:

- MedGuides and manufacturer-prepared "patient package inserts" (PPIs) can be designed to meet all the requirements for useful patient information detailed in the Keystone Action Plan adopted by the U.S. Department of Health and Human Services in the mid-1990's. Indeed, Dr. Svarstad, lead researcher in the University of Wisconsin study has noted that the few PPIs that were encountered in the study rated highest in meeting the usefulness criteria.

- PPIs and MedGuides can be imprinted with barcodes containing the product's National Drug Classification (NDC) code – a goal supported by FDA for Rx and OTC products intended for distribution to healthcare facilities – as well as lot number, and manufacturer-provided expiration date.

- Implementing this existing, proven patient information technology makes the manufacturer the paramount drug information source, which is desirable to manufacturers according to PhRMA. It also prevents drug information from being changed onsite by the pharmacist, as often occurs today according to the National Association of Chain Drug Stores.

- Requiring that approved patient information be attached to pharmaceutical packaging – especially unit-of-use formats – will make it significantly more difficult to produce counterfeit medications.

- Consumers deserve drug product information that is at least on par with that provided for packaged food, and over-the-counter drug products. No lesser standard should apply to prescription drugs where the possibility of patient injury or death is usually far greater.

- A mandatory system is the only way to guarantee that useful patient information is consistently provided at the dispensing site.

- For consumers with literacy and visual challenges, the advantages of approved, manufacturer-produced patient information are significant. Printing technology can readily incorporate color, graphics and other visual cues that facilitate comprehension and help protect against mistaking a medication for a similar, look-alike or even counterfeit product. These advantages come into play in all distribution channels, not just those employed in pharmaceutical distribution sites.

- Consumers in possession of manufacturer-provided, FDA-approved leaflets are more likely to use the information, increasing both patient safety and drug compliance. Many commented at the agency's 2003 hearing that – with regard to credibility and patient appreciation – there is no comparison between approved patient Rx information and a leaflet stapled to a pharmacy's paper bag containing an amber vial.

- Dr. Svarstad's study showed that patient literature was being distributed with 89 percent of prescriptions filled for some very common drugs. Even with 89 percent as the current base level, achieving 95 percent distribution is likely unobtainable by 2006. By employing the approaches recommended by the PPLA, the success rate for distributing useful patient information can realistically reach 100 percent.

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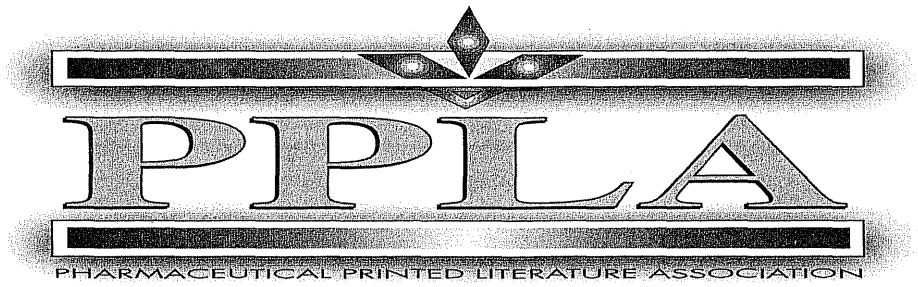

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WHITE PAPER, SUMMER 2004

THE VOID IN USEFUL CONSUMER RX INFORMATION: PAST, PRESENT AND FUTURE

Congressional Deadline For Action May be Impossible to Meet With Pharmacy-Based Systems

Introduction

This paper, sponsored by the Pharmaceutical Printed Literature Association (PPLA), explores the state of useful printed prescription (Rx) information for patients, and weighs approaches toward realizing the goals Congress set out for 2006 relative to useful prescription drug information for patients under Public Law 104-180. The law requires that, by 2006, 95 percent of new prescriptions filled will be accompanied by written information that is complete, consistent, accurate, comprehensible and legible. The law also required interim progress toward this goal to be assessed in 2001. That year, a study sponsored by the U.S. Food and Drug Administration (FDA) concluded that none of the information distributed with sampled prescriptions met all legal parameters for patient usefulness.

The PPLA supports manufacturer-produced and FDA-approved patient information for all prescription medications as the best means of achieving Congress's 2006 goals. This paper will show that the solution can be implemented readily, cost effectively, and in the best interest of consumers.

The PPLA is the world's sole trade group exclusively representing printers of pharmaceutical inserts, labels and cartons. Chartered in 2001, the not-for-profit trade association serves as the voice of manufacturers, and provides a forum for members to advance patient safety and risk communication. The PPLA supports health care professionals, and advocates use of printed literature to legislative, regulatory and other decision-making bodies. In addition, the PPLA is an educational resource for strategic partners and the public.

While PPLA members share a business interest in the advancement of manufacturer-produced, FDA-approved drug information, this interest is set aside for purposes of this paper. The PPLA instead is employing this platform to add our voice to that of public interest groups that are calling for consumer-friendly printed Rx information to help patients derive the greatest benefit, while avoiding dangerous and costly risks, from their drug regimens.

Executive Summary

Inadequate access to useful patient prescription drug information contributes directly to unnecessary and costly emergency room visits and hospital admissions. In 1995, FDA estimated that the cost of these hospitalizations was $20 billion annually. In 2000, the Institute of Medicine reported that 7,000 hospital deaths resulted from medication errors caused in part by improper administration of drugs. The same report found that 10 percent of adverse drug events were linked to errors in the use of drugs as a result of communication failures.

Consumers spend billions of dollars on prescription drugs annually, yet very few are appropriately advised via written drug information how to achieve maximum benefit, while avoiding potentially fatal adverse events, from their drug regimens. Even fewer consumers realize that there is no federal review of the overwhelming majority of printed material they receive when filling prescriptions.

For three decades FDA has struggled, and failed, to institute requirements and conventions to afford consumers useful prescription drug information with every new prescription filled. Now the opportunity is at hand to require FDA approval of prescription information such that patients will find it to be accurate, legible, consistent, comprehensive and comprehensible. Scientific and anecdotal evidence affirms the effectiveness of useful printed drug literature in assuring appropriate patient compliance and risk avoidance with drug regimens.

Although PL 104-180 directs FDA to assure that year 2006 goals are met, the agency has handed off execution to this end to private, unregulated parties that consistently have demonstrated their inability to meet FDA standards for useful printed drug information. FDA has taken public comment on the problem, and commissioned research on it. The results continue to call into question how, and if, year 2006 objectives can be met given the track record of private vendors in reliably delivering high quality prescription drug information to patients.

The PPLA joins with public interest, health care and trade organizations in calling upon FDA to immediately require agency approved patient prescription drug information in the form of patient package inserts (PPIs) or medication guides. FDA's own research has shown that these leaflets meet high standards of quality and usefulness. In fact, the agency briefly required manufacturers to provide them with all prescription drugs until political and economic forces favoring for-profit private suppliers prevailed.

This paper presents evidence that approved patient literature for all prescription drugs is not only feasible but the most-likely-to-succeed means of achieving Congress's 2006 directives. It further serves as a call to action in the interest of public safety through gold-standard risk communication.

At present, FDA regulates only a small portion of prescription information that consumers receive. The agency requires medication guides (MedGuides) to accompany a limited number of drug products that pose a serious or significant health concern. Medications in this class include the acne drug Accutane, which has been decisively linked to suicide and birth defects. MedGuides are the only form of mandatory FDA-approved patient information that pharmacists must distribute with each prescription filled for this limited number of drugs.

There are a few other types of patient-safety information that the agency approves and requires manufacturers to produce. However, there is no requirement obliging pharmacists to distribute them when filling prescriptions. These information types are the following:

- **Package Insert (PI)** — FDA requires manufacturers to produce PIs as part of mandatory labeling for all prescription medications. Although PIs contain some information useful to patients, they are written for health care providers in great detail using highly technical language.

