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

NOTICE OF MEETING and AGENDA
Communication and Public Education Committee

Contact Person: Virginia Herold
(916) 445-5014 X 4005

Time: 9:30 – 11 a.m.
Date: July 7, 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 **9:30 a.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. Miscellaneous Consumer Issues/Articles in the Media

H. Update on the Board's Public Outreach Activities

I. Adjournment **11 a.m.**

Meeting materials will be on the board's Web site by June 30, 2005

Agenda Item B

State of California Department of Consumer Affairs

Memorandum

To: **Communication and Public Education Committee** **Date: June 29, 2005**

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

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

One year ago, 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 series 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.

So far, four fact sheets have been developed, and a fifth is undergoing work by the board. The first fact sheets prepared -- "Lower Your Drug Costs to Help you Keep on Taking your Medicines," "Generics," "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.

The goal had been to develop three fact sheets per quarter. The first three fact sheets were developed and provided to the committee in January. Two additional fact sheets were developed and shared at the March meeting.

For this meeting, Dr. Soller advises that he does not have any additional fact sheets to share. The good news is that he now has 13 students who have recently agreed to develop at least three fact sheets each.

For this influx of fact sheets, a list of topics has been designed to focus the students initially:

1. Taking your Medicines Right (four fact sheets)
   - How to Use an Rx Label
   - How to Use an OTC Label
   - How to Use a Dietary Supplement Label
   - How to Use a Food Label
2. Take Only as Directed (three fact sheets)
   - Dangers of Double Dosing
   - Disposal of Out of Date Medicines
   - Tips on How to Take your Medicine Safely
3. Ask your Pharmacist or Doctor
   - Have a question?
   - Ask your Pharmacist for Native Language Materials/Labeling
4. Questions to Ask About your Condition or Medicine:

- Diabetes: Questions to Ask
- Cardiovascular Disease: Questions to Ask
- Asthma: Questions to Ask
- Depression: Questions to Ask
- Arthritis and Pain: Questions to Ask

5. What Can I do to Prevent Disease?
   - Regular Check Ups
   - Screening
   - What Medicare Offers
6. Childhood Illnesses and Conditions
   - Head Lice
   - Fever Reducers: Questions to Ask
   - Immunizations: Questions to Ask & Schedules
7. Questions to Ask About Your Medicines
   - What Are Drug Interactions?
   - Ask Your Pharmacist: Medicare Part D Prescription Drug Benefit
   - Medication Therapy Management – What Is It?
   - Drinking and Taking Medicines
8. Learn More about your Medicine
   - Credible Sources on the Internet

The committee plans to evaluate the project after one year. As such, this review will take place at the December meeting.

Agenda Item C

State of California | Department of Consumer Affairs

Memorandum

To: **Communication and Public Education Committee** **Date: June 30, 2005**

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

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

At last year's 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 no meetings since the April Board Meeting, but the partnership had held monthly meetings since September 2004 through March 2005. 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 was May 2005, which was seniors' month. Promoting materials about generic drugs were the focus of this effort. Various materials about generics from the FDA and the board's new consumer fact sheet were among the materials promoted at public education events attended by the board.

Executive Officer Patricia Harris presented a poster display of the activities of the partnership at the National Association of Boards of Pharmacy. We will display this poster at our July meeting.

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 seeking grants to allow more extensive promotion of health messages developed or endorsed by the partnership. Funding has been received for the early detection tests for cancer. Regular meetings of the partnership will resume in July.

Agenda Item D

State of California | Department of Consumer Affairs

Memorandum

To: Communication and Public Education Committee

Date: June 17, 2005

From: Virginia Herold

Subject: Update on *The Script*

The next issue of the board's newsletter, *The Script,* is undergoing review, and should be printed and distributed by the end of July or in early August.

Articles will promote the new award for pharmacists who have been licensed for 50 years, as well as the Subcommittee on Medicare Drug Benefit Plans formed by the board. The bulk of the newsletter's articles will provide amplifications of Pharmacy Law.

Agenda Item E

State of California Department of Consumer Affairs

Memorandum

To: Communication and Public Education Committee

Date: June 29, 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. The bulk of the articles have been written, and several are undergoing peer review. Completion of the articles for this issue is scheduled for late summer 2005. After this board review and layout of the issue will occur. The University of the Pacific will provide CE for those who complete the examination that will be published in the newsletter.

Agenda Item F

State of California | Department of Consumer Affairs

Memorandum

To: Communication and Public Education Committee

Date: June 29, 2005

From: Virginia Herold

Subject: Redesign of the Board's Web Site

I have been working with the board's Web master to redesign the layout of our Web site.

In December, when the board converted its Web site to the requirements established by the Governor's Office, a number of items were relocated. Unfortunately, many of us who use the Web site frequently are still unable to find items we seek that we know are on the Web site. Believing that if we cannot find the items others cannot either, we are trying to improve the logic of our Web site.

Before the end of the summer, a better layout for the Web site will be in place. I will share the direction we are headed at our July committee meeting.

Agenda Item G

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

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

Share now, pay later

- Many people take pills prescribed for others; they save money but risk their health.

By Daniel Costello, Times Staff Writer

Family physician Mary Frank couldn't understand why one elderly patient with high-blood pressure wasn't responding to his medication. She had been steadily increasing his dose, but his blood pressure remained unstable

Finally, the man admitted he had been sharing his pills with his wife. He also would stop taking his medication a few days before his appointment hoping his blood pressure would be higher so that he and his wife could then split a higher-dose drug.

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But the practice put the couple at risk of a stroke or heart attack. "This is not something people should take lightly. It's truly dangerous and frustrating," said Frank, of Rohnert Park, Calif.

When it comes to prescription medications, many people embrace the adage to share and share alike. Armed with good intentions and largely unaware of the dangers, they gladly hand over leftover antibiotics, asthma inhalers, antidepressants, insulin and pain pills. After all, if the drugs worked for them, then perhaps they'll help similarly suffering family members friends or colleagues. And, considering the drugs' expense, throwing away excess, out-of-date or ineffective pills can seem like a waste.

Some consumers even appear to be sharing medications for prolonged periods of time out of necessity. With the costs of drugs and medical care rising, they have trouble paying for their own prescriptions or the doctor visits required to obtain them.

Researchers say those most likely to share prescription drugs are the poor and the elderly, as well as family members who have a common chronic illness, such as diabetes.

"If you ask people why they are doing this, they say they have no other option," said Chien-Wen Tseng, an assistant professor at the University of Hawaii who has studied the ways people deal with rising prescription drug prices. "To many of them, it's better than not taking the medication at all."

Such cost-saving tactics have not been extensively studied, but dozens of interviews with researchers, doctors, pharmacists and senior centers in California and across the country suggest the problem is growing.

Moreover, the number of pills that can be shared is multiplying; almost half of Americans take a prescription drug and 17% take three or more. The dangers of sharing medications may be overlooked, experts say, by a public overly confident in its ability to self-medicate — a perception amplified by the dramatic rise in direct-to-consumer pharmaceutical advertising in recent years.

When the AARP asked seniors last fall about sharing medications, about 4% of Medicare

beneficiaries — or nearly 1.7 million people — said they had shared prescription medications with family and friends in the last year. By comparison, in a smaller 2002 study, UCLA found that 2% of people shared medications.

Doctors say many patients don't acknowledge sharing medications because they fear they'r breaking the law — in some cases they may be — and many suspect the number may be higher.

Although no one tracks adverse events caused by drug sharing, adverse drug reactions overall are responsible for up to 7% of hospital admissions. In some circumstances, sharing drugs can be extremely dangerous because one of the people taking the drug hasn't been seen by a physician to determine if he or she indeed needs the drug, what dosage, or possible allergic reactions.

"It's possible that people are ending up in the hospital and even dying from [sharing prescriptions]," said Dr. Stephen Soumerai, director of drug policy research at Harvard Medical School.

