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Sideline Safety — The FDA's Inadequate Response to the IOM

Sheila Weiss Smith, Ph.D.

Having been commissioned by the Food and Drug Administration (FDA) to evaluate the U.S. drug-safety system, the Institute of Medicine (IOM) published a report, *The Future of Drug Safety*, in September 2006 identifying weaknesses in the laws, regulations, resources, and practice of ensuring drug safety.¹ Some of the IOM's recommendations were directed toward Congress, which it believed should increase FDA funding and regulatory authority. Some outlined ways in which other federal agencies could work in partnership with the FDA for the public good. But most of the report outlined deficiencies that the FDA itself — or the Department of Health and Human Services (DHHS), to which it belongs — should correct.

In general, the IOM implored the agency to "embrace a culture of safety" by increasing the priority accorded to the safety of patients. Such an emphasis could have ramifications for medical care that would be as broad and positive as those that the 1999 IOM report on medical error, *To Err Is Human*,² has had for the health care system. Sadly, the FDA's official response falls far short of what the American public expects and deserves.³ Indeed, it highlights the very reason that the agency — with which I have had some firsthand experience — is in need of monumental change: its philosophy is no longer aligned with its regulatory mandate.

The basic criterion for approval of a new drug is that its benefits outweigh its associated risks — so benefits must be considered in light of the drug's toxicity and known safety problems. In its response to the IOM report, however, the FDA described its "fundamental dilemma" as weighing the "tradeoff between safety and access."³ Under the 1992 Prescription Drug User Fee Act, resources were provided to accelerate access to new drugs, and the FDA shortened review times and began to approve certain drugs earlier in the clinical development process.⁴ Safety was affected in several ways. First, some drugs were approved on the basis of surrogate end points and fewer safety data than had previously been required. Second, user-fee funds could not be used for postmarketing safety assessments; this restriction changed in 2002, but even now such use is permitted only in limited circumstances. Third, mechanisms intended to speed access to potentially lifesaving medicines were broadly interpreted. Drugs for the treatment of common chronic conditions such as diabetes (troglitazone), obesity (dexfenfluramine), and pain (rofecoxib) were

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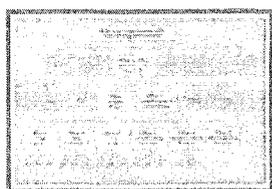
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approved under expedited programs and later were withdrawn from the market for safety reasons.

The public expects the FDA to be the final arbiter of drug safety. Accelerated development programs and expedited reviews hasten the introduction of lifesaving drugs, but they should not be an option for treatments intended for chronic conditions; these drugs should have safety standards that tolerate minimal uncertainty. By pitting safety directly against "access and innovation," the agency betrays its mandate to ensure that U.S. drugs are both safe and effective.

Moreover, the very structure of the FDA marginalizes safety. All regulatory authority lies within the drug-evaluation divisions of the Office of New Drugs (OND) in the Center for Drug Evaluation and Research (see [organizational chart](#)); staff members in these divisions evaluate and approve drugs, negotiate labeling, and request risk-management programs and postmarketing studies. Despite the agency's theoretical emphasis on epidemiology, such expertise is often absent from these divisions. The FDA's safety experts work in a separate Office of Surveillance and Epidemiology (OSE) — which is not even a part of OND — and serve only as consultants to the review divisions, having no direct regulatory authority. Although they may be asked to provide background information as context for interpreting an application, they do not regularly participate in drug reviews.



Current Structure of the Food and Drug Administration.

The Division of Neurology Products and the Division of Psychiatry Products are part of the Office of Drug Evaluation I.

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Several IOM recommendations speak to the importance of including safety experts as integral players in the drug-review process. Yet instead of undertaking a fundamental restructuring to integrate the relevant offices, the FDA merely initiated two pilot projects that involve OSE personnel in drug reviews to determine the "logistics and value" of doing so. But something akin to a pilot had already been done. More than 10 years ago, Greg Burkhart moved from the Epidemiology Branch (now the OSE) to the Division of Neuropharmacological Drug Products (now the Divisions of Neurology Products and Psychiatry Products in one of the Offices of Drug Evaluation). His successor in the latter post, Judith Racoosin, who had trained as a postdoctoral fellow in the OSE, spoke to the IOM committee in January 2006 about her work as a safety team leader.¹ It is partially on the basis of her experience that the IOM report argues that a critical step in promoting a culture of safety is to change the role of the safety expert from occasional consultant to vital participant in the day-to-day work of regulatory decision making.

Of course, even with such participation in preapproval reviews, premarketing clinical trials would have limited ability to identify uncommon adverse events. A safety data set supporting a new drug application for treatment of a chronic disease typically includes fewer than 3000 patients, some of whom have had only a single exposure to the drug. Postmarketing surveillance for adverse events and ad hoc safety studies are therefore crucial, but although responsibility for these activities falls to the OSE, all regulatory authority remains with the division that approved the drug. In the postmarketing realm, the IOM committee recommended establishing joint regulatory authority, so that

either the OND or the OSE could take regulatory actions. The agency responded by creating two process-review teams, hiring external consultants to improve communications, and developing standard operating procedures that will, it says, "articulate the division of responsibility between OND and OSE" in presenting safety data to advisory committees. Although the FDA claimed that it is committed to ensuring that the "safety staff has a strong voice" in safety-related decision making, it did not confer any regulatory authority on the OSE.

The sidelining of safety experts extends to the FDA's external advisory committees, which are composed of physicians with expertise in a given therapeutic area, along with a biostatistician, a patient representative, and an industry representative. Safety experts serve on a separate Drug Safety and Risk Management Advisory Committee, which sometimes meets with other advisory committees, and individual safety experts are sometimes asked to consult on particular safety issues. In response to an IOM recommendation that scientists with expertise in pharmacoepidemiology or public health be included as regular members of all scientific advisory committees, the agency has proposed that it include such expertise "when safety issues are an important component of the issues before the Committee." But safety should always be on the agenda. Such expertise is critical for evaluating and interpreting often sparse safety data at the time of drug approval, for evaluating proposed postmarketing studies, and for assessing risk-management action plans. The FDA's response once again highlights the low priority it assigns to its responsibility for arbitrating drug safety.

Recognizing the pervasiveness of this marginalization at the agency, the IOM recommended that DHHS appoint an external management advisory board to help find ways of transforming the agency's culture. The FDA responded, instead, with a series of internal initiatives, pilot studies, and further evaluations that leave safety experts working largely in isolation, with limited resources and outdated technology.⁵

In my view, the FDA's response to the IOM report demonstrates a lack of understanding of the magnitude of the changes required to create a culture of safety. Apparently, the agency's leadership has yet to recognize that the adoption of such a culture would benefit all stakeholders — industry, the community of scientists, and most important, the American public.

Dr. Smith reports having served on a number of FDA advisory committees as an ad hoc member and having served as a consultant to the IOM panel. She reports receiving grant support from PhRMA and Sanofi-Aventis, serving as a consultant on lawsuits for Bayer and Spectrum and against Abbott Laboratories, and serving on Covance's scientific advisory board on isotretinoin risk management. No other potential conflict of interest relevant to this article was reported.

Source Information

Dr. Smith is an associate professor at the Center on Drugs and Public Policy, Department of Pharmaceutical Health Services Research, University of Maryland School of Pharmacy, and in the Department of Epidemiology and Preventive Medicine, University of Maryland School of Medicine — both in Baltimore.

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Protecting Patients Popping Piles of Pills

September 11, 2007 05:50 PM ET | Comarow, Avery | [Permanent Link](#)

Millions of Americans suffer from polypharmacy, booms the TV. Are you among them? That'd stop you cold on the way to the kitchen during a commercial break, wouldn't it? Polypharmacy means taking a large number of medications, which indeed millions of Americans do. More than 20 million people take six or more prescription and nonprescription drugs; more than 12 million take *eight* or more.

It's not hard to see how it can happen. Combine a history of heart disease with a couple of everyday complaints like acid reflux and the occasional rebellion from the lower digestive tract and you're talking half-a-dozen meds, easy—a beta blocker, an ACE inhibitor, a cholesterol-lowering statin, and an aspirin for the heart; a proton-pump inhibitor for the heartburn; dietary psyllium fiber for the digestive difficulty. As the typical drug count increases with the pill-taker's age, so does the risk of drug interaction, as well as the possibility that you'll be the victim of newly discovered hazards in one or more of the medications, especially if they haven't been marketed that long.