- **Patient Package Insert (PPI)** — FDA further requires manufacturers to provide more patient-friendly PPIs for perhaps 150 drugs not life-threatening enough to warrant a MedGuide, but for which side effects and inappropriate compliance significantly impact treatment outcomes. For example, PPIs are required for birth control pills. They must be distributed at pharmacies with every prescription for which they apply only if they are part of the manufacturer's original packaging.

- **Direct-to-Consumer (DTC) Drug Advertising** — Patients also have access to FDA-approved drug information that is required to accompany DTC ads, such as those printed in magazines and newspapers. This information for the most part closely models a drug's PI and therefore is better suited to health care providers. The balance of risk information to promotional messaging further calls usefulness into question.

FDA's current policy placing patient prescription information almost entirely in the hands of private, unregulated third parties is virtually unknown to consumers. The prescription information an unsuspecting public usually receives, assuming any is provided, typically consists of single-page sheets that are printed out as prescriptions are filled and then stapled to, or stuffed in, the pharmacy bag. Compiled by drug data vendors and software companies that contract with pharmacies, these leaflets receive no federal review. As a result, a consumer filling the same prescription at five different pharmacies could receive five different drug sheets, or none at all. Worse still, private system leaflets have been found to lack key compliance enabling and patient-safety information such as indications and adverse events.

Overview

The United States is unique when it comes to educating consumers about the prescription drugs they consume Throughout Europe, Asia and other parts of the world, printed literature intended for patients is prepared by the Rx drug manufacturer, reviewed by government officials, and attached to drug packages. But in the United States, for nearly all drug products, the only required information prepared by the manufacturer is intended for physicians and pharmacy personnel, not the patient. With no national legal standard requiring that reliable consumer information accompany Rx drug products, consumer interest groups have argued for decades that the U.S. prescription drug distribution system is woefully inadequate and results in serious personal injury and death every year.

To address this long-standing concern, Congress passed legislation in 1996 (Public Law 104-180) requiring FDA to achieve the 95 percent standards outlined in this paper's introduction by 2006. If these cannot be met under the existing, pharmacy-based paradigm, Congress calls for FDA to intervene potentially with requirements, like those in place throughout the developed world, compelling pharmaceutical manufacturers to prepare consumer leaflets, and pharmacists to distribute them. Now, as the 2006 deadline approaches, it appears unlikely the existing system will meet congressional goals.

What is at stake? Certain industry and public interest groups assert that the existing U.S. system cannot be "fixed" due to factors that include:

- Reliance on unregulated vendors that supply pharmacies with hardware, software and content for generating Rx leaflets.

- Pharmacy printing systems that are capable of printing only a limited amount of information.

- The ability of pharmacies to alter information from Rx drug manufacturers.

FDA's 2001 research revealed additional causes for concern. The study entailed a survey of 384 pharmacies nationwide. Conducted at the agency's behest by the University of Wisconsin School of Pharmacy and the National Association of Boards of Pharmacy (NABP), the study sought to gauge whether two PL 104-180 milestones established for 2001 had been met:

1. 75 percent of patients received written information when filling new prescriptions.

2. The information received was "useful" as rated under measures endorsed by the U.S. Department of Health and Human Services (HHS), under which FDA operates. The standards were accuracy, consistency, non-promotional tone and content, specificity, comprehensiveness, understandable language, and legibility.

While the 2001 results found that nearly 90 percent of survey participants received some form of written information when filling prescriptions, it revealed that 11 percent of pharmacies handed out no literature whatsoever.[1] More significantly, it showed that ***none of the information dispensed met the stipulated usefulness criteria; instead, on average, it met only about 50 percent of the prescribed usefulness measures.*** These results boded ill for industry's ability to meet the far more challenging 95-percent requirement for 2006.

With these findings, and under law, HHS was to have promptly taken public comment on remedial strategies. Yet HHS and FDA failed to do so until the advocacy group Public Citizen filed suit in 2003 demanding compliance. In settling the suit, and at long last, the agency took public testimony in July that year.

During the agency hearing, numerous public interest organizations presented data and anecdotal evidence showing that private industry is at once endangering consumers and failing to meet legal requirements. Several groups argued that the means exist to achieve the usefulness goal by 2006, if not earlier, simply and cost effectively, by expanding or revising information already prepared by drug manufacturers, and approved by FDA.

Private industry representatives testifying in 2003 predictably argued in favor of the status quo, claiming repeatedly that the current unregulated system is working, even though it has failed for decades to consistently deliver useful drug information as defined by law. One representative comment was made by John Coster, vice president of policy and programs for the National Association of Chain Drug Stores: "I would not characterize the initiatives of the private sector as failed...I think we're on the right track."[2]

Why is Useful Patient Information Important?

According to the Institute of Medicine, more than 300 studies show that health-related materials far exceed the average reading ability of adult Americans.[3] Health literature is filled with compelling evidence that illustrates the wellness benefits associated with printed information for Rx medications that patients can understand, refer back to, and easily carry with them. These data correlate to two desired outcomes:

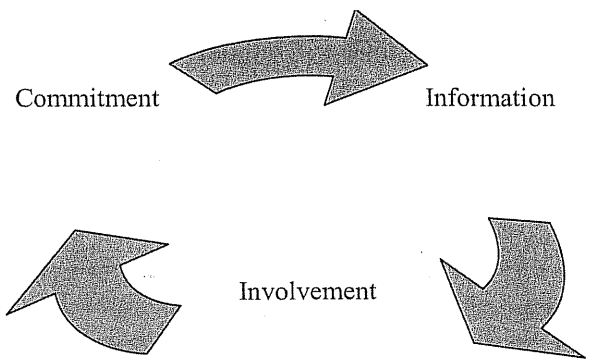
maximum benefit from prescription medications, and avoidance of potentially life threatening, painful and costly adverse events.

Realizing Maximum Benefit

Prescription drugs are prominent in the news today, with headlines about costs, Medicare drug benefits, drug re-importation and counterfeiting featured daily in the print and broadcast media. Useful patient information can help individuals and the health care system maximize the enormous benefits of prescription drugs.

Hundreds of billions of dollars are spent each year on prescription drugs. The actual numbers are difficult to pin down, and sources ranging from the Centers for Medicare and Medicaid Services to *The Wall Street Journal* put the dollar count for total U.S. spending on Rx drugs in 2003 at a staggering $181 billion and $216 billion, respectively.[4] These huge sums are paralleled by those spent within the pharmaceutical industry on research and development, as well as on advertising and marketing. The payoff is innumerable "miracle" drugs that consumers invest in heavily for relief of suffering and improved quality of life. Rx drugs lower blood pressure and cholesterol levels; they make life more livable for those suffering from such debilitating conditions as arthritis and depression. They save lives in emergency rooms.

In his best-selling book, *The Seven Habits of Highly Effective People*, Stephen Covey provides a model that applies to useful patient information.[5]



While this model may not be associated frequently with drug labeling and packaging, it seems apt in conveying the importance of information relative to positive human behavior. Covey's paradigm also has been widely accepted in the corporate world for its universal applicability in engendering human engagement. Its utility in modeling effective paths toward patient compliance seems equally unassailable. High quality drug information enables the patient to become more involved in his or her drug regimens, and therefore more committed to the prescribed course of therapy, which in turn results in improved compliance. This premise is born out by research:

- According to a 2003 report published by the World Health Organization, only about 50 percent of patients in developed countries suffering from chronic illness follow prescribed drug regimens. In the United States, a mere 49 percent of individuals treated for hypertension adhere to prescribed therapies. Among the causes for noncompliance cited in the report was "misunderstanding of treatment instructions."[6]

- In a widely publicized report by the Institutes of Medicine (IOM), entitled *To Err Is Human: Building a Safer Health System* (2000), one cited study found that 10 percent of adverse drug events were linked to errors in the use of the drug as a result of communication failure.