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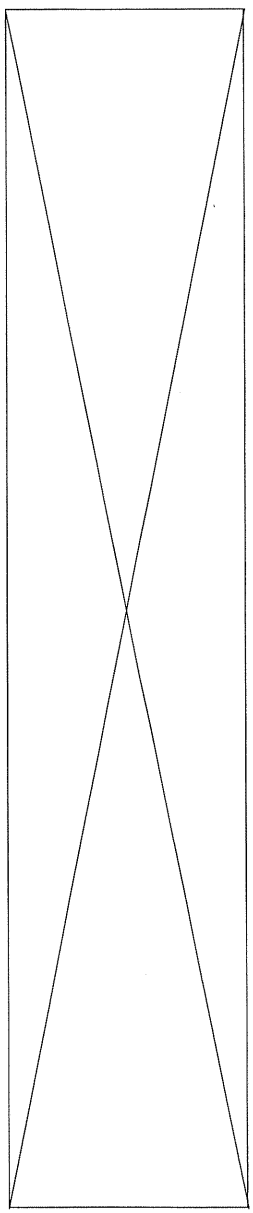

A growing trend

Dr. Yehuda Handelsman, a Tarzana endocrinologist, estimates that as many as 15% of his diabetes patients share diabetes drugs or other medications with family members to save oı costs, something he saw only "rarely" a few years ago.

In Beverly Hills, internist David Alessi said he sees up to "several patients a month" who are sharing medications. Last month, a 42-year-old man came to his office after using his wife's leftover antibiotics from a foot infection to treat his sinus infection for two weeks. By the time the patient arrived, the infection had spread into his eye socket and showed signs of moving into his brain, a potentially deadly scenario. (He's now on an aggressive antibiotics regimen and is expected to survive.)

Teenagers are also likely to give and take others' medications. A report from the Centers foı Disease Control and Prevention in 2003 found that 20% of girls and 13.4% of boys share medications with friends, although cost wasn't usually the motivation. Many share sleeping pills and acne medication such as Accutane, the report found. Sharing Accutane is extremely worrisome; the drug is believed to cause birth defects, and girls and women of child-bearing age are supposed to take a birth control pill while taking the medication.

The risks of prescription-sharing vary dramatically depending on the user and the medication.

For example, although some users might think all blood pressure medications are the same doctors choose from among dozens of varieties depending on the patient's weight, medical history and other diseases. Taking high blood pressure medication improperly can lead to strokes, heart attacks and heart failure.

People with diabetes, likewise, may need different drugs; some drugs can be safe for some users, but cause potentially dangerous allergic reactions in others. Those who take too little or too much of a diabetic drug can risk going into insulin shock or damage their liver. Giving antidepressants to someone who seems depressed but is actually manic depressive can worsen the disorder. And many patients, of course, may not realize how one drug could interact with others they are taking.

More broadly, antibiotic-sharing not only fuels overall resistance levels to the drugs, but it can also increase the chances of a lingering individual infection. "It's hard to convince people, but this is like driving 90 mph in a 25 mph zone," said Handelsman of Tarzana.

The Food and Drug Administration generally forbids the redistribution of prescription drugs once they have been dispensed to consumers, but states can supplement that with their ow regulations.

*

Making costs bearable

Although many patients are reluctant to talk with their physicians about drug costs, doctors and patient advocates say that's where cost-cutting begins. If patients ask, doctors may be willing to prescribe generic medications or double-dose pills that can then be split in half. Some people may qualify for federal or state assistance or one of the pharmaceutical companies' assistance programs, which can often be accessed through local senior centers or on the Internet.

In March, the industry trade group Pharmaceutical Research and Manufacturers of America pledged $10 million to create a clearinghouse (www.Rxhelp4ca.org) that directs Californians to 350 drug programs run by manufacturers, nonprofits or governments.

The California state legislature is debating whether to compel drug companies to offer heavily discounted drugs to people with incomes up to four times the federal poverty level, c $38,280 for an individual. And the upcoming Medicare drug benefit may alleviate some cost for seniors, although many people will still have large drug bills.

Alessi, of Beverly Hills, said doctors must become more vigilant about asking patients if they're sharing medications, even if they don't have any reason to suspect a patient is doing it. "You feel badly for people who can't afford to fill their prescriptions," he said. "But people need to trust us that this isn't the solution to their problems."

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Coverage & Access | New Consumer Web Site Will Explain Clincial Trial Information
[Jun 15, 2005]

The *Wall Street Journal* on Wednesday examined patientINFORM, a Web site that will offer free access to medical journal articles on cancer, heart disease and diabetes and "plain-language explanations" of the studies' implications for patients. The project is a collaboration by the American Cancer Society, the American Diabetes Association and the American Heart Association. Each month, the groups will review hundreds of published studies from more than two dozen journals, and experts will then translate the studies into lay language for consumers, including explanations of the studies' meaning, how they compare to current knowledge on the issue and how patients should use them in making treatment decisions. According to the *Journal*, the project comes as "pressure continues to mount" for medical journals to provide the public with better access to research. Christine Laine, senior deputy editor of the *Annals of Internal Medicine*, said, "We need to show how a particular study integrates into a greater body of evidence, and medical journals haven't done a very good job of doing that." The site, which currently is in a pilot phase, next month will begin posting content on studies (Landro, *Wall Street Journal*, 6/15).

Daily Health Policy Report

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Prescription Drugs | *Associated Press* Examines Effects of Increased Prescription Drug Use in United States
[Apr 18, 2005]

The *AP/St. Paul Pioneer Press* on Sunday examined the amount of prescription drugs used by U.S. residents, with many researchers and public health experts saying people are "buying and taking far too much medicine, too readily and carelessly, for their own health." According to CDC data, about 130 million U.S. citizens use prescription drugs every month. A recent IMS Health report stated that the number of prescriptions issued annually in the United States has increased about 67% in the last 10 years to 3.5 billion. U.S. prescription drug sales in 2004 totaled $250 billion, or $850 per U.S. resident. Meanwhile, according to an *Associated Press* analysis of projections from 1990s studies, more than 125,000 U.S citizens die from "drug reactions and mistakes" annually, the *AP/Pioneer Press* reports. According to the *AP/Pioneer Press* , that would make prescription drugs the fourth-leading national cause of death, following heart disease, cancer and stroke. While some prescriptions, including some antibiotics and HIV/AIDS medicines, "yank many people away from almost certain death," the benefit and risk analysis of prescriptions that treat "common, persistent, daily life conditions" is "harder to strike," according to the *AP/Pioneer Press*. Former *New England Journal of Medicine* Editor in Chief Marcia Angell, author of the book, "The Truth About Drug Companies," said, "What the drug companies are doing now is promoting drugs for long-term use to essentially healthy people. Why? Because it's the biggest market." However, Pharmaceutical Research and Manufacturers of America spokesperson Jeff Trewhitt said, "We now have more medicines and better medicines for more diseases" (Donn, *AP/St. Paul Pioneer Press*, 4/17).

FDA Web site lists latest drug dangers

By Alison Young
KNIGHT RIDDER NEWSPAPERS

WASHINGTON – The U.S. Food and Drug Administration has begun issuing alerts to patients and doctors on its Web site about emerging drug-safety concerns, including dangers posed by drugs prescribed for unapproved purposes.

The new feature, called Drug Watch, marks a significant change in how the agency communicates risks to the public. In the past, the FDA has spent months or years privately weighing and debating risk information with drug companies until a final determination was made on the scientific significance of the danger.

After being bashed by Congress and consumers for its slow response to emerging information about heart risks posed by blockbuster pain medications such as Vioxx, the FDA now is beginning to make risk information available to the public much sooner.

"This is really a fundamental change," said Dr. Steven Galson, the acting director of the FDA's Center for Drug Evaluation and Research. "We do intend to give companies a heads-up before posting something new about their drugs, but we're not going to discuss it with them. They're not going to review it."