Pharmaceutical manufacturers are supposed to run studies of a new drug's safety after the drug goes on the market, but getting doctors and patients to sign up for these studies has been difficult. Patients and physicians can directly report problems to the Food and Drug Administration's MedWatch program, but it, too, has had spotty success. An analysis published today in the *Archives of Internal Medicine* shows that the number of deaths and injuries reported to MedWatch almost tripled between 1998 and 2005, four times faster than the growth in the number of prescriptions written. The FDA says much of the increase is simply due to better reporting. The study authors disagree. Coauthor Curt Furberg, a professor of public health sciences at Wake Forest University School of Medicine and longtime critic of MedWatch, says that the sharp rise "shows [that] current efforts to ensure the safety of drugs are not adequate, and that physicians and patients are unaware of these risks."

How, then, can individual patients learn about drug interactions and other dangers?

Hugo Stephenson, an Australian physician who relocated to the United States many years ago, thinks he can help. Next month he plans to launch iGuard, a service that will assign a five-level "risk rating" to each drug entered by a patient into a personal medical profile, which is housed at the iGuard website after the patient registers. The risk will represent not only the hazards of individual drugs but also potential drug interactions, all keyed to the patient's medical history. Once registered in the iGuard system, patients will receive alerts when new findings emerge. There won't be any charge—Stephenson will strip out details that identify individual patients and sell the data to researchers—and the rather complicated way in which various risks are determined

EVERY COMAROW

U.S. News's Avery Comarow is the senior editor of the America's annual rankings since the late 1990s. In his reporting on clinical medicine from the cholesterol guidelines to the effort he has kept one question in his mind: What does this perspective qualify him to observe the efforts by hospitals to improve care and patient

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seem sound to me.

As of mid-September, the iGuard site is open for registration, but Stephenson agrees that it isn't ready for use. Currently, drugs are assigned risk levels, but the nature of the risk is not explained. Stephenson promises that when the site is officially up and running, it will feature explanations that patients can then bounce off their doctor. I hope iGuard can deliver. Nothing else has.

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This release was updated on Nov. 1, 2007 to include changes to the fourth paragraph.

FDA News

FOR IMMEDIATE RELEASE
November 1, 2007

Media Inquiries:
Christopher Kelly, 301-827-6242
Consumer Inquiries:
888-INFO-FDA

FDA Says Consumers Continue to Buy Risky Drugs Online *Self-medication a concern; FDA-approved generics may be cheaper alternative*

A yearlong U.S. Food and Drug Administration (FDA) investigation into drugs mailed to the United States from foreign countries suggests that consumers may be buying drugs online to avoid the need for a prescription from their physician. The FDA sampling of imported drugs also indicates that consumers continue to spend money unnecessarily on potentially risky drug products bought over the Internet.

The investigation found 88 percent of the 2,069 drug packages examined appeared to be prescription medicines available in the United States. Of the remaining products, some were dietary supplements, some were foreign products with labeling that was illegible or incomprehensible, and some were medications not available in the United States. More than half (53 percent) of the products sampled have FDA-approved generic versions, likely sold at lower costs, according to earlier studies that have shown generics in the United States to be generally cheaper than a comparable drug in Canada or Western Europe. In fact, approved generic versions of approximately half (47 percent) of the sampled products can be bought for \$4 at several national chain pharmacies, a price often lower than the shipping costs for the same drugs purchased online.

"The data lead us to believe that many people are buying drugs online not to save money but to bypass the need for a prescription from their doctor since these Web sites typically do not require the purchaser to have a prescription," said Randall Lutter, Ph.D., FDA's deputy commissioner for policy. "In essence, they seem to be getting and using prescription drugs without a prescription, an intrinsically risky practice."

These data are based on surveys conducted from September 2006 to August 2007 in international mail facilities and courier facilities across the country. At each city surveyed, a selection of parcels suspected by U.S. Customs and Border Protection of containing pharmaceuticals were stopped. FDA then recorded data on the contents of these parcels, before handling them in accordance with its usual procedures.

In general, a Web site can appear legitimate, but in fact be a front for an illegal operation. FDA urges consumers to beware of unregulated Internet drug sellers, because many of their products might not contain the correct ingredients and could contain toxic substances. Several drugs found in this survey require special monitoring by physicians or other health care professionals for potential adverse events and to ensure their effectiveness. These include antibiotics, antidepressants, the blood thinner warfarin, and levothyroxine (a thyroid replacement hormone).

For more information:
FDA Finds Consumers Continue to Buy Potentially Risky Drugs Over the Internet
<http://www.fda.gov/bbs/topics/NEWS/2007/NEW01663.html>

Buying Medicines and Medical Products Online
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Health

Drugs That Go Untaken

Too often, lifesaving medicine is prescribed but not used

By Katherine Hobson

Posted September 29, 2007

Damian Galvan knew it was time to own up. The nurse overseeing his cancer treatment at M.D. Anderson Cancer Center in Houston had summoned him from his home in Brownsville, Texas, saying his latest lab results indicated his disease—chronic myelogenous leukemia—had returned. The lifesaving medications Galvan was on must not be working, he said. "I asked the nurse to close the door," Galvan, now 33, remembers. "I said, 'I have to be honest with you—it's not that the medications aren't working. I haven't been taking them for six months.'"

You'd think Galvan would be a rarity, that anyone with a life-threatening medical condition would diligently take his medicine. But according to an August report by the National Council on Patient Information and Education, only about half of patients take their medications as prescribed, and the longer someone is on a drug, the more likely he is to start skipping doses. The global cost of medication nonadherence (or non-compliance), as the doctors call it, is estimated at \$177 billion a year, including indirect costs like lost productivity.

The human cost is high, too. A study in the September 10 issue of *Archives of Internal Medicine* found that heart disease patients who skipped their meds had more than twice the chance of a heart attack, stroke, or other cardiovascular event compared with those who took them faithfully. Another recent study found that breast cancer patients who were instructed to take tamoxifen were 16 percent more likely to die if they failed to fill at least 30 percent of their prescriptions for the drug than if they filled all prescriptions. Glaucoma patients can go blind without treatment, yet one study found that only 58 percent of those who had lost sight in one eye were taking their medications as directed. Even a few organ transplant recipients eschew drugs, says Robert Hobbs, a cardiologist at the Cleveland Clinic. In some cases, he says, "it's clear that when they stopped taking their medications, they died."

It's not a problem ripe for a quick fix. The reasons for nonadherence are diverse, which means the solutions must be, too. "Medicine is not set up to worry about what happens when people leave the doctor's office," says Alan Christensen, a psychologist at the University of Iowa who has researched adherence. The NCPPIE report calls on the government, healthcare workers, and professional societies

to make adherence a top priority, recommending a national education campaign, professional training, more federal funding for research, and improvements in health literacy.

Why skip doses? One biggie: side effects. Tamoxifen, for example, can cause menopause-like symptoms, and aromatase inhibitors, a newer class of breast-cancer medicines, may provoke musculoskeletal problems. After surgery, a patient may be told to take either or both for years, to prevent a recurrence. But a new study found that 13 percent of women on aromatase inhibitors stopped because of problems like tendonitis, arthritis, and other aches and pains. "Many people don't take advantage of their treatment," says Marisa Weiss, an oncologist in Philadelphia and founder of breastcancer.org. If a drug's side effects are bugging you, she says, talk to your doctor, who may be able to prescribe a substitute, change the dosage, or give you a brief supervised break to see if symptoms disappear.

For some, expense is the sticking point. A recent study in *Health Affairs* found that retirees who had annual benefit limits on their health plans were more likely to stop taking their meds than those without caps on their benefits. If you can't afford your prescriptions, tell your doctor. He may switch you to a cheaper alternative, give you free samples of the drug, or help you enroll in a pharmaceutical company's assistance program, which can provide no- or low-cost drugs to patients who can't otherwise afford them.

Confusion. Many patients are simply confused about how to take their meds, says Ruth Parker, a health literacy researcher and expert contributor to the NCPIE report. Studies show that people misunderstand doctors' instructions and prescription labels, and their confusion can be compounded by old age and multiple medications. Parker wants to see standardization of labels; for now, keep an updated list of your drugs, including the dosage, and your understanding of when and how to take them. Carrying that list with you lets you review your prescriptions with your doctor or pharmacist, she says. And if you're a caregiver to someone who may forget to take medications, keep that list for yourself—and find a way to remind the person of her dosage schedule, maybe with phone calls, Post-Its, or the classic days-of-the-week pillbox.