- The same report observed that management of complex therapies, particularly among the elderly, is highly challenging and requires special methods to address the patient's ability to understand and remember dosage timing and amount, and modifications in behavior the regimen requires.

- A 2004 IOM report, entitled *Health Literacy: A Prescription to End Confusion*, noted that the ability of "patients and consumers to manage their own health and medical care can be improved through better provider-patient communication and greater inclusion of the patient in treatment decisions."[7]

- Poor compliance with medication and care regimens can be dangerous, yet serious mistakes may occur because the patient cannot read the instructions. HIV-positive adults with low functional health literacy missed more treatment doses than those with high health literacy because they were confused by the instructions in a study of 182 patients.[8]

Avoiding Adverse Events

Inadequate access to useful patient information is a major cause of inappropriate use of prescription medications that contributes directly to unnecessary emergency room visits and hospital admissions. In 1995, FDA estimated that the cost of these hospitalizations was $20 billion annually.[9] Other organizations estimated the costs to be as high as $77 billion,[10] which was the same amount the U.S. spent on prescription medications in 1995.[11] According to FDA's calculations, during that year alone Americans spent one extra dollar for every dollar spent on prescription drugs as a result of avoidable adverse events.[12]

In a 2001 analysis of 265 reports of medication errors, FDA discovered that 20 percent of the reported errors were attributable to drug labels and labeling, including 1.9 percent directly related to the drug insert and printed or electronic reference information.[13] Additional data further indicate the effectiveness of useful patient prescription information in helping consumers avoid adverse events:

- Up to 5 percent of costly hospital admissions are attributed to drug-related illness that could have been mitigated by useful printed patient information.[14]

- Adverse drug reactions linked to lack of useful drug information occur in 20 percent of ambulatory patients.[15]

- Written information about medicines can help patients recognize problem side effects and then give that information to their doctor or pharmacist.[16]

Useful printed Rx information for patients, as defined by HHS, holds another key role in the public interest. Approved patient information that is mandatory, as are MedGuides, is the only objective source of drug-safety information available to consumers who are deluged with DTC drug advertising through every American media channel.

What is Useful Patient Information?

Patient advocates generally agree with HHS's definition of usefulness; printed leaflets must be scientifically accurate, consistent, non-promotional in tone and content, specific, comprehensive, understandable and legible. The PPLA joins with these groups, adding that usefulness can only be achieved if Rx information is consistent with, or derived from, professional labeling; approved by FDA; manufacturer produced; and required to be distributed with every prescription filled. Even the most informative and readable leaflet, such as the PPI, cannot be considered useful if consumers do not receive it, as they may not unless pharmacies are compelled to distribute them. Clearly, as the University of Wisconsin study revealed, patient Rx leaflets today fall lamentably short of these quality standards.

Under the current pharmacy-based system controlling the type and quality of prescription information patients receive, the same consumer can fill a prescription for the same medication at several different pharmacies and receive a different drug sheet, or no drug sheet, each time. The leaflets may be illegible because of printer quality at a given pharmacy; they may even contain different information because pharmacies sometimes omit important text to accommodate a single-page format.

According to *The Washington Post*, pharmacies of a major grocery store chain serving the Washington, D.C., area routinely altered Rx drug sheets, unbeknownst to consumers. As reported in the *Post*, the chain was prohibited by contract from altering the drug information provided to them by vendor Facts and Comparisons. However, a review conducted in 2002 showed that "the patient information printed by [the pharmacies] was not the full file created by Facts and Comparisons. Three sections omitted from the pharmacy-produced leaflets were titled: 'Before using this medication,' 'Overdose,' and 'Additional information.'" According to the *Post*, these missing sections were restored only after the chain was contacted by a reporter. The company's spokesperson confirmed that stores had opted only "'to provide the basic information.'"[17]

Even when patient information from third-party data vendors is not omitted from leaflets, many still fail to help consumers. The Institute of Medicine offered this text from an actual patient information sheet:

> "Therefore, patients should be monitored for extraocular CMV infections and retinitis in the opposite eye, if only one infected eye is being treated."[18]

The IOM followed up with the research-based finding that 40 million Americans cannot read text like this at all, and 90 million have difficulty understanding complex text. Among many anecdotes the report provided was a case involving a mother attempting to properly administer oral prescription medicine to her toddler for an ear infection. According to the report, "After carefully studying the label on the bottle and deciding that it doesn't tell how to take the medicine, she fills a teaspoon and pours the antibiotic into her daughter's painful ear," furthering the child's discomfort while negating the medicine's efficacy.[19]

As was explained in the Executive Summary, the only mandatory, FDA-approved, consumer-friendly information currently available to the public exists in the form of MedGuides that are required for a small number of drugs or drug classes FDA considers particularly dangerous when used improperly. Patients filling prescriptions also may receive, on rare occasion and mostly at the manufacturers' discretion, FDA-approved PPIs with some drug products and a large variety of drug samples. By specific request of the pharmacist, consumers usually can obtain the drug's package insert, which is not written in consumer-friendly language.

Under the current pharmacy-based system, the average consumer will, at best, receive an unregulated and very brief leaflet. The vendors producing these sheets need not, and so usually do not, conform to a single standard guiding content and format. Nor are these vendors obliged to account for where the information has originated. During FDA's July 2003 hearing, the National Association of Chain Drug Stores' Dr. Coster told the agency that their members often do not know where their vendors get the leaflet information.

How is FDA Progressing In Meeting Congressional Requirements?

Attempts to establish mandatory, gold-standard prescription information for patients have been controversial and bitterly contested by private industry even when precipitated by tragedy. FDA's first PPI requirement was enacted in 1968 for asthma inhalers following deaths due to inappropriate use. Subsequent decades were marked by seesawing regulatory sorties in which FDA proposals were presented and final rules issued, only to be reversed as presidential and congressional leadership shifted, and industry successfully lobbied in protest of further regulation.

Opponents of regulation consistently prevailed with arguments that new rules would require extra investments that would make prescriptions more costly, and that more information is not needed or wanted by consumers. The first point will be examined later in this paper. The second point was well countered by Dr. Janet Woodcock, former director of FDA's Center for Drug Evaluation and Research, during a 2000 public workshop in which she observed, "A century or more of a professional model that didn't trust patients with information has created much inertia to be overcome."[20]

A brief recap of PPI and MedGuide history picks up in 1970, two years after the first PPI requirement, when FDA required approved patient inserts to be included with packaging for hormone drugs, or birth control pills. Ten years later, FDA issued a final rule requiring PPIs for a large number of Rx drugs, only to reverse itself following intense protest from the private sector and the installation of a new presidential administration.

In 1995, FDA issued its "MedGuide proposal" requiring medication guides for drugs most likely to cause harm if not taken properly, and requiring PPIs for all drugs not accompanied by MedGuides. As FDA was taking comment on the proposal, Congress passed PL 104-180 prohibiting the agency from imposing additional patient information rules, and allowing private industry instead to voluntarily work to meet the objectives of FDA's 1995 proposal.

This act of Congress set the milestones discussed earlier for private industry to reach in implementing the desired targets for widely available and useful Rx information. The milestones were to be monitored by FDA, and the agency was to evaluate the usefulness of patient information. While the law barred FDA from implementing uniform content or formatting if private industry was meeting the stipulated availability and usefulness goals, this provision was to be revoked if, by 2001, 75 percent of individuals receiving new prescriptions failed to also receive useful written information. If these criteria were not met, the law called for public input to meet the goals.