The safety alerts posted so far on the site – www.fda.gov/cder/drugsafety.htm – are notable also because they emphasize risks posed by doctors prescribing drugs for purposes never approved by the FDA. It's a practice called "off-label prescribing" because it involves using drugs in ways and to treat conditions not covered by the safety and effectiveness determinations on their FDA-approved labels.

"That's a very important aspect of this," Galson said. "As you know, we don't regulate the practice of medicine. We have no way of preventing physicians from using drugs off-label."

But Galson said the agency does have a responsibility to let people know about known risks of off-label uses. "This is very controversial, of course," he said.

Some off-label drug uses are beneficial and based on good science, others have little proof of effectiveness and still others have been proved worthless in studies.

Officials at the American Medical Association, which represents doctors, and the Pharmaceutical Research and Manufacturers of America, which represents drug makers, declined to comment, saying they are evaluating the Drug Watch site and will submit formal comments to the FDA.

Advocates for patients called the site an incremental move in the right direction, even though it requires patients to seek out the information on the Internet, rather than it being given to them when they pick up their medicines. The emphasis on early and off-label risk information is a departure for the FDA, they said.

"I don't think they had the political courage even a few years ago to take these kinds of steps," said Larry Sasich, a pharmacist with Public Citizen's Health Research Group, a consumer watchdog that publishes a searchable database of drug risks at www.worstpills.org.

Sasich said he thinks the FDA is realizing that the only way to change risky prescribing is for consumers to know more about the drugs they take. Changing the official labeling on drugs and sending letters to doctors about new risks hasn't worked, he said.

Sasich expressed concern that elderly patients – who are the biggest consumers of prescription drugs – won't have enough access to Drug Watch information that's available only on the Web.

Cynthia Pearson, executive director of the National Women's Health Network in Washington, praised the direct communication of risks listed atop several drugs on the site.

"Our position always has been: Get people access to good information and they can make good decisions," Pearson said.

The Drug Watch site, still being developed, lists information on about 200 drugs. Most of them include routine prescribing information.

Among those tagged with an "FDA Alert:

Accutane, a drug for severe acne; Cytotec, also called misoprostol, a drug approved to prevent ulcers; Zyprexa, Risperdal and several other psychiatric drugs called atypical anti-psychotics; Amiodarone, marketed also as Cordarone and Pacerone, a popular heart drug approved only to treat a specific life-threatening rhythm disorder; Gabitril, a drug approved to treat seizures.

IN THE KNOW

The U.S. Food and Drug Administration has launched a new Web site, called Drug Watch, about the safety risks of drugs prescribed for unapproved purposes:
▶ www.fda.gov/cder/drugsafety.htm

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News

In world of drug ads, there's a pill for every ill

Critics say lesser problems are 'medicalized,' even if they don't need treatment.

By Steve Wiegand and Dorsey Griffith -- Bee Staff Writers
Published 2:15 am PDT Monday, June 27, 2005

Get weekday updates of Sacramento Bee headlines and breaking news. Sign up here.

Ed Keet. า, a retired state worker from Sacramento who takes nine prescription medications, has become an attentive student of drug advertising. He's not alone. A 2001 survey by the Kaiser Foundation found that 30 percent of adults had talked to their doctors about a specific drug they had seen advertised on television.

• See additional images

Sacramento Bee/Andy Alfaro

Burping up stomach acid? Maybe you should check out Nexium, "the purple pill." Erectile dysfunction? Try Levitra, "strong and lasting." Fast-food diet pushed your cholesterol too high? Crestor recommends you "talk to your doctor today!"

In fact, if anything at all is bothering you, just turn on your television or pick up a popular magazine. Chances are good there will be a prescription drug ad for what ails you - whether or not you're really sick.

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Drug industry figures show that spending on consumer advertising quadrupled between 1996 and 2003, to $3.2 billion annually. That's twice the rate of increase of the industry's spending on research and development over the same period.

There's disagreement in the health care world about whether that's healthy. Some medical professionals blame the boom in drug ads for a host of deleterious side effects, ranging from "medicalizing" normal conditions that don't need treatment, to treating symptoms rather than underlying causes, to convincing people there's a cure for everything.

"The drug companies are very interested in exploiting very common symptoms, because the potential markets are huge," said Dr. Richard Deyo, a professor at the University of Washington and co-author of a new book about America's obsession with medical miracles.

"If you market a drug for chronic myelogenous leukemia, you sell a few a year. But if you can market a drug for heartburn, you've got half the population."

To create such markets, Deyo and other critics say, the drug company ads are aided by an armada of health foundations and organizations and institutes that bombard consumers with sobering statistical data, typically packaged in slick public relations press kits that state:

* An estimated 25 million adult Americans have gastroesophageal reflux disease.

* 36 million have seasonal allergic rhinitis.

* 32 million have chronic dry eye.

* 16 million have restless legs syndrome.

* 9.5 million have adult attention deficit disorder.

* And 102 million have high, or borderline high, cholesterol levels.

That comes to 220.5 million instances of afflictions with just six health problems - more than one problem for each of the 215 million adults in the United States today.

"It's the wheezingest, sickest, most decrepit nation on the face of the Earth," said Arthur Caplan, director of the Center for Bioethics at the University of Pennsylvania. "It's amazing anyone gets out of bed."

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Notwithstanding the tongue-in-cheek tone of Caplan's observation, there's little doubt Americans seem to be increasingly afflicted with a host of ailments - and increasingly confronted by a cornucopia of cures offered in television commercials, radio blurbs and lengthy newspaper and magazine ads.

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Drug advertising has big payoff

For the pharmaceutical industry, it's been advertising money well spent. A Henry J. Kaiser Family Foundation study in 2003 found that every dollar spent on drug promotion resulted in an additional $4.20 in sales.

Overall prescription drug sales rose from $85.3 billion in 1996 to $229.4 billion in 2004, a 169 percent increase. Moreover, the industry averaged a 17.8 percent net profit margin over the past five years, according to the securities analyst firm Value Line Investment Survey, making it one of the most profitable in the country.

Drug industry officials argue the main purposes of consumer ads are to educate people and motivate them to seek medical attention if there's something wrong.

"We fundamentally believe in the value of making health information accessible, accurate, understandable and motivating," said Pat Kelly, president of Pfizer U.S. Pharmaceuticals, in an e-mail. "In many cases patients don't end up with the medicines we advertise, but more importantly, they receive an appropriate treatment."

Many doctors, however, say 30-second or 60-second ads about serious health issues are hardly educational.

"Educating patients is different than promoting a product," said Dr. Sharon Levine, associate executive director of the Permanente Medical Group in Northern California. "When direct-to-consumer advertising first began, many of the early ads focused on a disease. The current crop of pharmaceutical ads is product promotion. There is a huge difference between disease education and marketing drugs."

The difference between the two isn't lost on Ed Keeton. A one-time big game hunter and avid fisherman, the 70-year-old Sacramento resident and retired state worker has developed a new pastime since he developed diabetes and neuropathy, a painful related complication: He's an attentive audience for drug company advertising.

"I am being exposed to these people who are trying to make money on drugs, and (the advertising) is naturally going to sound good to someone with a problem," said Keeton, who takes nine prescription medications for diabetes, high cholesterol, depression and pain. "I am receptive to most of that stuff, at least to the point that I will ask the doctor about it."

Keeton said his doctor usually dismisses his therapeutic suggestions. But while he understands that skepticism, he doesn't plan to quit the practice.

Asked to recall the last time he asked his doctor about a drug by name, Keeton couldn't remember, citing his increasing forgetfulness. "I would definitely be interested (in a drug to enhance memory)," he said. "I will start bugging the doctor about that."

A 2001 survey by the Kaiser Foundation found that 30 percent of adults had talked to their doctors about a specific drug they had seen advertised on television, and 44 percent of those had received a prescription for it.

The same survey also found that 70 percent learned little or nothing from the ad about the condition the drug treated.