That low-tech solution can work. A study in the October 1 issue of *Clinical Infectious Diseases* showed that passing out pillboxes to HIV patients at high risk of skipping their meds—a \$5 investment per person—improved adherence by 4 percent and cut their risk of progressing to full-blown AIDS by 11 percent. Drug companies are also working to make it easier to take meds, by combining two drugs into one pill, or reformulating drugs so they can be taken less frequently.

Some patients may not understand why they're on a medication—and why they need to stay on it, even if they feel well. A study released this summer looked at veterans who'd been prescribed statins—at low or no cost—to prevent heart problems. Within six months, more than half stopped taking the drugs or weren't taking them correctly. The nonadherers were more likely to say they didn't see themselves at high risk of a heart attack, believed a low-fat diet they'd adopted made the drug unnecessary, or figured that once their cholesterol levels came down, they were "cured." "There's a communication problem," says Devin Mann, an author of the study and an internist at Mount Sinai School of Medicine in New York. "We all need to start out on the same page so patients know why they're on a drug and how long

they'll be on it."

Improving one's communication with doctors may be the cheapest and most far-reaching step the average person can take. But Christensen says doctors need to take responsibility, too. "It can even be something like asking the patient whether he'd prefer the once-daily or once-monthly form of a treatment," he says. "It's like when you're trying to get your 4-year-old to eat his vegetables. You don't say, 'Eat your vegetables,' you say, 'Would you rather have the peas or the carrots?'"

Patients' mistaken beliefs or misguided attitudes are increasingly problematic in the treatment of cancer, where it's becoming common for patients to take oral drugs for years. "People get tired of being reminded they have cancer," says Maurie Markman, vice president for clinical research at M.D. Anderson.

For Galvan, the decision not to take his drugs resulted from a combination of unpleasant physical effects—he hated giving himself a weekly injection as well as the rashes that followed—and a desire to escape the reality of a shocking diagnosis. "I felt this sense of urgency to be normal again," he says. "I went from only taking a Tylenol once in a while to having a big Ziploc gallon bag full of pills, another full of syringes, and another full of vials." It was the post-confessional heart-to-heart he had with his nurse and doctor that made a light bulb go on. "They told me, 'You're not the first person to do this, but if you don't take your medicine, you will die.'" Now healthy—and taking his medication as prescribed—he still returns to M.D. Anderson twice a year to make sure his cancer hasn't returned. But he's no longer being monitored more frequently to be sure he's complying. "They saw," he says, "that I'm a man of my word."

TALK WITH THE DOC

The best route to consistent and proper use of prescription drugs, experts say, involves making sure the doctor and you—or the loved one whose care you're overseeing—are on the same page. Some things you need to know whenever a doctor writes you a prescription or a pharmacist fills it:

- Why am I taking this medicine?
- How does it work in my body?
- What's the dosage schedule, and how do I take it?
- Will it safely mix with the other medicines I'm taking?
- What should I do if I accidentally skip a dose?
- What side effects might I experience? Which can I ignore, and which do I need to report?
- How will I know if the medicine is working?
- What should I do when I'm about to run out?

Source: American Society of Consultant Pharmacists

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October 31, 2007

Non-English Speakers Charge Bias in Prescription Labeling

By ANNE BARNARD

Pharmacies across the city routinely fail to help non-English speakers understand their prescriptions, raising the chances that customers could harm themselves by taking medicines incorrectly, immigrant advocacy groups charge in a discrimination complaint that they plan to file today with the New York attorney general's office.

The complaint names 16 pharmacies in Brooklyn, Queens and Long Island, most of them operated by chains. It argues that federal civil rights law and state health regulations require pharmacies to provide linguistic help to guarantee that people who speak little or no English receive equal access to health care. That assistance should include interpreters at pharmacies and written translations of medication instructions, the advocates say.

Nisha Agarwal, a lawyer for one of the groups filing the complaint, said the attorney general's office had already issued subpoenas to several pharmacies listed in an earlier version of the complaint filed in July. The new version names more pharmacies, and an accompanying report includes more examples of comprehension problems non-English speakers have had.

"The idea is that people should not be placed in danger by not understanding their medication regimen," said Andrew Friedman, an executive director of Make the Road New York, one of the groups filing the complaint, along with New York Lawyers for the Public Interest and the New York Immigration Coalition.

Jeffrey Lerner, a spokesman for the attorney general's office, said only, "We have an ongoing investigation."

The pharmacies named include six operated by Rite Aid, three CVS stores, three Duane Reade stores, a Walgreens and a Wal-Mart. CVS said it was cooperating with the attorney general. The other companies declined to comment on the pending legal matter, but said they were trying to provide good service for diverse populations.

Tiffani Bruce, a spokeswoman for Walgreens, said the chain provided medication labels in 14 languages and kept a nationwide database of its pharmacists who speak other languages, enabling a pharmacist to call a colleague who can talk to a customer.

CVS said it provided telephone interpreters in 150 languages, and Rite Aid said it tried to hire bilingual pharmacists and provided labels in 12 languages.

In a survey of pharmacists at 200 New York drugstores to be published next month in the Journal of Urban Health, 88 percent said they saw non-English-speaking customers daily, and 80 percent said they had the ability to translate labels, according to Linda Weiss, a senior research associate at the New York Academy of Medicine, who conducted the study. But only 34 percent said they translated labels daily, and 26 percent said they never did.

Many states require hospitals to provide translation and interpretation services in emergency rooms. Last year, New York State's Department of Health tightened regulations to require that all hospital departments provide interpreters to non-English speakers within 20 minutes.

Health advocates have increasingly used federal civil rights law to push hospitals, nursing homes and clinics to provide language services. Language barriers to health services constitute discrimination based on national origin, they argue, a violation of federal civil rights law, which applies to hospitals because they receive federal funds through Medicare and other programs.

The latest effort aims to expand similar requirements to pharmacies. The complaints also cite the New York Education Law, which requires that medications be labeled in a way that ordinary people can understand. That is meaningless if they are in a language the patient does not comprehend, Mr. Friedman said.

This month, California enacted a law requiring the state's pharmacy board to implement new requirements for clear prescription labeling by 2011, and to "consider" the needs of non-English speakers.

The advocacy groups provided The New York Times with a copy of the complaint and the accompanying report.

The report chronicles the stories of more than a dozen New Yorkers who said they struggled to understand their prescriptions at local pharmacies. Reyita Rivera, 47, for example, who speaks and reads only Spanish, said she could not understand the printed instructions that came with her antidepressant medication, and ended up taking too much. She said she had to be admitted to a Queens hospital after the medication caused a racing heartbeat.

"That experience scared me a lot. I felt very bad — I thought I was just going crazy," Mrs. Rivera, a Dominican immigrant, said in an interview, speaking through an interpreter.

She said she could not communicate with the staff at her pharmacy in Ridgewood, Queens, and received no printed explanation of the medication in Spanish.

José Cadavid, 63, of Woodside, Queens, said he usually could not get his pharmacists to explain his medication in Spanish. "Whenever I go to the pharmacy I see a lot of people struggling to communicate," said Mr. Cadavid, who immigrated from Colombia. "There's no one helping them. It affects a lot of people."



Your kid has a cold -- what now?

- Story Highlights
- Parents seek answers after FDA advises against cold medications for young kids
- Doctors recommend alternative therapies such as massage and essential oils
- One expert says big doses of vitamin C can help

By Elizabeth Cohen
CNN

Empowered Patient, a regular feature from CNN Medical News correspondent Elizabeth Cohen, helps put you in the driver's seat when it comes to health care.

ATLANTA, Georgia (CNN) -- On the popular parenting Web site urbanbaby.com, a writer asks whether it's OK to give an 18-month-old "a tiny bit of Robitussin" for her "cold/cough and fever."

"No flames please," the parent requests.

But flames she got.

"Idiot," one user writes.

"The answer is *of course not*," another writes. "Come on ... these cough syrups are totally ineffective in ameliorating the common cold and are harmful to your child."

Over-the-counter cough and cold medications for a child under 6 goes against the advice of the Food and Drug Administration -- and apparently that of many fellow parents on the Internet. These medications have been blamed for more than 100 deaths and at least thousands of trips to the emergency room.

But what else can a parent do?

"I use these types of meds at night so we can all get some sleep," writes another parent on urbanbaby.com. "It's the only thing that helps with her cough at night," another says.

Or as one parent puts it succinctly on the Craigslist parenting forum: "It sucks not knowing what to do."

Here are a few alternatives that physicians give their patients when little ones are miserable with a cough or cold.