Time continued to elapse and, in 2001, FDA commissioned the NABP study on useful Rx information for patients, in compliance with PL 104-180. NABP brought in the University of Wisconsin School of Pharmacy to conduct the study, led by Dr. Bonnie Svarstad, to see what pharmacies were giving to patients filling new prescriptions. Dr. Svarstad's team hired a professional shopping firm to fill

prescriptions for four widely prescribed drugs in different classes at 384 randomly selected pharmacies nationwide. The study concluded that while 89 percent of shoppers posing as patients received some drug information — well in excess of the 75-percent goal — the average usefulness of the information was only about 50 percent, alarmingly short of the legal requirement. With this finding, FDA was to take public comment on corrective strategies. The agency failed to do so, however, until 2003 when it scheduled a hearing in response to the lawsuit filed by Public Citizen.

At the hearing, consumer groups called for FDA to take regulatory action to correct usefulness deficiencies, collectively observing that private industry is failing to meet legal usefulness objectives. Industry, on the other hand, said the voluntary system is on track to meet congressional targets as evidenced by the finding that 89 percent of patients received leaflets. Some representatives of private industry disagreed with the University of Wisconsin findings that most leaflets were not useful.

As of summer 2004, FDA had issued no further guidance or rules in response to the 2003 public hearing. Instead, the agency appears to be applying its resources to exhaust all private industry options in advance of 2006. Usefulness will prospectively be studied again in 2007. If, at that time, government-sponsored research establishes that private industry continues to fail consumers with regard to useful information for prescriptions, and barring legislation that amends PL 104-180, FDA may be compelled to issue further regulations.

What Are the Key Factors, Positions and Issues Moving Forward?

Public safety advocates have repeatedly questioned FDA's rationale for maintaining a system and policy that have been shown for decades to be flawed and not in the best interests of the public. This section reviews the various participants in the issue, and the positions they have taken relative to regulatory policy. In explaining the current thinking at FDA, Arthur Levin, consumer representative for FDA's Drug Safety and Risk Management Advisory Committee, commented in 2004 that former FDA Commissioner Mark McClellan:

> "...could have chosen to make a 'bold' decision and mandate that drug makers provide written prescription drug information for consumers meeting FDA criteria for scientific accuracy and usefulness. I suspect that his failure to act decisively to provide consumers with, in his own words, 'information they can trust to make smart decisions' is another example of Dr. McClellan's pragmatism. Rather than boldly engaging in battle with the anti-regulatory forces of industry, the Bush administration and a conservative Congress, Dr. McClellan has chosen to ignore his own words and risk the public's health."[21]

Intense industry opposition to further regulation could be a determining factor behind FDA's inaction. Agency officials also have stated in numerous public meetings that FDA does not have the resources to review additional PPIs or MedGuides that might arise should their use become mandatory.

Pharmaceutical manufacturers also are seeking to phase out printed literature intended for health care professionals as demonstrated in 1999 when manufacturers announced plans for a "paperless labeling initiative." Sponsored by the pharmaceutical industry's trade group, Pharmaceutical Research and Manufacturers of America (PhRMA), the program seeks to replace printed PIs with electronic alternatives. A primary benefit of the system cited by PhRMA is that it would enable faster information updates.

The first trial of PhRMA's paperless labeling initiative was a proof-of-concept alpha test at ten pharmacies in 2002; a larger trial was slated for 2004. In June 2004, PhRMA announced a beta test to begin the following month at 265 of America's estimated 55,000 pharmacies.[22] Evaluation of the system was slated for late 2004. Provided that results are positive, PhRMA projected nationwide deployment to tens of thousands of additional pharmacies sometime in 2005. While the program's scope and roll out schedule are aggressive when weighed against a drawn out, multi-year launch, the initiative has support within FDA.

The PhRMA program is focused on health care providers, but it has implications to the information patients may receive when filling prescriptions. The system employs third-party vendor prescribing information, both physician and patient focused, which has been shown to be inferior for consumers. PhRMA's partners in the initiative, notably the primary content provider Thomson Healthcare, see the program as a means of meeting congressional goals for year 2006. According to Mukesh Mehta, vice president of regulatory affairs and labeling at Thomson:

> "This initiative will insure that every dispensing site in the United States and its territories will have access to the most current FDA approved prescribing information. The ultimate impact is that the patient will benefit by receiving better information from the health care providers. This effort will also promote better health care and patient safety by reducing medication errors due to the use of outdated [prescribing] information."[23]

Dr. Mehta does not address how usefulness, specifically, will be established on the consumer's behalf through such a system, were it to be successfully deployed as envisioned by PhRMA. Based on comments filed with FDA, and public testimony by the trade group and its constituents, the paperless labeling initiative represents little more than a higher-tech version of the existing private system whose well documented shortcomings far exceed the technical.

Moreover, successful implementation of a paperless system rests on the ability of some sponsors to provide computer equipment to all drug-dispensing points, free of charge. With this equipment installed, labeling information and updates could be sent to users in unalterable files. PhRMA has indicated that there may be financial incentives to create such a system because it would serve as a "direct portal" to physicians and pharmacists.

While such a system could help improve the timeliness of Rx information for professionals, a number of issues, beyond the sheer scope of this considerable implementation, must be carefully weighed before PhRMA's system can be used as a replacement to printed prescription labeling. Among these considerations are the following points:

- FDA has no authority to regulate the use of electronic databases in pharmaceutical dispensing sites; therefore the public has no guarantee that these systems will operate properly.

- Although PhRMA's plan calls for the no-cost provision of needed computer equipment at pharmacies and other dispensing points, no entity has been publicly identified to take responsibilty for these resources. Lacking such a sponsor, pharmacies could be compelled to

bear the costs of additional systems. Many pharmacies, particularly small, independent and rural ones, lack such resources.

- Field doctors, pharmacists working from mobile dispensing sites, and those in rural areas of the country cannot be served effectively by electronic means.

- Pharmacy and hospital health care personnel must always have access to critical prescription drug information; in emergency settings and situations, health care practitioners in immediate need of prescribing information would be challenged by the system.

- Electronic formats are subject to power outages, equipment failure and corruption.

Another participant in FDA's effort to meet year 2006 goals is the National Council on Patient Information and Education (NCPIE). This not-for-profit organization was formed in 1982 with support from FDA's Committee on Patient Education. NCPIE serves as a major coordinating body for private-sector initiatives working to improve communication about prescription medicines to consumers. FDA supported NCPIE's formation the same year the agency withdrew its 1979 proposed rule requiring PPIs for about 375 prescription medicines.

In 2002, after the University of Wisconsin study results revealed that sorry state of in-pharmacy Rx sheets, FDA enlisted NCPIE to serve as a catalyst to help private industry do a better job in providing quality prescription leaflets. In response, NCPIE launched its Consumer Medicine Information (CMI) Initiative in 2003. To date, NCPIE has formed three committees to drive the CMI Initiative: Criteria, Education and Implementation. Objectives and challenges also have been identified. Any further progress as of mid 2004, however, has not been discernable through FDA's public channels.

Despite a head start of nearly 19 years, NCPIE had not succeeded in coalescing private industry toward meeting regulatory goals. A great many of NCPIE's members have close ties to the private system, and health literacy is conspicuously under-represented within the organization. With these factors in play, the question arises whether NCPIE has the ability to affect success relative to congressional goals for 2006.

PhRMA and NCPIE were among the organizations testifying during FDA's July 2003 hearing to evaluate the status of useful printed Rx information for patients. Also testifying were patient-safety groups Public Citizen, the Center for Medical Consumers, and the PPLA, among others. In testimony and comments filed with FDA afterward, the latter three organizations called for mandatory, FDA-approved, manufacturer-produced printed prescription information for patients. Other groups, including the National Organization for Rare Disorders and the Pharmacists Planning Service, indicated support for this position, either in its entirety or its spirit.