"No question, patients are watching TV, looking at ads and going into physicians' offices and either requesting a product or having a question about it," said Dr. David Siegel, an internist and infectious disease specialist at the Department of Veterans Affairs Medical Center at Mather Field. "(But) they have no basis upon which to evaluate the validity of any of these claims."

Sometimes neither does the doctor. The drug companies "don't tell us anything," Siegel said.

Referring to commercials and ads for erection enhancement drugs that include vague cautionary statements, Siegel said: "I would not know what to do if one of my patients called and said, 'I am taking this medication, and if my erection lasts more than six hours I am supposed to call you.' Gee, that's nice. I hope it was worth it. I don't have any special knowledge of this. What am I supposed to do? Tell them to take cold showers?"

Erectile dysfunction provides a compelling example of how drug companies create diseases along with the drugs they mass market to treat them, said Dr. David Campen, medical director of drug information, utilization and technology for Kaiser Permanente Northern California.

"Erectile dysfunction was not in the lexicon prior to Viagra," Campen said. "With that it became a unique disease and you got Bob Dole on TV."

Ads boom after limits relaxed

There's nothing new about businesses creating problems to fit their solutions.

In the early 1920s, Lambert Pharmacia was having trouble peddling its antiseptic as an aftershave or a cure for throat infections. It improved bad breath, but that malady wasn't talked about in polite circles.

Then an enterprising ad writer dug up an obscure word from a medical dictionary. "Bad breath" became "halitosis," a social faux pas became a medical condition, and Listerine became a household word.

In the 1980s, the drug company GlaxoSmithKline launched Zantac, a drug for treating ulcers. But the ulcer market was fairly narrow. Hoping to widen the market for the drug, the company began "raising public awareness" about gastroesophageal reflux disease (GERD), a condition whose most common symptom is heartburn.

The company established an institute, rolled out a mammoth public relations campaign called "Heartburn Across America" and sponsored surveys that found, among other things, that Americans were relying too heavily on over-the-counter heartburn remedies. The result was that Zantac became the world's best-selling prescription drug, with two-thirds of its sales for the treatment of GERD, not ulcers.

But the real boom in aggressively marketing drugs began in August 1997, when the federal Food and Drug Administration relaxed its rules concerning consumer advertising.

Prior to that, companies could not extol their drug's virtues, or even mention the ailment it treated, without an exhaustive summary of its possible side effects, how it interacted with other drugs and how effective it was in clinical trials. In print ads, drug companies could buy an extra page and fill it with tiny print. But the restrictions made advertising on radio or television highly impractical.

Under the new FDA rules, companies only had to mention a few of the most prevalent potential side effects and provide a toll-free number, Web page or referral to a print ad.

Ad monitoring falls short

The change in policy meant the United States joined New Zealand as the only countries in the world that allow ads for prescription drugs.

In the first three years after the new rules went into effect in 1997, U.S. drug advertising jumped 125 percent and has climbed steadily ever since.

The flood of advertising has created new difficulties for the FDA in monitoring drug ads for accuracy. The agency has regulatory authority to issue warning letters to drug companies if their ads are deemed misleading. But companies face no penalties as long as they agree to withdraw the offending material.

In most cases the agency lacks legal authority to review drug ads before they are released. And with a staff of about 40 reviewers trying to plow through more than 35,000 pieces of promotional material a year, monitoring sometimes badly lags behind the ads.

In February, for example, the FDA sent a letter to Centecor, Inc., warning the company that a pamphlet for the arthritis drug Remicade was misleading. The company had stopped using the pamphlet four months before the letter was sent.

Critics of the proliferation of drug advertising point to the pain reliever Vioxx as a lesson in the damage heavily hyping a prescription drug can do.

Originally promoted as a remedy for people who had osteoarthritis and stomachs too sensitive for other drugs, Vioxx took on the aura of a "super aspirin."

Starting with its release in August 1999, the drug was among the four or five most heavily promoted in the world. In 2000 alone, Merck & Co. spent $160 million advertising Vioxx. That's about the same amount spent on TV advertising for both the Bush and Gore presidential campaigns that year. Vioxx sales reached $2 billion a year.

But the drug was pulled from the market last fall after it was found to be a potential source of cardiovascular problems. The removal discomfited millions of people who didn't have arthritis but were taking Vioxx anyway as their pain medication of choice.

Writing in the Jan. 19 issue of the Journal of the American Medical Association, Cleveland cardiologist Eric Topol said Vioxx and similar drugs, called COX-2 inhibitors, "were mass-marketed from the moment they were commercially available in the new world of direct-to-consumer advertising, with unrealistic expectations about pain relief, marked gastrointestinal protection and safety."

Topol, one of the country's leading heart specialists and an early critic of the COX-2 inhibitors, wrote that "the unbridled promotion exacerbated the public health problem" created by building an army of pain sufferers who looked for relief from Vioxx, only to have it snatched away when the drug was pulled back.

Drug industry weighs curbs

In the face of such criticism, some pharmaceutical companies are rethinking their advertising approach. In mid-June, Bristol-Myers Squibb Co. announced it would not pitch new drugs directly to consumers for at least a year after they are approved, although marketing to doctors and hospitals will continue. In addition, the company said its future ads would strive to better educate potential users about the drugs' risks and benefits.

The drug industry's lobbying association, the Pharmaceutical Research and Manufacturers of America, also announced it was preparing a voluntary code of advertising conduct for its members. The code, which could be voted on by the association's board of directors next month, is not expected to go as far as the Bristol-Myers approach.

Last Tuesday, the American Medical Association adopted recommendations urging the FDA to develop better ways to monitor drugs after they've been approved, and to work more closely with doctors to explain potential risks.

But as in previous years, the AMA declined to endorse a moratorium on prescription drug ads. Citing concerns that such a ban would violate drug companies' free-speech rights, the association voted instead to study the issue further.

Many drug company executives insist that even if heavily advertising their products creates some pressure on doctors to prescribe them, the ads generally benefit both doctor and patient by improving communication between them.

They point to a 2002 FDA survey of physicians that reported only 28 percent of the doctors polled felt "somewhat" or "very" pressured to prescribe a specific drug if asked by a patient.

"The goal of our advertising is to make people aware of serious medical conditions," said Pfizer's Kelly, "and motivate them to talk to their doctor so they can receive appropriate diagnosis and treatment."

Many medical people worry that kind of motivation makes consumers more insistent about getting an advertised pill for what ails them rather than heeding doctors' advice on less expedient, and less costly, remedies such as changes in diet, increased exercise, or adequate sleep.

Most frustrating about such advertising, said the University of Washington's Deyo, is that it feeds the notion that every uncomfortable aspect of being human can be assuaged or eliminated by modern medicine.

"There's an assumption in our society that no one should ever have symptoms," he said. "No one should ever have a headache or a backache or diarrhea, and if you do, there's a failure of medical care somewhere.

"But you know, those kinds of symptoms are simply a fact of everyday life as a human being. And despite medical advances, they are going to continue to be."

ABOUT THE WRITER:

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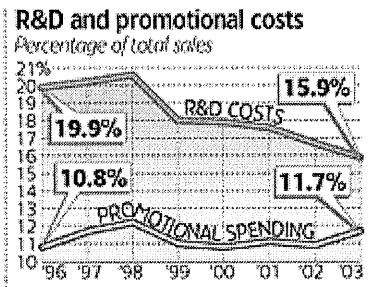
Consumer advertising

Total drug company promotional spending, research and development spending, and U.S. drug sales

In billions of dollars YEAR	DIRECT TO CONSUMER ADS	TOTAL DRUG COMPANY PROMOTIONS*	RESEARCH AND DEVELOPMENT	SALES
1996	$0.8	$9.2	$17.0	$85.3
1997	$1.1	$11.0	$19.0	$94.0
1998	$1.3	$12.5	$21.1	$102.4
1999	$1.8	$13.9	$22.7	$126.0
2000	$2.5	$15.7	$26.0	$145.0
2001	$2.7	$19.1	$30.3	$172.1
2002	$2.6	$21.2	$32.3	$193.7
2003	$3.2	$25.3	$34.5	$216.4



*Total drug company promotions includes DTC advertising, medical office and hospital sales visits, and professional journal advertising

Sources: IMS Health, PHRMA, NIHCM, GAO, Bee research Sacramento Bee/Olivia Nguyen

Ranking drugs

The 10 prescription drugs that were most heavily advertised in 2004, and their rank among 20 top-selling prescription drugs.