Music and a massage

"Gentle massage with an essential oil such as lavender may help to promote sleep," says Dr. Michelle Bailey, a pediatrician and associate director of education at Duke Integrative Medicine, which blends traditional medical treatments with alternative therapies.

She says minimizing stress, since it weakens the immune system, is important, too. "There is a connection between the mind and the body, so relaxing the mind may have a positive relaxation effect on the body during times of illness," she says. "Relaxation tapes or CDs may help reduce stress."

Tea and a bath

"I like to recommend ginger tea with honey," says Dr. Paula Gardiner of Harvard Medical School's Osher Institute. (For babies under 1, hold the honey -- it could make them sick). She also tells patients a warm bath with eucalyptus oil helps open stuffed-up nasal passages. Bailey says menthol in the bath works, too.

Vitamin C and vapor rub

Vitamin C also is worth trying, says Dr. Kathi Kemper, a professor of pediatrics at Wake Forest University School of Medicine in North Carolina and a specialist in integrative medicine. But she says there isn't enough in orange juice. "Doses need to be several hundred milligrams, depending on the age of the child," she says. "My 10-year-old gets two grams daily when he starts to get a cold."

She also recommends a vapor rub for stuffy noses -- except for infants under 1 month. (She says applying it under the nose can cause apnea in such infants.)

These suggestions, the doctors say, are in addition to the basics that any pediatrician would recommend: warm liquids, a humidifier, a saline nose spray and a nasal bulb syringe to suck out what's stuffing up your little one.

But even with all these tricks, there's nothing that will magically make your child's cough or cold go away -- or magically get them to sleep.

All About Pediatrics

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Los Angeles Times

<http://www.latimes.com/features/health/la-he-coupons3dec03,1,2732046.story?track=rss>
From the Los Angeles Times

Heading to the drugstore? Clip a coupon -- but read the fine print

Many consumers don't know that deals are available on prescription medication. But generics are often still cheaper.

By Francesca Lunzer Kritz
Special to The Times

December 3, 2007

The next time your pharmacist hands over a prescription and the bill, consider handing something back -- a coupon.

More than 200 drug coupons available online or from doctors or pharmacists have face values that could save individual consumers tens to hundreds of dollars each year.

But few patients seem to know about them. Only about 1% of the 286 billion grocery coupons distributed last year were redeemed, according to market research firm CMS Inc., but the percentage is even lower, for now, for prescription drug coupons.

Drug companies often do little marketing for the discounts, says David Harrell, chief executive of Optimizerx.com, a website launched early this year that posts links to drug coupons for consumers. The money-saving offers include not just coupons, but free trials, rebates and loyalty cards that save money on future prescriptions.

Increased marketing of the offers is likely to build awareness. Even for consumers who aren't generally coupon clippers, these offers might be worth a second look.

They might also warrant a second thought -- the savings may not actually add up.

More companies have begun to create enticements for particular brand-name drugs, partly in response to a growing number of lower-cost generic versions, says Carl Cohen, president of marketing solutions for CegeDIM Dendrite, a market research firm that looks at efforts by drug companies to promote drugs to consumers. For example, Lipitor, the top-selling cholesterol-lowering drug, whose competitor, Zocor, lost its patent last summer, now has a variety of company-sponsored price cuts on its site, Lipitor.com. And of the five top-selling prescription drugs in 2006, ranked by trade publication MedADNews, three offer discount coupons.

Meanwhile, prescription coupon sites such as Optimizerx.com and Internetdrugcoupons.com, launched in July, are making it easier to find the offers. A third site, Reduceprescriptioncosts.com, has coupon links and other tips for saving money on drugs. And some general coupon sites, such as fatwallet.com, have been adding drug coupon links as well.

By and large, the three main drug coupon sites have similar offers, though a recent check found coupons for osteoporosis drug Actonel on the first two, but not the third. And of those sites, Optimizerx is the only one to bombard users with ads. A click on a Lipitor offer, for example, also launched ads for eHealth insurance, pet medicines, drugs from Canada and a natural way to lower your cholesterol.

Where to find them

Looking for offers? Pharmacies often have tear sheets on a bulletin board near the pharmacy or the main door. Doctors' offices may have additional information, though those deals are sometimes available only through a physician. And a drug's website usually posts such information prominently. For example, Advair, an asthma drug, offers a free prescription on its site via a message to "click here for savings."

Some offers require a bit more searching to find, such as for Diovan, a blood pressure drug. People who visit that site need to know to click on the "BP [blood pressure] Success Zone Program" link, and then search further under "program benefits." The Internet coupon sites typically do the searching for you. Click "Diovan" on Internetdrugcoupons.com, and the site explains how to get the discount offer.

Although the average grocery coupon has a face value of \$1.02, according to CMS, drug offers can run far higher. Recent ones have included up to a \$20 rebate on a one-month prescription of the overactive-bladder drug Detrol LA, a voucher for a seven-day supply of the sleeping pill Ambien (retail price, \$35 at drugstore.com) and a free one-month supply of three breast cancer drugs.

That doesn't mean consumers should jump at every money-saving offer.

People being treated for a specific condition may not actually receive better care if they switch from their current medication to a new one simply because of a \$10-off coupon. And, especially if the coupon is for one time only, the new drug could cost more in the long run.

Reading the fine print is crucial, says Matthew Tilley, head of marketing at CMS. Drug coupons cannot be used by people insured by most federal and state insurance plans such as Medicare and Medicaid (Medi-Cal in California), because the federal and state governments consider coupons a kickback to consumers. However, programs that involve no money back, such as free trials, are often allowed.

Some coupons are simply handed in with a prescription for an immediate price reduction; others, such as the offer for Detrol LA, are rebates that need to be mailed to the company along with the original receipt from the pharmacy. Wording on the coupon will explain whether it can be used for a co-pay. If so, and if the coupon's face value is higher than that of the co-pay, consumers will get only the value of the co-pay.

Consumer-friendly?

Recent chatter on coupon blogs suggests consumers like drug coupons, with many posters saying they had found a coupon for a drug they, a child, parent or even a grandparent takes. But not everyone considers the coupons consumer-friendly. The Food and Drug Administration is planning a study of consumer perceptions of drug coupons to see if, when partnered with a drug ad, the allure of the discount keeps consumers from adequately paying attention to side effects and other risks.

Last year, the FDA posted a federal register notice asking for public comments on the proposed study. The agency has since pulled the notice, spokesman Sandy Walsh said, in order to refine the parameters of the study, but in the meantime, comments voicing opposition to coupons came into the agency. The Prescription Access Litigation Project, for example, a group devoted to lowering the cost of prescription drugs, filed comments representing 23 consumer groups calling for an outright ban on prescription drug coupons. Among the complaints: that coupons interfere with a doctor/patient relationship by leading consumers to ask their doctor for a drug for which they've seen or received a coupon, and that they deceive consumers into using high-priced brand names over generics.

"A \$10 coupon is nothing compared [to] the long-term savings from using a cheaper generic drug, particularly for long-term maintenance drugs," says Alex Sugarman-Brozan, the group's director.

Still, for certain consumers, the coupons can pay off.

"Coupons are a meaningful money-saver for people whose doctor has determined that [this] is the drug they should be on," says Dr. William H. Shrank, a pharmacoepidemiologist at Harvard Medical School. "But patients should be aware that, even if they are insured, they may be charged a large amount once the coupon is used, as insurers often require high-tier co-payments for these branded drugs."

Patients interested in a coupon should determine whether a generic is available -- and then ask their physician if the generic is appropriate. Because brand-name drugs can be two to four times more expensive than generics, the brand-name drug is often more costly even if a coupon is available, says Steven Findlay, a healthcare analyst with Consumers Union.

A look at several sites turned up few drugs with coupon offers for which there was a generic equivalent, and in those cases, the coupon didn't bring the brand name down to the generic's lower price.

Synthroid, for example, a brand-name drug from Abbott Laboratories that treats thyroid hormone insufficiency, costs \$13.99 per month at drugstore.com, versus \$8.99 for the generic. But the coupon Abbott is now promoting only takes \$3 off of each prescription, making the generic cheaper by \$24 per year.

Although generic drug manufacturers rarely, if ever, offer coupons, specific insurers may. Blue Cross of California has a program called Generic Advantage, for example, which will often cover the cost of the co-pay each month if consumers choose a generic version of a drug.

And although the coupon deals may save money, consumers will almost always have to give up some privacy. Drug companies usually require personal information including name, age, address, phone number and e-mail address in exchange for the offer.

Some sites let consumers opt out of receiving additional information, but doing so can preclude getting future discount offers.