Particularly notable among the comments FDA heard at the 2003 meeting was the following from Amy Allina, program and policy director for the National Women's Health Network:

> "Those of you who know my organization know that we've been involved in trying to get useful information to patients about medication since we were founded 27 years ago...[A]fter listening to everything over the course of the day, I can't help but say that there's been an

> enormous amount of time [spent] by a huge number of people invested in this over 25 years...But we're still in a situation where the information that's getting to consumers is either inaccurate or not useful, not comprehensible and that's in cases where it is getting to consumers...[I]t seems clear to me that... it's long past time for this — the process of getting written information to patients to be made mandatory and to be overseen by the FDA."[24]

Drug manufacturers Merck and Pfizer also urged FDA to encourage use of manufacturers' Rx information. In comments filed with FDA, both companies requested greater emphasis on FDA-regulated materials in the voluntary system. Merck took a particularly strong stand on the matter in written comments, stating, "To date, voluntary private sector efforts have failed to meet the goals [of the 1996 law]...Because they are FDA-approved, these PPIs are the best sources of current information about prescription drugs."

Other challenges have been raised in support of the existing pharmacy-based system. They are presented below, with counterpoints:

- **It has been argued that additional regulations will interfere with the patient-care provider interface and counseling.**

  This challenge might be compelling were it not for the fact that, with or without additional regulations, research has shown that very little counseling actually takes place at drug dispensing sites. According to Dr. Bonnie Svarstad in testimony before FDA in February 2000, the University of Wisconsin study revealed that, in Dr. Svarstad's words:

  > "...[O]nly 35 percent of the written information sheets were given to the client or the patient, patient observer, with some kind of mention or with some kind of oral review, or with some kind of encouragement to read it. In other words, in the majority of the cases, according to the state inspectors, these written information sheets are beingstuffed in the bag. They are not being discussed, reviewed, or mentioned in a positive way by the pharmacist. And I would warn us all to remember that what evidence we do have on the effects of written information would suggest that their efficacy depends on oral review...If you are not encouraged to read it, many people will not read it. But if you are encouraged to read it, people will read it."[25]

  The Institute of Medicine also observed shortcomings in provider-patient communication. The IOM's 2004 health literacy report cited as related factors the "relative infrequency and brevity of visits, language barriers, differences between providers' and patients' agendas and communication styles and other cultural barriers, lack of trust between the patient and provider," and so on.[26]

- **Others say that pharmacies cannot store all the leaflets that would be required for mandatory FDA-approved patient information.**

  The means currently exist — and are being employed at present by a number of manufacturers for many products — to attach approved, manufacturer-produced, patient information directly to pharmaceutical packaging, thereby alleviating storage and fulfillment challenges at dispensing locations. This cost-effective and existing technology affords benefits that extend beyond storage solutions. If manufacturers were required to attach removable leaflets as part of their

approved labeling, consumers would benefit from having constant access to useful Rx information, and dispensing sites would not need to alter workflow practices to provide the public with important drug information.

- **Some claim that the financial burden of mandatory patient information will not justify the benefits.**

The technology and resources are in place today to implement a mandatory program at virtually no additional cost to industry or consumers. Manufacturer-produced, FDA-approved Rx information has already been developed for all drugs for which manufacturers employ direct-to-consumer advertising in publications. Many of these do not comply with regulators' usefulness guidelines, but could easily and affordably be made compliant with funds budgeted for print advertising. In this way, one consumer-friendly document can serve several risk and liability management purposes to manufacturers' economic benefit. Additionally, the required PI is a source of a great deal of information that can be made consumer-friendly with simplified language.

For pharmacies, the financial impact of mandatory patient information would seem equally negligible, if not favorable. Such a program would free pharmacies from the need to contract with data vendors, and improve efficiency and customer service because printed-out leaflets would no longer be required.

Conclusions and Recommendations

As the taxpayer-funded guardian of medical consumer safety, FDA has a fiduciary and legal responsibility to correct the failing pharmacy-based system for printed patient literature. FDA should address this issue immediately and aggressively in light of the well established fact that this information lacks utility to consumers, and that one in ten pharmacies do not distribute any information at all. Barring quick and decisive rulemaking on FDA's part, pharmacies will continue to withhold drug information that patients need and want. This need is amplified by the unfortunate reality that too many consumers receive the bulk of their Rx information in DTC advertising — hardly an objective medium.

The impact of further inaction is likely to be carried into other consumer information channels, as well. As Dr. Leander Fontaine noted in the journal *Drug Safety*, barring changes to the current system, "...other sources of product information will grow even more important and reduce the effectiveness of labeling for risk management. These sources include pocket guides for [health care practitioners], medication books for patients, information offered on the internet and for electronic office, pharmacy and hospital information systems, which may not be fully consistent with labeling, and not current."[27]

It is time for FDA to act decisively in the best interest of American consumers. The current approach has proved a failure, and has provided a direct link to increases in patient risk and health care costs. Even the agency's own Drug Safety and Risk Management Advisory Committee urged FDA to exercise its authority to take over this critically important task from private industry. Key risk information available with every prescription will not be consistently, comprehensibly and legibly provided unless the agency compels manufacturers to take the lead.

To this end, FDA would be well advised to convene a work group comprised of regulatory officials, learned intermediaries and literacy experts to address the task of developing MedGuides or PPIs for all drugs currently lacking them. If the Agency opts to continue its present course, however, stakeholders are left with no recourse other than to appeal directly to lawmakers in the Senate and House of Representatives to petition in favor of more consumer-supportive statutes and regulatory leadership.

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For more information about this white paper and the current status of useful printed prescription information for patients, please contact the Pharmaceutical Printed Literature Association at 703-538-5799, or via e-mail at info@pplaonline.org. Visit the PPLA on the Web at www.pplaonline.org.

Additional Resources

Center for Medical Consumers:
http://www.medicalconsumers.org/pages/advocacy.html#written_prescriptiondrug_info

Useful Printed Patient Information — Testimony of Arthur Levin, Consumer Representative, FDA Drug Safety and Risk Management Advisory Committee; Director, Center for Medical Consumers:
http://www.medicalconsumers.org/pages/advocacy.html#written_prescriptiondrug_info

Public Citizen, Health Research Group:
http://www.citizen.org/hrg/

Useful Printed Patient Information — Testimony of Sidney Wolfe and Larry Sasich, Public Citizen Health Research Group:
http://www.citizen.org/publications/release.cfm?ID=7269&secID=1685&catID=126

National Council on Patient Information and Education:
http://www.talkaboutrx.org

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[19] Report: "Health Literacy: A Prescription to End Confusion," Institute of Medicine, 2004, p. 3, http://www.iom.edu/report.asp?id=19723.

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PHARMACEUTICAL PRINTED LITERATURE ASSOCIATION

Pharmaceutical Printed Literature Association

Improving Patient Safety and Risk Communication

The Pharmaceutical Printed Literature Association (PPLA) is the world's sole trade group exclusively serving printers of pharmaceutical inserts, labels and cartons. Representing the majority of the North American pharmaceutical printed-insert industry, the not-for-profit trade group was chartered in 2001 to serve as the voice of manufacturers, and to provide a forum for members to advance patient safety and risk communication. The PPLA supports health care professionals, and advocates use of printed literature to legislative, regulatory and other decision-making bodies. In addition, the PPLA is an educational resource for strategic partners and the public. More information about the PPLA is available via the Web at http://www.pplaonline.org.

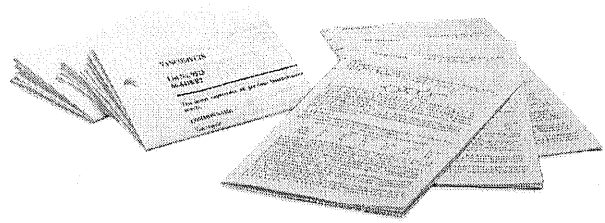
Our Policy Positions:

The PPLA operates an active government and public affairs program to assure that member interests are carried forward to industry regulators. Our policy positions include support for:

- Greater availability of FDA-approved printed prescription information for patients
- Printed drug information technologies to guard against counterfeiting
- Prescription leaflets that are accurate, consistent, comprehensible and legible
- Labeling for dietary supplements should be held to the same standard as that required for over-the-counter drug products

Our Mission:

The PPLA serves as the voice of manufacturers of pharmaceutical printed package information, providing a forum for members to promote and improve delivery of information for the protection of patients, and in support of healthcare professionals. The PPLA further represents members' interests to legislative and regulatory agencies, supports members' economic welfare, and provides industry education to advance the trade group's strategic objectives.