RANK	NAME OF DRUG	APPROVED USE	AMOUNT SPENT In millions of dollars	RANK IN TOP 20 U.S. SELLERS
1	Lexapro	Depression and generalized anxiety	$168.5	n/a
2	Celebrex	Arthritis	$130.1	11
3	Crestor	High cholesterol	$125.0	n/a
4	Bextra	Arthritis	$121.1	*
5	Lipitor	High cholesterol	$114.0	1
6	Advair Diskus	Asthma	$107.0	9
7	Vioxx	Arthritis	$96.5	**
8	Zoloft	Depression, panic disorder, obsessive-compulsive disorder, post-traumatic stress disorder	$95.9	6
9	Nexium	Gastroesophageal reflux disease	$93.6	4
10	Singulair	Asthma, hay fever	$92.9	16

*Ordered off market in April 2005 **Ordered off market in October 2004

Source: IMS Health Sacramento Bee/Olivia Nguyen

History of drug advertising in the U.S.

1708

A Boston newspaper runs an ad for "Daffy's Elixir." The ad is believed to be the first American ad for a patent medicine.

1938

Congress prohibits drugs from being marketed without having been approved by the Food and Drug Administration, but assigns regulation of drug advertising to Federal Trade Commission.

1951

Federal law requires potentially dangerous drugs to have a prescription from a doctor.

1962

FDA gains authority to oversee drug ads, in the wake of revelations that use of the drug thalidomide in Europe caused thousands of birth defects.

1981

First direct-to-consumer print ad for a prescription drug (a pain reliever called Rufen) appears. It's followed in two years by Rufen television commercials.

1983

FDA requests voluntary moratorium on direct-to-consumer drug advertising so it can study whether adequate safeguards exist. Moratorium is lifted in 1985.

1989

Pharmacia & Upjohn pioneer use of infomercial for a prescription drug. The product is hair-loss drug Rogaine.

1996

Drug companies spend $600 million on direct-to-consumer advertising, 10 times what they spent in 1991.

1997

Under intense pressure from the drug industry, the FDA softens its rules to allow companies to pitch specific drugs without having to supply detailed information about them. Instead, the ads can refer viewers to toll-free numbers, Web sites, magazine ads or brochures.

2004

Direct-to-consumer advertising tops $4 billion

2005

Bristol-Myers Squibb Co. announces it will not advertise drugs to consumers for at least one year after the drugs are approved. Decision is in response to criticism of drug advertising.

Source: Bee research

Ads by Google

Acid Reflux Resources
Learn About Acid Reflux Disease: Causes, Symptoms & Treatment
www.AcidReflux.com

Your Cholesterol High?
Find out what you can do. Talk to your doctor and visit
www.managingcholesterol.com

Unblock Arteries Quickly
An advanced liquid Edta chelation it's safe, effective & economical
www.cardiorenew.com

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Los Angeles Times
latimes.com

http://www.latimes.com/business/custom/admark/la-he-drugads20jun20,1,3010338.story?coll=la-headlines-business-advert

Wary, and weary, of drug ads

The messages are everywhere, but now some lawmakers, consumers and physicians are saying, "Enough."

By Melissa Healy
Times Staff Writer

June 20, 2005

Don SCHILLING, a Los Angeles public relations consultant, is a savvy consumer of marketing ploys and, at 57, a man growing more attuned to the allures of pills and potions that promise to boost his health. For drug makers pitching their prescription medications directly to American consumers, Schilling, a retired Army officer, refers to himself as a "high-value" target.

They haven't captured him yet. But the drug makers keep pounding away with their ads, and Schilling admits to more than a few moments of surrender.

"I look at these [drug advertisements] and I don't know how much to believe," said Schilling. "I know it's just a blatant ad. But they're fun to watch.... These twentysomethings that put these things together, they know the hot buttons to push."

Schilling is not alone in his wary fascination. Americans who watch TV, listen to the radio or flip through a magazine these days are bombarded with advertisements designed to pique interest in a most unlikely consumer product: prescription drugs.

But at a time when the safety and cost of such medications have become hot-button political issues, politicians, patients and those who tend to the nation's health are viewing these ads with a new wariness. The result is a simmering national debate over how, when and even whether drug makers should appeal directly to American consumers.

As lawmakers plot new restrictions on the practice, the drug industry, in a bid to preempt, is scrambling to voluntarily reform itself.

Just last week, Bristol-Myers Squibb Co. announced that it would not promote any of its new drugs directly to the public for at least one year.

Michael Guarini, a partner with the advertising leader Ogilvy & Mather Worldwide, calls this "the perfect storm" in drug advertising, as many forces gather to reform the young industry. Guarini acknowledged that much prescription drug advertising has left its sponsors open to attack.

"I hate to use the word 'slick,' but [they've become] a bit too consumerized," said Guarini. "There's not enough balance between risk and result."

Peter Pitts, a former associate commissioner of the Food and Drug Administration, goes further. "People need to see that pharmaceutical companies are not only hucksters trying to sell you pills but also squarely in the public health business."

The debate over prescription drug advertising has gained new momentum since the popular arthritis drug Vioxx was withdrawn from the market in September 2004 over safety concerns. For several years, Vioxx was the most aggressively promoted drug on the market, with direct-to-consumer advertising spending reaching almost $300 million between 2000 and 2001.

Celebrex, which came under scrutiny by the FDA and is being marketed now with stronger warning labels, was a close second in its promotional budget. The evidence that advertising had caused a rapid nationwide shift to the new drugs led the Journal of the American Medical Assnto warn in December 2004 that "the combination of mass promotion of a medicine with an unknown and suspect safety profile cannot be tolerated in the future."

Until the late 1990s, physicians were virtually the only members of the public who heard drug companies' pitches. But in 1997 the FDA — which regulates the claims that can be made about prescription drugs — issued new, more relaxed guidelines for advertisements aimed at the public. Suddenly a new form of commercial appeal — the direct-to-consumer drug ad — became the fastest-growing segment of the advertising business and a staple of daytime TV, talk radio and glossy magazines.

Today the direct-to-consumer advertising of prescription drugs is a $4.5-billion industry, with its own creative gurus, Internet bloggers and federal regulators hanging on every 30- and 60-second spot. Since 1997, drug makers have increased their spending on advertising almost fivefold, with television advertisements leading the way.

These ads appear to work too: A Kaiser Family Foundation survey in 2001 found that 30% of Americans had spoken to a physician about a specific medication they had seen advertised. And 44% of those — about 13% of the American public — reported that they came away with the prescription they asked about.

Drug advertising has succeeded in doing many things, arguably both good and bad. Studies have demonstrated that direct-to-consumer advertising boosts the sale of advertised drugs and drives overall healthcare costs upward.

Other studies suggest that it enhances communication between patients and their physicians, that it increases the diagnosis of many serious conditions, and that it has helped remove the stigma of many illnesses, such as depression and erectile dysfunction. It may even help patients who are already on medication regimes stay on them.

A recently published study tracking TV ads in Atlanta found that, during one week in 2001, commercials for prescription drugs represented 2.3% of all ads, and that women — who make the majority of healthcare decisions for their families — and the elderly are the prime targets. The

authors, from Emory University School of Medicine, estimated that an average viewer was probably exposed to more than 30 hours of drug ads in 2001 — about a third of them for drugs available only when prescribed by a doctor.