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FDA Considers Easing Curbs on Drug Makers

Research on Off-Label Use Could Be Sent to Doctors

By Christopher Lee
Washington Post Staff Writer
Saturday, December 1, 2007; A04

The Food and Drug Administration is considering allowing pharmaceutical makers to provide doctors with medical journal studies of unapproved uses for drugs, a move critics say would undermine long-standing restrictions on marketing medicines for "off-label" purposes.

Under a draft "guidance" prepared by the FDA, drug and medical device manufacturers could distribute unabridged reprints of peer-reviewed research from reputable medical journals as long as the articles were not written, edited or otherwise "significantly influenced" by the manufacturers or people with financial ties to them. No other promotional materials could be attached to the reprints, which would have to be labeled as describing uses for the products that have not been approved by the FDA.

The proposal would be a break with the FDA's prohibition on the marketing of drugs and medical devices for unapproved purposes, which dates to 1938. It is legal for doctors to prescribe approved drugs for off-label uses, however, and the practice is common for some types of drugs.

In 1997, Congress created a temporary exception allowing companies to distribute reprints so long as they submitted them to the FDA for advance review and had formally asked the FDA to approve the new use. That exception expired in 2006. In recent years, the marketing restrictions have been the subject of legal challenges on free speech grounds.

Rep. Henry A. Waxman (D-Calif.), chairman of the House Committee on Oversight and Government Reform, said creating a new path to promote off-label uses could improperly influence doctors' prescribing habits. In a letter yesterday, Waxman urged FDA Commissioner Andrew C. von Eschenbach to suspend drafting of the new guidance and cooperate with a committee inquiry into the issue.

The draft guidance "would open the door to abusive marketing practices that will jeopardize safety, undermine public health, and lead to an increase in unapproved uses of powerful drugs," Waxman wrote.

Companies would be less likely to conduct definitive scientific studies and seek formal FDA approval for alternative uses of drugs and devices if they could promote and profit from off-label uses anyway, Waxman contended. He said the proposal could grant undue influence to incomplete or distorted studies, some of them industry-funded. And he pointed to several high-profile cases in which drugs such as Vioxx and Celebrex were trumpeted in flawed journal articles that either underreported dangers or overstated benefits.

"While there may need to be a balance between First Amendment and protection of the public health," Waxman wrote, "the answer is not to open the door to unrestricted dissemination of potentially questionable information about drug safety and effectiveness."

FDA spokeswoman Rita Chappelle said the agency does not comment on letters from Congress.

Ken Johnson, senior vice president of the Pharmaceutical Research and Manufacturers of America, said it is "premature" to comment specifically on the FDA draft, but that providing the articles to doctors could help them make better prescribing decisions.

"These off-label uses or treatment regimens may be important and may even constitute a medically recognized standard of care," the guidance says.

Some people depend on off-label uses of drugs, said Diane Dorman, vice president for public policy at the National Organization for Rare Disorders.

"There are nearly 30 million people in the United States affected by almost 7,000 known rare diseases," Dorman said. "Consequently, most of those disease states are treated off-label because there is no therapy specific for their disease. So getting that information to physicians, I would consider to be very, very important for the patient."

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Intelligence for the pharma industry



Oncology Summit Europe

Improving patient compliance with low-cost wireless technologies

(10/11/2006)

Patient non-compliance represents significant lost revenue to pharmaceutical makers. Industry experts estimate that 50% of all prescriptions filled are never consumed, 20% of all new drug prescriptions are never filled the first time, and 30-40% of initial prescriptions are never refilled.

According to Datamonitor, patient non-adherence costs the pharmaceutical industry in excess of \$30 billion a year. In the US statin market alone, non-adherence in a single year adds up to an estimated \$3.9 billion in lost revenues for the industry.

Improving patient compliance, even slightly, can have significant impacts on revenues for drug makers, expenses for third party payers and outcomes for patients. For a \$1 billion product, a 5% increase in patient adherence can reap \$30-40 million in revenue.

According to Jane Martin, a respiratory therapist and founder of pulmonary patient support programs in Michigan, the most successful patient compliance interventions come down to "patient education made so simple and convincingly logical, that there is little reason for a patient not follow the prescribed instructions."

In Martin's case, she identified the areas of development, chemistry, engineering, user-friendly product design, and distribution as all being vital components in the success of inhaled pulmonary medications for her COPD patients. But she encourages the pharmaceutical industry to work on methods of integrating technology with the human element to improve the level of adherence.

"You have to impact the patient's behavior as well as educate them about the relative benefits of the medication" suggests Robert Nauman, Principal at BioPharma Advisors. "Patients need consistent information reinforcement to change their behavior. Relevant content is the key to the adoption of positive behaviors."

As outlined in previous eyeforpharma articles (www.eyeforpharma.com/search.asp?news=45652), the following behaviors have been identified as some of the top reasons for patient non-adherence:

- simply forgetting (65%);
- concerns about the drugs themselves (45%);
- and feeling the drug is unnecessary (43%).

Phil Cohen of Mobile Reach Media believes wireless technologies offer just the kind of simplicity Martin and Nauman advocate, while providing a quick and effective solution to the three leading reasons for non-compliance.

Cell phones are a user friendly, yet multi-faceted technology that allow those concerned with patient adherence to identify non-compliant patients, determine the key issues hindering their adherence, and respond in an effective, timely and simple manner.

Cohen says that although wireless technologies, like SMS, have been around for a few years now, wireless carriers have made the technology nearly impossible to execute effectively for the purpose of improving adherence. But that's all changing, he says, "as carriers want more volume of transactions on their networks, prices are falling and richer media driven content is being made available to subscribers."

Cohen believes the timing and fit are ripe for wireless technologies to help pharmaceutical companies, healthcare providers, insurers, and governments initiate programs that improve patient compliance.

Applying wireless technologies to improve patient adherence

According to a recent World Health Organization report on patient compliance, studies consistently find significant cost-savings and increases in the effectiveness of health interventions that are attributable to low-cost interventions for improving adherence. In many cases investments in improving adherence are fully repaid with savings in health care utilization and, in other instances, the improvement in health outcomes fully justifies the investment.

Pharmas investing in patient compliance initiatives stand to benefit to the tune of tens of millions of dollars per project, while those who are not, risk leaving hundreds of millions of dollars on the table across their portfolios.

Solving adherence problems really shouldn't require 'rocket science.' Issues hindering adherence are usually not technical matters, but are related to cognitive behavior. A solution begins with effectively identifying and understanding the 'trouble spots' from the patient's perspective in order to be able to selectively apply a relevant solution.

For patients that simply forget to take their medication - the leading reason for non-compliance - an effective wireless solution can be used to detect non-adherence and to intercede with an increase in relevant information. Treatment regimen reminders and relevant content delivered in a timely manner (i.e. when their dose is getting late and may be missed) provide a significant improvement over education alone. That additional information helps patients questioning the efficacy of their treatments at a time when they may begin to 'drop off' their medication. A timed communication protocol, in which patients are encouraged to look for both the subtle and overreaching signs of their progress helps reinforce the need to stay on the medication as prescribed by their physician.

Patients also may become non-adherent in response to concerns about drug side effects (45%). Cohen suggests a simple, interactive wireless communication can be used to both detect and instantly respond to side effects. Such communication, he says, will either generate a level of comfort among patients that some side effects are 'normal' or initiate a response by appropriate medical staff for instances of adverse side effects, driving increased awareness of the issue in both cases.

The third key impediment to compliance – feeling like the prescribed medicine is unnecessary – also can be addressed with wireless intervention. Self-efficacy ratings collected in real-time with the aid of wireless compliance technologies may more accurately document a patient's true attitudes about the effectiveness and perceived side effects of the prescribed drug than recollections collected on a paper questionnaire at a later time are able to capture. In addition, incremental reporting offers opportunities for educational interventions that reassure patients that the effects they are feeling (or not) are "normal" or desirable with a given drug and to reinforce the importance of adhering to the prescribed drug and dosing protocol.

Wireless technology makes sense as an educational tool because its messages are, by definition, short and to the point. In a world where we are constantly bombarded with messages from various media, wireless messaging can often 'hit the spot' in a quick and effective manner. Furthermore, the wireless device today, is a medium that often gets priority treatment; cell phone calls rarely go unanswered, and short messages, are almost always retrieved right away, because it can be done without significant interruption to other activities.