We Invite You to Join Us

Why The PPLA Was Formed

The PPLA was chartered to address the significant need for representation of an industry that plays a critical role in assuring patient safety through improved prescription drug compliance. Numerous studies have shown the connection between positive health outcomes and printed prescription (Rx) drug information that is complete, accurate, legible, readily accessible and comprehensible to patients.

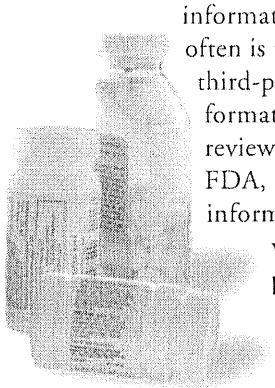
Yet, according to the U.S. Food and Drug Administration (FDA):

- Only about 50 percent of consumers receive useful information to correctly take medication when filling prescriptions.
- This problem costs an estimated $20 billion a year in preventable drug-related illnesses.

Moreover, regulators, federal advisory groups and private industry are weighing strategies that could significantly impact access to printed patient drug information. The PPLA proactively employs educational, government affairs and strategic alliance programs to help improve risk communication and medication compliance through continued and expanded access to printed drug information that is FDA approved, manufacturer produced and consumer friendly.

Why FDA-Approved Printed Information is Important for Each Rx Filled

Today, when a consumer fills a prescription, chances are that FDA-approved information about the drug and how to take it for maximum benefit is not provided. To the extent that consumers do receive printed Rx information at the pharmacy, it most often is the product of an unregulated third-party vendor whose content and format have received no regulatory review or approval. According to FDA, 50 percent of the patient information prepared by third-party vendors, and provided with prescriptions, is illegible, incomprehensible to the average consumer, inconsistent, incomplete, or all of the above.



The result is preventable medication errors that cost taxpayers billions of dollars each year. Compelling data exists supporting the safety benefits of useful printed patient information in offsetting or preventing harm to consumers:

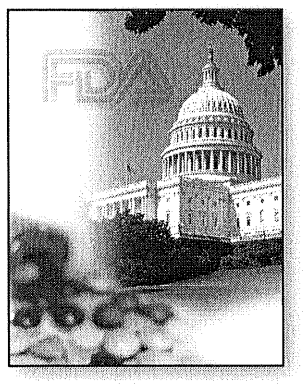
- Up to 5 percent of costly hospital admissions are attributed to drug-related illness that could have been mitigated by useful printed patient information. The case fatality rate from drug-induced disease in hospitalized patients is 2 percent to 12 percent.
- According to FDA, written patient information is necessary not only to improve prescription adherence and compliance rates, but also to inform patients about precautions. Adverse drug reactions linked to lack of useful drug information occur in 20 percent of ambulatory patients.
- Improper use of prescription drugs leads to unnecessary illnesses, emergency room visits, hospital admissions and deaths. FDA estimates extra healthcare costs from preventable drug-related illnesses to be at least $20 billion a year.
- Prescription labels and self-care instructions are among the most important written materials patients receive. Poor compliance with medication and care regimens can be dangerous, yet serious mistakes may occur because the patient cannot read the instructions. HIV-positive adults with low functional health literacy missed more treatment doses than patients with high health literacy because they were confused by the instructions in a study of 182 patients.

How the PPLA Helps Members

The PPLA's primary strategic initiatives encompass government affairs, public affairs, and statistics and survey research. Through these and other programs, the PPLA advances member interests in support of patient safety to industry and governmental decision makers. Despite this trade group's youth, the PPLA has built a track record of uniquely and proactively representing members and allies through:

- Testimony before FDA
- Filing formal comments with FDA and others regulatory organizations

- Building strategic alliances with powerful interest groups
- Leveraging key industry events to spread our message and build support for our objectives



As a result, our profile has increased considerably, and we have developed a variety of tools that will serve our members well moving forward. Through our work, and that of our complementary organizations, printed drug labeling remains a staple in protecting the public, and the integrity of pharmaceutical manufacturers' products. The PPLA continues to guard against efforts in several quarters throughout the industry to discount this utility in favor of far less secure, portable and tangible formats.

Benefits of PPLA Membership

The PPLA works aggressively to tackle challenges to its members and the public that include Federal regulations that may greatly change printed inserts for drug products. Additionally, accurate and accessible patient information is badly needed yet largely absent. The high cost of errors in drug administration is mitigated by printed literature. Until the PPLA's formation, the pharmaceutical printing industry lacked a voice to regulatory authorities. A dedicated resource for monitoring critical legislative developments did not exist. The PPLA was chartered to serve the industry and members on each of these fronts. Specifically, the PPLA's benefits to members include:

- Two member newsletters covering industry and regulatory trends and developments. These newsletters are the quarterly printed *PPLA News* and the monthly electronic update, *PPLA E-Bulletin.*
- Expert government affairs resources in Washington, D.C., representing member interests.
- Information on key conferences relating to pharmaceutical literature and patient safety.
- Two annual member meetings featuring an educational program and top industry speakers.
- Research data on production trends and industry challenges.
- Deeply committed leadership team comprised of seasoned industry executives representing the majority of the North American pharmaceutical printing industry.

How You Can Join

The PPLA welcomes printers, print suppliers, machinery manufacturers, and others involved in the production of printed literature used by the healthcare industry. Our trade group has an important mission and much to accomplish, and our goals are certain to be met more quickly and thoroughly through the largest possible membership base.

If your company has an interest in medicinal therapies — whether prescription drugs, over-the-counter products, or dietary supplements — we welcome your participation in our association. For complete membership details, please visit us on the Web at www.pplaonline.org, or e-mail us at info@pplaonline.org. Please also feel free to call our headquarters in suburban Washington, D.C., at 703-538-5799.

Member Structure and Fees

Corporate Members with sales of:

More than $8 million/year	$7,500
$4 to 8 million/year	$5,000
Less than $4 million/year	$2,500
Associate Members	$2,500
Honorary Members	No Dues

Corporate members include businesses engaged in the manufacture or sale of printed literature or packaging intended to accompany drug and health care products (over-the-counter or prescription). Corporate members also are manufacturers of raw materials or equipment used to produce printed literature (including paper, paperboard, ink, label materials, printing machinery, folding machinery, etc.). Corporate members enjoy voting privileges and are eligible for service on the PPLA Board of Directors.

Associate members are businesses that *are not eligible* for corporate membership in the PPLA, but are engaged in commercial or educational activities that support or promote the purposes of the PPLA. Associate membership also is available to manufacturers of raw materials or equipment used in the production of printed literature that would otherwise be eligible for full membership but choose not to join at that level. Associate members agree to relinquish their voting rights and are not eligible for service on the PPLA Board of Directors.

Honorary members typically are individuals or organizations dedicated to health safety education and advancement. They are invited to join the PPLA on a case-by-case basis via nomination and election by the Board of Directors. Honorary members pay no dues, may not vote, and are not eligible for service on the PPLA's Board of Directors.

For More Information...

To learn more about the PPLA, visit us on the Web at www.pplaonline.org. The PPLA's Annual Report, positioning statements, fact sheets, quarterly newsletter and other informational materials are available online under *News and Resources*, and elsewhere on the site. You also may contact us at our headquarters near Washington, DC:

The Pharmaceutical Printed Literature Association
131 East Broad Street
Suite 206
Falls Church, VA 22046

www.pplaonline.org
info@pplaonline.org
Tel: 703-538-5799
Fax: 703-538-6305

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Agenda Item I

State of California Department of Consumer Affairs

Memorandum

To: Communication and Public Education Committee

Date: March 15, 2005

From: Virginia Herold

Subject: California Health Policy Forum

The following is a description of a new health policy consortium that is being formed. This is provided for your information.