Schilling says he finds the ubiquitous advertisements for the erectile dysfunction drugs Viagra, Cialis and Levitra clever and a bit enticing. Though he does not suffer from the condition, he acknowledges, "I'm tempted to go to my doctor and say, 'Hey, doc, lemme try this out.' "

A few years ago, shortly after he learned that he had high cholesterol, Schilling remembers seeing an advertisement for a cholesterol-lowering drug and thinking, "Wow, there's medicine for this! Maybe I don't have to give up the butter!"

Reactions like these have prompted concern among physicians, federal health officials and those — including lawmakers — who have watched in alarm as the cost of healthcare has risen faster than at any time in history. They fear that advertising prescription drugs to the public encourages the widespread use of costly brand-name medications, often by people who do not need them, who should not take them, or who could use older, safer and cheaper treatments for treating their conditions.

These critics also worry that patients are pestering their physicians for drugs they've seen advertised, and that many doctors — too pressed for time or too eager to please — will send these patients home with the stuff they asked for. They worry that rather than telling their patients, as Schilling's doctor did, "No, you really do have to give up the butter," some doctors will pull out a prescription pad and write the name of the product that they themselves hear touted by the drug company's sales force, see advertised in journals, magazines and on TV, and that their patients are now requesting by name.

*

Skipping the middleman

Some, like Dr. Marcia Angell, author of "The Truth About the Drug Companies," have argued that drug companies should not be allowed to take their appeals to the broad public. Others have called for closer government oversight and a removal of government tax breaks that help to underwrite the ads.

"More and more drug companies are treating doctors as a middleman they wish to skip," said Sen. Ron Wyden (D-Ore.) in late May as he proposed legislation stripping drug companies of the tax deduction for advertising directly to the public. "They make a lot more if patients without medical degrees are encouraged to start writing their own prescriptions, whether the drug is the right one or not."

Congress is considering a raft of legislation that would impose new limits on the advertising of prescription drugs. Several bills, including Wyden's, would limit or eliminate the drug companies' tax deduction for marketing and advertising campaigns.

Another would create an FDA office of drug safety that would, among other tasks, review and approve advertisements before they reach the public if a medication is new to the market, if it is considered high risk, or if its safety is not the subject of ongoing studies. (Currently the FDA requires that prescription drug advertisements be submitted for review at the time they go into public circulation.)

One legislative proposal, however, has been spurred by sheer embarrassment. Rep. James P. Moran (D-Va.) has proposed legislation that would bar the airing of ads for erectile dysfunction drugs between 6 a.m. and 10 p.m. It was no coincidence that Moran unveiled his legislation just a few weeks after the 2005 Super Bowl broadcast, during which many Americans found themselves diving for the mute button during ads for erectile dysfunction drugs.

The growing outcry over drug ads appears to have spurred increased vigilance from federal regulators as well. Of roughly a dozen warning letters issued in the last nine months, two have derailed multimillion-dollar ad campaigns, including a Dr. Seuss-inspired ad for the cholesterol-lowering drug Crestor and an advertisement for Viagra in which the "V" is shown emerging, like horns, from a man's head, with the tagline "He's Back!"

Reaction to the sudden swirl of controversy has the drug industry and its advertising partners in a hurry to react. In March, Johnson & Johnson Pharmaceuticals' William Weldon, in his opening remarks as chairman of PhRMA — Pharmaceutical Research and Manufacturers of America, the drug industry's most prominent trade association — acknowledged that drug advertising "may inadvertently minimize the importance and power of medicines — and their risks."

"If our industry is to retain the important right to talk directly to consumers," Weldon warned drug makers that they would have to go beyond pitching their own products and use ads more to "educate and counsel consumers."

Although Weldon's comments touched off a bitter debate among drug company executives, the industry has moved quickly to preempt tighter government restrictions and regain the confidence of shaken consumers. In the next several weeks, PhRMA's president and chief executive, former Congressman W.J. "Billy" Tauzin, has said that drug companies will unveil a voluntary code of conduct for the advertising of prescription medications.

Although still under wraps last week, that code is expected to include a call for greater balance in the presentation of drugs' risks and benefits and a heightened focus on using ads to raise awareness of treatable diseases and their symptoms.

Pitts, the former FDA associate commissioner, sees this as an opportunity for drug companies to help educate the public about the dangers and symptoms of under-diagnosed health threats such as diabetes and high blood pressure. In so doing, he says, they could restore an image tarnished by market withdrawals, concern over drug prices and public distrust of their advertising. "Right now, any congressman or senator who orates on the evil of the pharmaceutical industry gets a freebie," said Pitts.

In many ways, consumers such as Schilling reflect the credibility gap that drug companies appear to have opened with their aggressive advertising of prescription drugs — and the benefits those companies could reap if they would show greater restraint.

Asked if he expects better advertising for prescription drugs on TV, Schilling said he doesn't. "Not so much on TV because they're just hawking stuff," he said. At the same time, he said, "I think they provide a good service to the public." And as Schilling takes in the ads "with a grain of salt," he hasn't given up on the possibility that someday one will show him something he really can't live without.

*

"That's clearly the direction things are going," he adds.

*

Levitra

You know her — that sexy forty-something pitchwoman, lounging on the couch with her neck-nuzzling honey, who touts the "quality sexual experience" that Levitra delivers. Unlike the makers of rivals Cialis and Viagra, the trio of drug companies that make and market Levitra (GlaxoSmithKline, Bayer and Schering-Plough Corp.) uses a female voice to appeal to erectile dysfunction sufferers — and their partners. In recent months they've also put more clothes on her; Levitra's pitchwoman used to wear "her man's" shirt, and seemingly nothing else. Unlike many prescription drug ads, the Levitra commercial makes a bold play at market share as well, urging those already diagnosed with erectile dysfunction to "switch" to Levitra's "strong, long-lasting" experience. (Studies show that pharmaceutical ads generally boost sales for a broad class of drugs but don't get many consumers to switch from one to another).

Makers of erectile dysfunction drugs spent some $400 million in 2004 to advertise them. U.S. sales totaled nearly $1.2 billion. But the ads' frank talk has prompted legislation that would forbid their airing during daytime and family-hour programming.

— Melissa Healy

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Different rules apply

In launching ad campaigns for prescription drugs, pharmaceutical companies strive to make a memorable impression on consumers. But they must be careful not to run afoul of Food and Drug Administration guidelines. The FDA does not approve ads before they air or run in publications — a practice that some proposed federal legislation would change. Once the ads are in broad circulation, however, the FDA is required to ensure that they adhere to regulations that differ depending on the type of ad. If regulators determine that an ad is not meeting those guidelines, they can send a "warning letter" to the drug maker that details the offense (for example, an unsubstantiated superiority claim or a failure to balance risk and benefit information).

In most cases, the FDA requires the problem to be fixed before the ad can be re-aired or published again, but sometimes it directs the company to run "corrective" advertising as well. In a number of recent cases, FDA warning letters have prompted companies to abandon a campaign altogether.

What's what in the world of prescription drugs ads?

• **Product ad:** If an ad names a prescription drug, it may only tout the benefits of that drug as a treatment for the use (or "indication") that the FDA has approved. It may not discuss other uses (known as off-label uses) for which physicians often — and quite legally — prescribe a medication. When an ad says what medical condition the drug treats, it must also identify the medication's major risks. The ad must further guide consumers to a place — a printed ad, toll-free number or website — where they can get a more detailed accounting of potential side effects. This FDA regulation is why viewers often hear a fast-talking voice-over or see small print at the end of an ad urging them to "talk to your doctor" or "see our ad" running in a general-interest magazine.

• **Reminder ad:** Usually a short adaptation of a longer product ad, the reminder ad is exempt from identifying a drug's risks, but it may not identify the condition that the drug treats. This is why consumers frequently see ads that mention a prescription drug without reference to what it's used for. Reminder ads are designed primarily to get consumers who are already on a medication to stay on it — and to help those who have seen longer product ads to remember the drug's name.