Overcoming inertia with the voice of a health 'leader'

"If industry experts say that 50% of all prescriptions are never consumed and 20% of all new drug prescriptions are never filled the first time, there is clearly a need for tools that will help patients overcome the initial inertia of beginning their treatments and understanding the relevant benefits of that action," says Cohen. "There is an obvious need to keep the patient's initial enthusiasm from the visit with their physician alive until they have actually filled the prescription and initialized an established routine of behavior that will bring about positive change."

Even though one's personal healthcare should be the most primal concern, there is evidence all around us that we behave to the contrary. One need only look at the number of smokers in the world or the level of consumption of unhealthy foods for anecdotal evidence that people are not taking action.

Sometimes all people need is a reminder from the 'right authority' with some rationale as to why it is important to them to take the medication as prescribed.

According to the UK Medicines Partnership project, people are more likely to adhere if they believe that their doctor, nurse, physician assistant or pharmacist cares whether or not they stick with the plan. Studies show that people who receive explanations from a concerned doctor are more satisfied with the help they receive and like the doctor more. And the more they like the doctor, the better they follow a treatment plan.

In the case of prescription non-compliance, the physician as a health 'leader' and influencer can be largely represented by an automated, wireless service with a simple message reminding patients what they must do to get healthy.

Nauman cites a pilot project done several years ago where a vaccine company was losing 85% of its patients before their second dose. Through cellular technology, physicians were given a microsite to register patients and enroll them in a reminder program. The results showed that 70% of the patients who were on the program came back for their second dose as a result of the reminder program.

Being able to reach patients at critical times, no matter where they are, and involving other parties to intervene directly with the patient in real-time when there is an identified risk of non-adherence may yield increased effectiveness and adherence.

Through the looking glass

A successful patient compliance program might begin, for example, with patients being encouraged (at the time a prescription is initially written) to participate in a proven adherence method to increase their chances of success, suggests Cohen. By getting communication started right away and by alerting a wireless adherence service provider quickly, the patient can be guided by educational messaging even before they start their medication.

Once a wireless adherence service is activated on a patient's mobile device, if non-adherence is detected, an automated reminder to comply can be delivered. If the reminder is not heeded, Cohen says, a friend, family member or even a willing physician can be automatically notified in real-time and may intervene with the patient. This is particularly true of parents with teenagers or young adults who may be on medication while at school.

If a patient's family, friends or other key influencers are playing the primary role in maintaining adherence, the physician may only receive periodic, aggregated patient activity notices as a secondary line of defense in adherence monitoring, Cohen points out. This gives doctors complete discretion, he says, as to whether their involvement is required, how much time they might want to invest and if office staff should intervene to investigate what is causing non-adherence with individual patients.

After a while, Cohen says, patients may stop using the adherence system altogether when good habits are established or may simply find it is not 'right' for them. Others may choose to change the key intervener for their service to friends and family. But the bottom line, he says, is patients should be allowed to opt out if they choose to do so to preserve patient satisfaction.

Most patients, however, will cognitively recognize the value and appreciate the intervention, Cohen says. Despite the significant impact wireless programs can have on improving patient compliance, however, an overall adherence solution should incorporate other adherence tools and efforts, each targeting specific patients, but combining to be greater than the sum of the parts.

Whose responsibility?

It can be argued that those who stand to gain the most financially should be the ones to invest the time and effort into ensuring patient adherence, Cohen says. But he warns patients are less likely to feel comfortable that it is in their best interests to remain compliant if they are being urged to do so by those with an obvious financial incentive to see them do so indefinitely.

Physicians, pharmacists and family members hold the most sway over encouraging adherence, because they have, presumably, already earned the trust of the patient. The challenge is to create a reliable system that allows these influencers to be involved in increasing health benefits to patients, while encroaching only minimally on their limited available time to do so.

"Programs need to be devised and coordinated at the level of the drug manufacturers and retailers, which manage and encourage physician involvement in this vital role," Cohen says. "But doctors must be duly compensated for increased time spent on adherence efforts with patients and for results achieved."

At least in the beginning, Cohen suggests, the pharmaceutical industry should foot the bill for compliance programs, since they have the most to lose financially from patient non-adherence. But ultimately, he says, early successes and lobbying power can be used to convince retailers, insurers and governments to contribute, as all will gain from better patient compliance.

In fact, a recent study sponsored by GlaxoSmithKline found that in the state of Ohio, one in five patients do not take their medications as recommended, adding \$700 million a year to healthcare costs statewide.

The bottom line for pharma: Compliance pays

Wireless solutions will likely be effective among only a sub-population of all patients in any given group. With 65-70% penetration of cell phones in the greater population, not everyone can participate. And among those that do participate, some attrition can be expected during the initial period of a program.

However, if a solution is cost effective and does a good job of increasing adherence among those who do participate, the net effect can be significant.

For example, Cohen says, maybe only 15% of a given patient population would be willing to participate in a wireless adherence program. And perhaps only 75% of those already have a phone, leaving 11% able to participate. If patient attrition from the program reached as high as 50% for various reasons during the first months of the program, only 6.5% from the initial 15% that showed interest in the program would remain.

But if the adherence rate among the remaining 6.5% could be increased from the average 40% rate commonly achieved to 85% with the program, net adherence rates among the entire group of patients ever written a prescription for the drug in question could be boosted by 2.5%.

If the drug in question costs \$80/month, for example, a pharma company's product generating 2 million prescriptions annually could reap increased annual revenues of \$48 million. In addition, patients' health would be improved and insurers would avoid additional expenses due to hospitalizations, surgeries or other protracted healthcare interventions. In the above scenario, if a typical wireless adherence service costs \$5 per patient per month, a return on investment from 300-600% can be achieved. That compares quite favorably with typical average returns on direct to consumer advertising (200%), traditional in-office details by sales representatives (172%) and e-detailing (248%).

Moving forward

According to the IFPMA's director general Harvey Bale, the industry's role should go beyond the traditional one of bringing the medicines to the market. Industry, he says, also has a necessary role in helping to inform patients about their products. This should be in such a way, Bale suggests, that broader and increased knowledge and understanding can support the patient's relation to, and dialogue with, the prescribing doctor and the other health professionals involved, such as nurses and pharmacists, in following the prescribed treatment to achieve the best outcome for both the patient and the health care system.

In many scenarios, wireless technologies can efficiently and cost-effectively improve patient adherence, but Cohen says the industry faces a few challenges moving forward. Pharmas, in conjunction with technology providers, must:

- Understand where improvements can be made within the confines of governmental regulations
- Choose technology that can enable the desired levels of adherence improvement in a flexible and cost effective manner
- Prove increased adherence, leading to exceptional ROI
- Validate ease of use among patients
- Understand that different situations call for different wireless technologies and deploy the easiest technologies and maintain ease of use among patients

The most logical place to begin as a proof of concept, Cohen suggests, is with high value drugs (blockbuster or semi-blockbuster products) taken at low dosage frequencies (e.g. 1-4 times per month) and carrying a fairly high price (i.e. \$60+/month). But significant returns on investment in wireless adherence programs promise to make the technology a "must have" for many products in pharma's portfolios.

Phil Cohen is the president of Mobile Reach Media Inc., a Toronto-based company specializing in wireless adherence and communication tools for the pharmaceutical industry. Phil can be reached at (416) 934-5565 or pcohen@echoalert.net.

Robert Nauman is Principal at BioPharma Advisors Network, a consultancy community. Rob can be reached at (919) 372-1658 or rnauman@MyBPA.net.

eyeforpharma's 3rd Annual Patient Compliance, Adherence and Education Congress USA is being held November 30-December 1 in Philadelphia. For more information or to register, visit www.eyeforpharma.com/pcusa06.



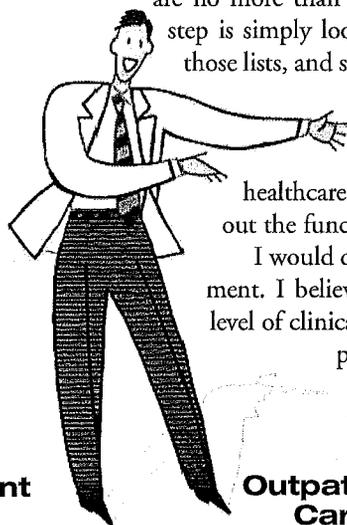
VIEWPOINT

Bruce Canaday, Pharm.D.

Whose job is medication reconciliation, anyway?

Who should take ownership of medication reconciliation? The Joint Commission tells us that medication reconciliation is a process made up of five steps: develop a list of current medications, develop a list of medications to be prescribed, compare the medications on the two lists, make clinical decisions based on the comparison, and communicate the new list to appropriate caregivers and the patient.