"Center for Health Improvement"
<info@chipolicy.org>
02/28/2005 02:23 PM

To: <info@chipolicy.org>
cc:
Subject: Capitol Health Conversations

[IMAGE][IMAGE]

For Immediate Release

Contact: Vonnie Madigan

February 28,2005

916.930-9200 ext 120

New CA Health Forum Launches

Capitol Conversations

Sacramento—Five California policy leadership organizations have launched the California Health Policy Forum (CAHPF), a new and independent platform for education, idea sharing, and conversations among state legislative and executive branch health policy staff about the complex health issues facing the state today. The nonpartisan, participant-driven, solutions-orientedCapitol conversations are modeled after the National Health Policy Forum.

"CAHPF seeks to inform the public policy-making process through a series of invitational briefing sessions featuring national speakers," said Patricia A. Powers, President and CEO of the Center for Health Improvement (CHI). "There is no other ongoing, integrated approach to discussing health issues in Sacramento."

CAHPFsteering committee includes CHI, California Department of Health Services (CDHS Director Sandra Shewry), Legislative Analyst's Office (Leg Analyst Elizabeth G. Hill), Public Health Institute (PHI President Joseph M. Hafey) and Senate Office of Research (SOR Director Donald B. Moulds). The California Endowment and The California HealthCare Foundation fund the CAHPF. Funding is also pending from The California Wellness Foundation.

The new forums consist of interactive briefings designed to inform legislative and agency staff on topical health issues. Findings from an annual legislative and executive branch staff survey, along with input from the CAHPF Steering Committee and Advisory Committee, determine what topics are selected and how forum sessions are structured. While particular policy solutions may arise during forum sessions, CAHPF is a nonpartisan organization that does not advocate any particular policy positions.

The inaugural forum entitled California Policy Implications and Choices for Medicare's Rx

Program (Part D) will be held in the state Capitol on Friday, April 29, 2005. The briefing is co-sponsored by the National Academy for State Health Policy in Washington, D.C.; featured speakers include representatives from the Centers for Medicare and Medicaid and state policy experts.

CAHPF is staffed by CHI. For more information visit www.cahpf.org.

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Agenda Item J

State of California | Department of Consumer Affairs

Memorandum

To: Communication and Public Education Committee

Date: March 14, 2005

From: Virginia Herold

Subject: Miscellaneous Consumer Issues and Articles in the News

In this section, I have gathered several items 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 they wish to propose future action at the next committee meeting.

Combination Therapy Might Be Better Choice Than Nevirapine Alone To Pre Vertical HIV Transmission, Researchers Say

Daily Health Policy Report

Email this story to a friend.
Print this story.
View entire Policy Report.

Prescription Drugs | AARP Launches Prescription Drug Comparison Web Site
[Feb 25, 2005]

AARP on Thursday launched a Web site that allows U.S. residents to compare the "safety, effectiveness and cost" of prescription drugs, *CQ HealthBeat* reports. The site offers data on drugs for nine medical conditions and includes information about generic alternatives and pricing. The Web site will be expanded to include drugs from 20 conditions in the coming months. According to AARP, the information provided on the Web site seeks to correct an "imbalance" in prescription drug information created by pharmaceutical company marketing efforts. An AARP poll released Thursday found that most physicians receive free samples of brand-name drugs and visits from brand-name pharmaceutical company representatives, but few receive free samples of generic drugs or visits by generic drug maker sales reps. "It's our hope that the online information will raise awareness among members and consumers about the relative effectiveness of prescription drugs, while helping them identify lower cost, yet equally effective, alternatives," AARP Policy Director John Rother said (*CQ HealthBeat*, 2/24).

Browse Topics

Health Financing
Health Plans
Health Policy
Health Privacy
Healthy Families
HIPAA
iHealth & Technology
Insurance Markets
Medi-Cal
Medicare
Physician Organizations
Prescription Drugs
Proposition 61
Proposition 63
Proposition 71
Special Populations
Quality
Workforce

Upcoming Events

- Science, Medicine and Public Perception and Trust at the Onset of the 21st Century
  March 9 | San Francisco
- AMGA Annual Conference: Learning from the Best
  March 10-13 | Los Angeles
- Medicare Rx: Key Issues for 340B Stakeholders
  Mar. 16-18 | San Diego
- Consumer Driven Health Plans: Innovation or Disruption?
  March 16-17 | San Francisco

Past Issues

Select Date

Other Resources

- Health Care Leadership Program
- Small Business Guide to Health Insurance (in English and Spanish)
- California Nursing Home Search
- What Patients Think of California Hospitals

Welcome. Visitors wishing to view more than two items will be asked to login or register.

Today in California Healthline

Sacramento Beat forward next article

Department of Managed Health Care Investigating Some Discount Card Companies

March 7, 2005

More than 150 people have filed complaints with state regulators about health discount cards that did not deliver promised savings, and state Department of Managed Health Care Director Cindy Ehnes said there are probably far more who have not contacted officials, the *Sacramento Bee* reports.

According to DMHC officials, an increasing number of primarily low-income and minority residents have "been lured by deceptive marketing and advertising" to buy health discount cards that offer little or no savings and require monthly premiums, the *Bee* reports.

The officials added that even legitimate cards might require patients to pay a monthly fee to qualify for discounts, some of which they might have received without the discount card because some doctors and hospitals give discounts to low-income uninsured patients.

Ehnes said DMHC has oversight of any company that collects regular fees from patients to refer them to a designated list of medical providers. DMHC first targeted two fraudulent discount card companies six months ago. Ehnes said more than 100 companies are currently under investigation.

Ehnes said, "These advertisements are now all over the Internet and late-night television targeting poor people who are desperate to get insurance for their families." She added, "If they are not selling a legitimate insurance policy or offering patients any legitimate savings, they are not going to be tolerated in California" (Rapaport, *Sacramento Bee*, 3/4).

***Oakland Tribune* Examines Issue**

The *Oakland Tribune* on Sunday also examined medical discount card companies and DMHC investigations of such firms (Vesely, *Oakland Tribune*, 3/6).

back next article

forward

Related Stories

- Department of Managed Health Care Tells Two Discount Card Companies To Cease Offerings
  09/24/2004

Daily Health Policy Report

Email this story to a friend.
Print this story.
View entire Policy Report.

Prescription Drugs | 'Black Box' Warnings on Antidepressants To Appear in Mid-March, Five Months After FDA Order
[Mar 02, 2005]

The labels for the five antidepressants most commonly prescribed to children will begin to include "black box" warnings this month to advise consumers that the medications could cause suicidal tendencies in individuals younger than age 18, *USA Today* reports (Elias, *USA Today*, 3/2). In October 2004, FDA ordered pharmaceutical companies that manufacture antidepressants to add the warnings, which consist of a black section with white writing that appears at the top of prescription drug inserts distributed to physicians and patients. The black box warnings are the strongest that the federal government can implement before a ban. FDA ordered the warnings for antidepressants based on an analysis of 15 clinical trials that found a "consistent link" between the use of the medications and suicidal tendencies in children. (*Kaiser Daily Health Policy Report*, 1/14). The warnings state that about two in 100 children who take antidepressants are more likely to have suicidal tendencies. Joel Gurin, executive vice president of Consumers Union, said, "It's unfortunate that it's taken this long. It was really important for parents to have had this information. Getting it out quickly was important for transparency and trust." However, FDA spokesperson Susan Cruzan said the process for revision of a prescription drug label takes time. FDA must approve applications from pharmaceutical companies for label revisions, and companies have 30 days after they receive approval letters to make the changes, she said. FDA in mid-January sent an approval letter to GlaxoSmithKline, which manufactures Paxil and Wellbutrin, and in mid-February sent letters to the manufacturers of Prozac, Zoloft and Celexa (*USA Today*, 3/2).