• **Disease awareness ad:** It's not quite a public-service campaign, but the disease awareness ad aims to educate the public about the dangers, symptoms and prevalence of a medical condition — typically one for which a drug company offers a treatment. The name of the sponsoring company typically appears, often with a website or toll-free number that will lead to product information. The name of that company's product usually is not mentioned. Drug industry leaders have called for more of these ads, which often help drive those with under-recognized conditions to see their doctors.

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PARTNERS: ktla Hoy

Public Ed

Virginia Herold
06/13/2005 09:58 AM

To: Bill Soller
cc:
Subject: Consumer Fact Sheets and FYI

Hi Bill,

Below are two articles I just saw and thought of you. I think we definitely need the medication compliance fact sheet!

LACK OF DRUG COMPLIANCE MAY INCREASE MEDICAL COSTS, RESEARCH SUGGESTS

Patients who exhibit non- or low adherence to recommended prescription drug therapy may incur higher costs due to hospitalization, according to the results of a new study.

The study involved a sample of more than 137,000 patients aged less than 65 years with diabetes, high cholesterol, hypertension or congestive heart failure. Savings were estimated by comparing the costs of a less compliant group of patients with a more compliant group o! f patients.

The study showed that every additional dollar spent on drugs saved an average of $7.00 in medical costs for patients with diabetes, $5.10 for patients with high cholesterol and $3.98 for patients with hypertension.

Total costs were also higher among those with low compliance. For example, average combined drug and medical costs for the most compliant patients with diabetes was $4,570 and $8,867 for the least compliant patients. Similarly, patients with high cholesterol had average combined drug and medical costs of $3,924 in the most compliant group and $6,888 among the group with the least compliance.

Risks of hospitalization also appeared to be higher among patients with low compliance. Specifically, patients with diabetes who exhibited low compliance had a 30 percent risk of hospitalization compared with a 13 percent risk a! mong those with high compliance, the study showed.&nb! sp;
& nbsp;
Reasons cited for non- or low compliance include costs, side effects, forgetfulness and lack of noticeable symptoms, particularly among patients with high cholesterol or hypertension.

"Increased medication compliance for chronic conditions can significantly cut medical costs and keep patients out of the hospital," said Dr. Robert Epstein, co-author of the study and chief medical officer of Medco Health Solutions Inc., which conducted the study. "Health care professionals . . . can play an

important role in encouraging medication compliance."

The study was published in the June issue of the journal Medical Care.
-=-

BROAD SUBSTITUTION OF GENERIC DRUGS COULD RESULT IN SUBSTANTIAL ABSOLUTE
SAVINGS, STUDY SUGGESTS

New research suggests that broad ! substitution of generic drugs could result in substantial absolute savings even though only a modest percentage of drug expenditures would be affected.

To estimate the potential savings related to broad substitution of generic drugs, researchers analyzed data from the 1997-2000 Medical Expenditure Panel Survey Household Component. The survey--which involved a cross-sectional, nationally representative sample of non-institutionalized U.S. adults--was conducted by the Agency for Healthcare Research and Quality.

Researchers found that 56 percent of all outpatient drugs were multisource products (that is, a drug available in a brand name and at least one generic formulation). Multisource drugs accounted for 41 percent of total drug expenditures; 61 percent of multisource drugs were dispensed as a generic.

Had generic drugs replaced all corres! ponding brand-name outpatient drugs in 2000, research! ers foun d that the median annual savings in drug spending would have been $5.9 billion for adults aged less than 65 years, or $45.89 per person, and $2.9 billion for adults 65 years and older, or $78.05 per person. The $8.8 billion total represents approximately 11 percent of all drug expenditures, researchers added.

"Interventions to stimulate competition in the generic market, to reduce the approval times for generic drugs by the U.S. Food and Drug Administration and to limit opportunities to extend the patent life of brand-name drugs could increase the potential savings," the study authors stated.

The study was published in the June 7 issue of the Annals of Internal Medicine.
-=-

Kaiser Daily Health Policy Report

Tuesday, June 14, 2005

Medicare

FDA Says It Supports Tracking Medication Safety Using Medicare Drug Benefit Data

FDA on Monday endorsed a proposal to establish a post-market surveillance system for prescription drugs that would use billing data and health care information collected from Medicare beneficiaries, the *Los Angeles Times* reports (Alonso-Zaldivar, *Los Angeles Times*, 6/14). CMS Administrator Mark McClellan earlier this month proposed the system. Under the proposal, CMS would collect adverse event information from Medicare beneficiaries who enroll in the new prescription drug benefit, which will begin on Jan. 1, 2006, and cross-reference the information with billing data to identify problems with medications (*Kaiser Daily Health Policy Report*, 6/6). The proposal would cover four of 10 prescriptions written in the United States and could help CMS officials identify the most cost-effective medications, as well as problems that result from the use of treatments for off-label purposes (*Los Angeles Times*, 6/14). The current FDA surveillance system uses voluntary submission of reports to the Adverse Event Reporting System database. The system collects about 400,000 reports of adverse events annually but detects only 10% of serious problems (*Kaiser Daily Health Policy Report*, 6/6).

FDA Comments

According to the *Times*, FDA officials "had previously been noncommittal" about the Medicare proposal. However, Janet Woodcock, the FDA's acting deputy commissioner for operations, on Monday said in a statement, "FDA strongly supports the use of data from Medicare ... to identify safety risks for recently approved medications and to learn more about real-world outcomes of medication use." FDA and CMS officials on Monday held a public meeting in Baltimore to seek comments on the proposal from health insurers, the medical community, the pharmaceutical industry and others. At the meeting, CMS and FDA officials said that they will partner to implement the proposal. "Access to (Medicare) data will play an important role in helping FDA meet its mission," Paul Seligman, director of the FDA Office of Drug Safety, said, adding, "Medicare beneficiaries ... take more medications and more combinations of medications for longer periods than people of any other age." The proposed system will provide an "important national surveillance function that has heretofore been unavailable," Seligman said (*Los Angeles Times*, 6/14).

Agenda Item H

State of California | Department of Consumer Affairs

Memorandum

To: Communication and Public Education Committee Members

Date: June 20, 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 attends as many of these events as possible, where attendance will be large and staff is available.

The board has a Power Point presentation on the board containing key board policies and pharmacy law. This is a continuing education course, typically provided by a board member and a supervising inspector. Questions and answers typically result in a presentation of more than two hours, 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. In recent months, the board has had a dramatic decline in requests for this presentation, perhaps signaling that the prescribers and dispensers in this state have begun to feel comfortable about the new laws for controlled substances.

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

- Supervising Inspector Nurse provided information about controlled substances dispensing requires in California to DEA agents from Oakland and San Jose on April 20.
- The board staffed a consumer information booth on April 30 in San Diego at the Better Business Bureau's 2005 Smart Consumer Expo, more than 300 people attended. DCA Director Zettel was one of the speakers
- Board Members Goldenberg and Conroy presented information about becoming involved and new pharmacy law to well over 100 UOP students on May 11.
- The board staffed a consumer information booth on May 7th in Sacramento at the 7th Annual Family Safety and Health Expo. ("Safetyville").

- Board President Goldenberg provided information about the challenges caused by the rising cost of prescription drugs at a Seniors Convention and Health Fair at the LA City Convention Center on May 7,where approximately 1,000 seniors were expected to attend.
- Supervising Inspector Nurse provided information about controlled substances dispensing requires in California to DEA agents from Sacramento and Fresno on May 16.
- The board staffed an information booth on May 19 at the City of Sacramento's employee health fair.
- The board staffed an information booth on May 21 at the Elk Grove community health fair, where approximately 200 people attended.
- Supervising Inspector Ratcliff provided information about new prescribing and dispensing requirements for controlled substances to pharmacist members of the California Employee Pharmacist Association on May 25.
- Supervising Inspector Ming provided information about new prescribing and dispensing requirements for controlled substances to 20Tenent Hospital staff directors on May 25.
- Executive Officer Harris provided information about California's security prescription forms for controlled drugs at the National Association of Boards of Pharmacy annual meeting. She also presented information about the California Health Communication Partnership's activities during this meeting.
- Supervising Inspector Ratciff provided information about new prescribing and dispensing requirements for controlled substances on June 8 to the Hollywood-Wilshire Pharmacists Association.
- President Goldenberg will represent the board at the founding meeting of the California Pharmacy Leadership Council on June 29.