An argument could be made that the first two steps are no more than making lists, the third step is simply looking for differences in those lists, and step five is communicating them.



Step four appears to be the only one requiring a trained healthcare professional to carry out the function involved.

I would disagree with this assessment. I believe there is a significant level of clinical expertise necessary to perform all five functions. Step one involves asking patients

what medications they are on, transferring medica-

tion lists between community and institutional pharmacies, and contacting prescribers to develop a list of drugs patients are taking. Step two, or choosing the "right" medications to prescribe for a patient, should be part of a very well thought out, patient-specific therapeutic plan requiring, at a minimum, knowledge of the patient's conditions, the desired outcomes, and a clear understanding of the risks, benefits, and proper use of each medication under consideration.

Similarly, step three should be a comparative clinical evaluation of the medications on the two lists based on the above criteria, leading directly to step four. Step four, the "clinical decisions" piece, requires the highest level of expertise to ensure that the "right" medications are used to optimize patient outcomes. The final step, communicating the new list to appropriate caregivers and the patient, while no less critical, should be handled by the best communicator available.

So who is best qualified to fulfill these five steps?

Successful execution of these five steps mandates a knowledge base that is, I believe, unique to the pharmacist. Certainly other professions can and do bring something to the table. I'm not saying that pharmacists are the only option. However, the person "responsible" for execution and the outcome should be a pharmacist since pharmacists are the best trained in medication management. To quote the old Carly Simon song, "Nobody does it better!"

But accepting that "medrec" is our responsibility is only half the battle. What does responsibility mean? If we are to accept responsibility, we cannot do so by remote control. I have seen too many pharmacists claim responsibility for medrec when all they've done is sit on a committee that designed a process of developing a medication listing on the front end. Meanwhile they've deferred the work of medrec to nurses, aides, and others.

Why are so many pharmacists content to sit on the sidelines and watch? Why are we not stepping up to use our professional expertise to deal with the issue of poor communication of medical information at transition points that is responsible for so many medication errors and adverse drug events?

Ultimately, the most common argument against having pharmacists do this is lack of resources—code for "money." While we have to be fiscally prudent, our ultimate responsibility must be to provide the best possible patient care. At the end of the day, resource allocation is not about how much money there is—there is a lot of money in health care—it is about how the money is allocated; it is about priorities. Shame on hospital administrators for not recognizing that having pharmacists actively engaged in this process should be a priority. And shame on us for not being able to convince our bosses, our colleagues, and our patients that our skills are worth paying for because we can reduce medication errors and adverse effects due to medications.

Personally, I think the "best care possible" standard is met by asking, "Would that be what I want for my mother?" In this case, the person I want making decisions about medication use for my loved ones—taking responsibility for medication reconciliation—will have "pharmacist" on his or her name tag.

THE AUTHOR is a clinical professor in the division of pharmacy practice and experiential education at the University of North Carolina. He is a former president of both APhA and ASHP.

Of Interest to Pharmacists

Medication reconciliation policies incomplete at many hospitals

Michael Barbella

Overall, most hospital pharmacists think their institutions do a good job of reconciling patients' medications. But two out of 10 know of incidents in which inadequate policies have led to patient harm, an exclusive *Drug Topics* survey concluded.

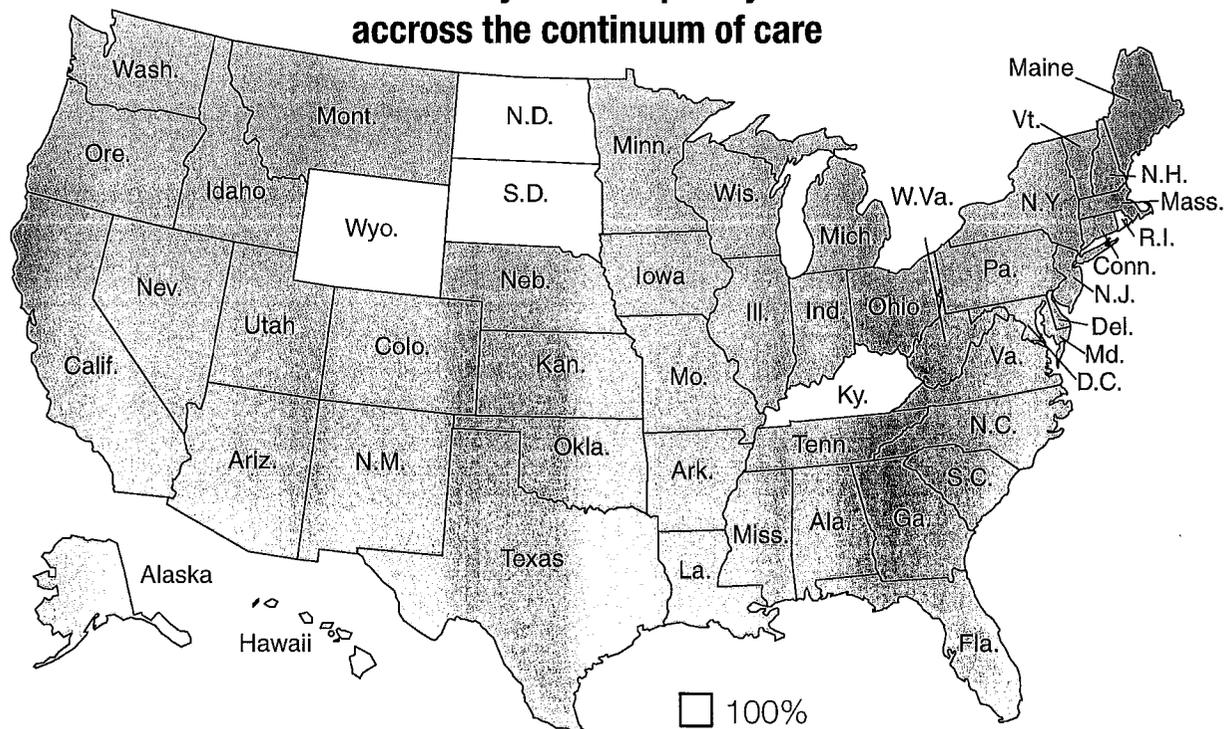
In many cases, respondents said their hospital's policies failed to catch a duplication of medication or missing doses, the survey found. In other instances, medications were omitted or there was no follow-up. And several respondents blamed their hospital's shoddy medication reconciliation policy on inadequate staffing.

Medication reconciliation "was done late in the evening when staffing was less than earlier in the day," one pharmacist wrote. "Patients being admitted during shift changes resulted in late med reconciliation, or it not being done at all." Another health-system R.Ph simply stated, "Took too long to reconcile home meds."

Drug Topics conducted the nationwide survey of hospital pharmacists from Sept. 27 through Oct. 10. The survey was sent to 12,105 subscribers of the magazine; 640 pharmacists responded.

Seven percent of those who responded said the Joint Commission found fault with the way their hos-

National Patient Safety Goal 8: Accurately and completely reconcile medications across the continuum of care



Source: The Joint Commission

Medication reconciliation process at hospitals suffered relapse in 2006

The nation's hospitals did a poor job last year of reconciling patients' medications. And the problem seems to have gotten worse.

A new report from the Joint Commission concluded that only two-thirds of American hospitals reconciled medications, down from 99.9% in 2005. There was a similar drop in reconciling medications across the continuum of care, including at discharge: 72.5% of the nation's hospitals consistently did so last year, a drop of 27.2% from 2005, according to the report, *Improving America's Hospitals: The Joint Commission's Annual Report on Quality and Safety 2007*.

"This is a test of hospital competency in redesigning care processes," said Joint Commission president Dennis O'Leary. "It's seemingly simple to get the list of medications from where the patient was to where the patient is going. But in fact it is a terrible challenge."

Medication reconciliation proved to be one of the biggest challenges for hospitals last year, the report stated. The commission identified nine issues that were most difficult for hospitals to meet, and medication reconciliation was the second-most problematic, recording a 54% compliance rate. Only one issue proved to be more difficult for hospitals to meet than medication reconciliation: improving the effectiveness of communication among caregivers. That issue had a 42% compliance rate, the report found.

Other difficult issues for hospitals last year included the proper and safe storage of medications, ensuring that medication orders are written clearly and transcribed accurately, proper pain assessment, improving medication safety, managing safety risks, and keeping a "complete and accurate" medical record of all patients served.

pitals handled medication reconciliation, the process by which healthcare practitioners obtain and document a complete list of a patient's current medications upon admission to a hospital or healthcare facility. A complete list of the patient's medications should ideally be given to the next healthcare provider upon discharge or transfer to another facility.