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FDA seeks more say on drug labels

The Boston Globe

Regulators want greater authority to dictate warnings

By Christopher Rowland, Globe Staff | March 2, 2005

The Food and Drug Administration asked Congress yesterday to give it more powers to dictate the warnings on drug labels, highlighting what critics call a weakness built into the US system for keeping drugs safe.

ADVERTISEMENT Sandra Kweder, deputy director of the FDA's Office of New Drugs, made the request at a hearing of the Senate committee that oversees healthcare.

The panel was examining how regulators dealt with Merck & Co.'s arthritis pain drug Vioxx, which remained on the market despite early evidence that patients taking the drug were subject to higher risk of heart attacks and strokes.

Among the focal points were labeling changes that took 14 months to make. In February 2001, an FDA advisory panel recommended stronger warnings on the Vioxx drug label to reflect possible increased risks of cardiovascular problems. But those changes were not made to the label until April 2002, after a round of negotiations with the company. Merck withdrew the drug from the market in September 2004 after a study of high doses of Vioxx affirmed the earlier indications of risk.

Kweder said the FDA needed more authority to dictate label changes in such cases.

"The lapse from my perspective was the delay that it took to get that information into the labeling," she told the Senate Committee on Health, Education, Labor and Pensions. "A strong ability to require changes in labeling would be helpful."

Congress is considering legislation to tighten rules on how the government keeps track of the safety of drugs after the FDA approves them. The proposals include a bill unveiled Monday that would require drug and medical device manufacturers to report findings of clinical trials in a publicly available database, including potential side effects, funding, and information on test subjects.

As a practical matter, the FDA has strong authority to dictate labeling language before a drug is approved. In such a case, if a drug maker does not accept the FDA's warnings, the agency could drag out approval or reject the drug. But the company is in a much stronger position after it wins market approval.

"Once a product is on the market, it's like a property right," said Robert Nicholas, head of the FDA practice group at McDermott Will & Emery, a law firm in Washington.

The FDA still has strong negotiating clout for label changes, because if a drug company refuses its suggestions the agency could initiate legal proceedings to remove a drug from the market, or it could ask the secretary of the Department of Health and Human Services to declare a drug an "imminent hazard." But short of those dramatic moves, the FDA's options are limited.

"There are lots of informal routes -- there is jawboning or discussions," Nicholas said.

But drug industry critic Sidney Wolfe, health director for the Washington consumer group Public Citizen, said even without FDA authority to dictate drug label language, the agency can in effect force change if it wants to. For instance, he said that if the agency publicly demanded a "black-box warning," the most severe safety warning that can be placed on a drug, its manufacturer would have a hard time resisting. Wolfe said he called for a black-box warning for Vioxx in 2001.

"The FDA didn't want to take that seriously," he said.

The drug industry's lobbying and trade group, the Pharmaceutical Research and Manufacturers of America, said it was reviewing Kweder's remarks and did not have a specific reaction. But in general, said PhRMA spokesman Jeffrey Trewhitt, "We do believe that FDA jurisdiction over product labeling is adequate."

Massachusetts Senator Edward M. Kennedy, ranking Democrat on the Senate committee, said the FDA needs more power.

"FDA needs clear authority to require relabeling of a drug if necessary after approval, once a risk is found," he said. "Negotiations with a drug maker should never delay accurate information for patients and doctors."

Christopher Rowland can be reached at crowland@globe.com. Material from Globe wire services was used in this report.

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Kaiser Family Foundation <KaiserFamilyFoundation@cme.kff.org>

11/22/2004 07:01 AM

To: Virginia_Herold@DCA.CA.GOV
cc:
Subject: Report Analyzes How Medicare Drug Benefit Will Affect Enrollees' Out-of-Pocket Spending

Low-income people with Medicare who sign up for new Part D drug plans and receive the additional subsidies - an estimated 8.7 million people - are projected to pay 83 percent less for prescription drugs in 2006 than they would have spent if the Medicare drug law had not been enacted, according to a new report released by the Kaiser Family Foundation. Those who enroll in the new drug benefit but do not receive the low-income subsidies - an estimated 20.3 million people -- are projected to pay on average 28 percent less out of pocket for their prescription drugs as a result of the new law, the analysis finds.

The analysis projects that 6.9 million people - or nearly one in four who sign up for the new drug benefit - could have spending in the "doughnut hole," where those with total drug costs exceeding the initial benefit limit ($2,250 in 2006) are projected to have out-of-pocket costs exceeding $750 in 2006. Nearly half (3.1 million people) of those who reach the doughnut hole are projected to receive catastrophic coverage under the new benefit because they incur at least $3,600 in out-of-pocket drug costs.

The new analysis is based on a model developed by the Actuarial Research Corporation for the Kaiser Family Foundation. The model generally conforms to the Congressional Budget Office's assumptions and projections about Medicare drug benefit spending and participation rates for the new benefit and for the low-income subsidy.

The report and other materials released today at a policy briefing in Washington are available online at http://www.kff.org/medicare/med112204pkg.cfm . A webcast of the briefing will be available after 5 p.m. ET.

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To subscribe or unsubscribe to email alerts from the Kaiser Family Foundation, please visit http://www.kff.org/register . If you need help or have questions,
please send an email to subscriptions@kff.org. If you know anyone who would be interested in this alert, please pass it on.
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-Message-Id: <20041122070108.C992.14052-4967@cme.kff.org>

Agenda Item K

State of California | Department of Consumer Affairs

Memorandum

To: Communication and Public Education Committee Members

Date: March 14, 2005

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 strives to attend 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, which usually are well-received by the individuals present.

Since the beginning of 2004, the board has provided presentations on SB 151 and the new requirements for prescribing and dispensing controlled substances in California. We have also presented this information via telephone conference call to large numbers of individuals.

Public and licensee outreach activities performed since the last report to the board are:

- Supervising Inspector Ratcliff presented information on new pharmacy law to 85 pharmacists and students at Phi Delta Chi at USC on January 20.
- The board staffed a booth at the Consumer Protection Day event in San Diego on January 29, 2005. Department Director Charlene Zettel was the keynote speaker at this event attended by approximately 1,500 individuals.
- The board staffed an information booth for two days at CPhA's 2005 Outlook on February 18-19. Over 500 pharmacists and students attended.
- Board President Goldenberg met with deans from the California schools of pharmacy, CSHP, and CPhA at the CPhA's Outlook 2005 Meeting.
- Board Member Jones presented information on new dispensing requirements for controlled drugs at the CPhA's Outlook 2005 Meeting in San Diego in February 2005 to over 200 pharmacists.

- Supervising Inspector Ratcliff presented information on prescribing and dispensing controlled substances to approximately 90 pharmacists to the San Fernando Pharmacy Association on February 16, 2005.
- Supervising Inspector Ratcliff presented information to 100 1st year students at UCSF's School of Pharmacy on February 22.
- Supervising Inspector Ming and staff presented information on prescribing and dispensing controlled substances, and applying for the pharmacist licensure examination to 85 students at Western University on February 25.
- Executive Officer Harris presented information about the board to 1st year students at UCSF on March 1.
- The board staffed an information booth on March 12 at UCD's Healthy Aging Conference in Sacramento; over 1,000 people attended.
- Supervising Inspector Ming will present information about new prescribing and dispensing requirements for controlled drugs at the San Mateo County Pharmacists Association Meeting on March 17 to 80 pharmacist and pharmacy technicians.
- Board Member Schell will present information on automated technology in pharmacies to pharmacy students during April 2005's Legislative Day.
- The board will staff a consumer information booth on April 30 in San Diego at the Better Business Bureau's 2005 Smart Consumer Expo
- The board will staff a consumer information booth on May 7th in Sacramento at the 7th Annual Family Safety and Health Expo.