State of California | Department of Consumer Affairs

Memorandum

To: Communication and Public Education Committee Members

Date: June 20, 2005

From: Virginia Herold

Subject: Report on Public Outreach Activities 2004-05

During the last fiscal year, the board participated in at least 17 public education fairs or outreach events, and 56 forums to educate the profession or other health care providers and law enforcement staff. Here is the detailed list of what was recorded.

Board of Pharmacy Outreach 2004-05

Public Outreach Events

- Board complaint staff provided information and brochures at the Asian Community Fair on July 15 in Sacramento, to a smaller than expected group of about 15.
- The board staffed a booth at the San Diego Better Business Bureau's Consumer Expo on August 7, 2004, a major consumer fair.
- Board staff provided information about the board and discount programs for drugs at the Triple "R" Adult Day Program in Sacramento on September 28.
- The board staffed a booth at the Yreka Health Fair, where 450 people attended.
- The board staffed a booth at the Sixth Annual Los Angeles County Health Fair and Senior Exposition on October 7—nearly 1,000 people attended.
- Board staff represented the board at the Circle of Advisors Meeting (regarding emergency contraception) on October 5.
- Supervising Inspector Nurse provided information about the new controlled substances requirements to the general public at a HICAP meeting in October.
- On October 16 board staff hosted a booth at the Healthy Aging Summit in Sacramento where 700 people attended.

- Board staff provided consumer information at the Paso Robles Senior Center's Senior Health Fair to approximately 400 people on November 6.
- The board participated as a sponsor at a brown bag consultation event with pharmacists hosted by KCRA TV and Rite Aid in Sacramento, about 6,000 people attended this event on January 8 and 9, 2005.
- 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 where 1,500 people attended.
- The board staffed an information booth on March 12 at UCD's Healthy Aging Conference in Sacramento; over 1,000 people attended.
- The board staffed a consumer information booth on April 30 in San Diego at the Better Business Bureau's 2005 Smart Consumer Expo, more than 1,000 people attended. DCA Director Zettel was one of the speakers.
- The board staffed a consumer information booth on May 7th in Sacramento at the 7th Annual Family Safety and Health Expo. ("Safetyville").
- Board President Goldenberg provided information about the challenges caused by the rising cost of prescription drugs at a Seniors Convention and Health Fair at the LA City Convention Center on May 7, where approximately 1,000 seniors attended.
- The board staffed an information booth on May 19 at the City of Sacramento's employee health fair.
- The board staffed an information booth on May 21 at the Elk Grove community health fair, where approximately 200 people attended.

To the Profession or Others:

- Board staff presented information to approximately 25 pharmacists regarding new controlled substances requirements at a leadership meeting of the Sacramento Valley Health System Society of Pharmacists (June 28).
- Board staff presented information to law enforcement agencies about CURES and drug diversion (May 27 and 28, not previously reported).
- Board staff presented information to audit staff of the Department of Health Services (June 30, not reported previously).
- Board staff presented information about compliance with California's sterile compounding requirements and radiopharmacy on July 8 to a group of about 10 pharmacists to a group in Southern California.
- Board staff presented information about the new prescribing requirements for controlled substances to physicians in San Luis Obispo on July 14, and to pharmacists and law enforcement staff on July 15.
- Board staff presented information about prescribing and dispensing controlled substances under the new California requirements to a group of over 40 physicians and other health care providers on August 3.

- Board staff presented information about drug diversion investigations to investigators of the Department of Justice on August 26.
- Board staff presented information regarding the new requirements for controlled drugs to investigators and staff pharmacists of the Department of Health Services on September 8, and to more than 50 pharmacists, physicians and other health care providers at a presentation hosted by the Pharmacy Foundation of California and Catholic Healthcare West.
- Board staff provided a major presentation at the CMA's annual pain conference in Sacramento on September 10 to more than 600 providers.
- President Goldenberg and Supervising Inspector Nurse presented information about new controlled substances requirements to the San Diego ASCP Chapter on September 13.
- Staff presented information about quality assurance programs and sterile compounding to the Sacramento Valley Society of Health Systems Pharmacists on September 17.
- Staff presented information about the board and new controlled substances requirements to the UCSF Medical Center on September 21.
- Board staff presented information about drug diversion investigations to investigators of the Department of Justice on September 28.
- Board staff provided consumer information at an adult day care program in Carmichael on September 28.
- Staff presented information about the new controlled substances requirements to a group of approximately 100 pharmacists, physicians and other health care providers at St Mary's Medical Center in Orange County on September 30.
- Supervising Inspector Ratcliff was a speaker at the California Primary Care Association's Tenth Anniversary Conference on October 7.
- Board Member Jones represented the board as a speaker at the Indian Pharmacist Association on October 9, where approximately 500 individuals attended.
- In October board presented a telephone session on the new controlled substances requirements with health care providers in Redding.
- Board staff presented information about new controlled substances requirements to Santa Clara Medical Society.
- Supervising Inspector Ratcliff spoke at the California Primary Care Associations' Tenth Anniversary Conference on October 7.
- On October 15 board staff presented a telephone session on the new controlled substances requirements to 50 health care providers in Redding.
- Board staff presented information about new controlled substances requirements to the Santa Clara Medical Society.

- Board President Goldenberg speaker on importation at the CSHP's 2004 Seminar in Long Beach in November. More than 500 people attended.
- Supervising Inspector Robert Ratcliff gave the keynote address at CSHP's 2004 Seminar in Long Beach in November 2004.
- Supervising Inspector Ming presented an "Update and What's New in Pharmacy Compounding" at the CSHP's 2004 Seminar in Long Beach in November 2004.
- Board staff presented information about the board and the new controlled substances requirements on November 18 to the Orange County Chapter of the CPhA, approximately 80 pharmacists attended.
- Board Member Jones and Supervising Inspector Ratcliff presented information on prescribing and dispensing controlled substances to 70 pharmacists at a Indian Pharmacist Association Meeting in Artesia on December 10.
- Supervising Inspector Nurse presented information to the Northern California Pain Initiative Executive Committee on December 14, 2004 via teleconference to approximately 50 prescribers.
- Supervising Inspector Ratcliff will present information on prescribing and dispensing controlled substances to approximately 60 pharmacists to the South Bay Pharmacy Association on January 6, 2005.
- Supervising Inspector Ratcliff presented information about new controlled substances law to approximately 50 pharmacists at Vietnamese pharmacists on January 12.
- Supervising Inspector Ratcliff presented information on new pharmacy law to Phi Delta Chi at USC on January 20.
- 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 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 to discuss items of interest to pharmacy students.
- 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.
- Supervising Inspector Ming presented information about new prescribing and dispensing requirements for controlled drugs at the San Mateo County Pharmacists Association Meeting on March 17 to 84 pharmacist and pharmacy technicians.
- Board Member Schell presented information on automated technology in pharmacies to pharmacy students during April 2005's Legislative Day.
- Board Member Schell presented information about issues before the board to a group of 40 pharmacists at the Chico area Pharmacists Association meeting on April 7.
- Board Member Schell presented information about automation technology to a discussion group of faculty members and students at UCSF on April 14.
- Supervising Inspector Ratcliff presented information about new prescribing and dispensing requirements for controlled substances to about 20 physicians on April 7 at the High Desert Medical Center.
- Supervising Inspector Nurse provided information about controlled substances dispensing requires in California to DEA agents from Oakland and San Jose on April 20.
- Board Members Goldenberg and Conroy presented information about becoming involved and new pharmacy law to well over 100 UOP students on May 11.
- Supervising Inspector Nurse provided information about controlled substances dispensing requires in California to DEA agents from Sacramento and Fresno on May 16.
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