The Joint Commission has included medication reconciliation on its list of National Patient Safety Goals for the past several years. The process also is endorsed by the Institute for Healthcare Improvement.

When asked if the Joint Commission found fault with their hospital's medication reconciliation policy, and, if yes, how, many pharmacists responded with a simple "not being done." Others said additional steps were needed in outpatient areas, while some said their program was not far enough along.

"Our policy didn't include reconciling home meds upon admission with home meds to be taken after discharge," one pharmacist explained. "It does now, but remains the problem area."

Another R.Ph. griped that there is "inconsistent following of the (medication reconciliation) policy" at his institution. "Some providers are very good, some not."

Still others said the Joint Commission faulted their policies because they were not uniformly followed throughout the hospital, or because physicians were not active enough in the process.

Seventy percent of respondents said their hospitals allow patients to bring in their own medications. Among those pharmacists, 53% noted they have run into problems identifying patients' medications.

When asked for suggestions to improve the patient handoff process at their hospitals, respondents proposed a better communication process, more accurate drug information, and increased involvement from pharmacists.

"Better communication [is required] with the patient to verify that he understands the medication changes that have been made," wrote one pharmacist. Other respondents challenged doctors, nurses, and pharmacists to be more communicative with one another, while some felt there should be more interaction during shift changes and at patient transfers. One pharmacist even placed the responsibility of improving the process on the patient, calling for "a better understanding for patients as to what they are expected to provide to caregivers." **DT**



Adverse Drug Events Spike

Reported fatal adverse drug events increased 2.7-fold from 1998 through 2005 to more than 15,000, and serious, non-fatal drug events jumped to nearly 90,000, researchers have found. The reason for the increases "is not completely known," said the Food and Drug Administration (FDA).

"Reported serious events increased four times faster than the total number of outpatient prescriptions during the period," said researchers writing in the Sept. 10 issue of *Archives of Internal Medicine*. "In a subset of drugs with 500 or more cases reported in any year, drugs related to safety withdrawals accounted for 26 percent of reported events in that group in 1999, declining to less than 1 percent in 2005."

Authors Thomas J. Moore, AB, and Michael R. Cohen, RPh, MS, ScD, of the Institute for Safe Medication Practices; and Curt D. Furberg, MD, PhD, of the Wake Forest University School of Medicine, analyzed 467,809 voluntary reports submitted directly to the FDA or through drug manufacturers to the Adverse Event Reporting System.

They found that fatal adverse events nearly tripled from 5,519 in 1998 to 15,107 in 2005 and serious, non-fatal events increased 2.6-fold—from 34,966 to 89,842.

"The increase was influenced by relatively few drugs: 298 of the 1,489 drugs identified (20 per-

cent) accounted for 407,394 of the 467,809 events (87 percent), the authors said.

The FDA said in a statement that it was aware of the growing number of reported problems and takes them seriously, but the reason for the increase "is not completely known."

"While some of this has to

do with the increasing number of prescriptions, there are clearly other factors responsible for this increase, such as the increase in public attention to drug safety, and use of the Internet to make it easier for the public to submit [reports]," Gerald Dal Pan of the FDA's surveillance and epidemiology office said in the statement.

Top 5 Drugs Linked to Fatalities or Serious Adverse Events 1998-2005

DRUG	FATALITIES
Oxycodone	5,548
Fentanyl	3,545
Clozapine	3,277
Morphine	1,616
Acetaminophen	1,393

DRUG	SERIOUS, NON-FATAL
Estrogens	11,514
Insulin	9,597
Infliximab	8,754
Interferon beta	8,320
Paroxetine	8,095

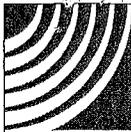
Source: *Archives of Internal Medicine*

Medicare Surety Bond Proposal Challenged

NCPA is strongly objecting to a proposal that would require independent pharmacies to purchase \$65,000 surety bonds to continue providing durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) to Medicare patients. The Centers for Medicare & Medicaid Services (CMS), which is proposing

the requirement, estimates that such bonds would cost \$2,000 each.

NCPA is pointing out to CMS and lawmakers on Capitol Hill that practicing pharmacists already are licensed and regulated by the states, so a surety bond is an unnecessary and burdensome requirement.



Zoledronic Acid Decreases Rate of Repeat Hip Fractures and Mortality

An annual infusion of zoledronic acid within 90 days after repair of a low-trauma hip fracture was associated with a reduction in the rate of new clinical fractures and improved survival. This conclusion was published in a study in *The New England Journal of Medicine* (published online before print, September 17, 2007).

Researchers found a 35% reduction in new clinical fractures and a 28% reduction in death from any cause compared with placebo. An editorial accompanying the study said, "No other controlled clinical trial has previously shown efficacy of any osteoporosis medication for reducing the recurrence of fracture in patients who already had broken a hip."

In a randomized, double-blind, placebo-controlled trial, 1,065 patients were assigned to receive yearly intravenous zoledronic acid (at a dose of 5 mg), and 1,062 patients were assigned to receive placebo. The infusions were first administered within 90 days after surgical repair of a hip fracture. All patients (mean age, 74.5 years) received supplemental vitamin D and calcium. The median follow-up was 1.9 years. The primary end point was a new clinical fracture.

Only 42% had osteoporosis that was diagnosed on the basis of measurement of bone mineral density by dual-energy x-ray absorptiometry (DXA) at the time of the fracture, which may reflect the insensitivity and inadequacy of DXA as a screening tool for identifying patients at risk for hip fracture, the authors report.

The rates of any new clinical fracture were 8.6% in the zoledronic acid group and 13.9% in the placebo group, a 35% risk reduction with zoledronic acid ($P = 0.001$); the respective rates of a new clinical vertebral fracture were 1.7% and 3.8% ($P = 0.02$), and the respective rates of new nonvertebral fractures were 7.6% and 10.7% ($P = 0.03$). In the safety analysis, 101 of 1,054 patients in the zoledronic acid group (9.6%) and 141 of 1,057 patients in the placebo group (13.3%) died, a reduction of 28% in deaths from any cause in the zoledronic acid group ($P = 0.01$). The most frequent adverse events in patients receiving zoledronic acid were pyrexia, myalgia, and bone and musculoskeletal pain. The rates of renal and cardiovascular adverse events, including atrial fibrillation and stroke, were similar in the two groups.

Researchers noted that patients in this trial could not tolerate or would not take an oral bisphosphonate, and a previous risedronate trial was not successful in reducing hip fracture in patients older than age 80.

The editorial also notes that the results "appear both powerful and compelling. The reduction in fracture incidence and death was striking and clearly establishes the need for pharmacologic intervention in patients who fracture a hip."

Adverse Drug Events Reported to FDA Increased

The number of serious adverse drug events (ADEs) reported to the Food and Drug Administration (FDA) more than doubled between 1998 and 2005, as did associated deaths, according to a report in the *Archives of Internal Medicine* (Arch Intern Med 2007; 167:1752-9).

FDA defined a serious ADE as one that resulted in death, a birth defect, disability, or hospitalization; was life-threatening; or required intervention to prevent harm. These events are voluntarily reported to FDA through its Adverse Event Reporting System (AERS), also known as "MedWatch." The reports come to FDA directly or through drug manufacturers, which are required to forward them to the agency, the study said.

Researchers from the Institute for Safe Medication Practices analyzed serious ADEs reported to FDA through AERS. The annual number of reports from 1998 through 2005 increased 2.6-fold during that period, from 34,966 to 89,842; a total of 467,809 serious ADEs were reported during that time. The number of fatal ADEs increased from 5,519 to 15,107 in the same time frame, a 2.7-fold increase.

"The overall relative increase was four times faster than the growth in total U. S. outpatient prescriptions, which grew in the same period from 2.7 billion to 3.8 billion," the authors said.

A total of 1,489 drugs were associated with ADEs, but a subset of 51 drugs, each of which having 500 or more reports in any year, accounted for 203,957, or 43.6% of the total ADEs reported in the study.

"Contrary to our expectations, drugs related to safety withdrawals were a modest share of all reported events

and declined in importance over time," the authors write. In the subset of 51 drugs with 500 or more reports in a year, the percentage of reported events associated with drugs related to safety withdrawals declined from 26% in 1999 to less than 1% in 2005.

In addition, "Among the most frequently reported drugs associated with fatal events, we observed a disproportionate contribution of pain medications and drugs that modify the immune system," researchers noted.

"The results highlight the importance of this public health problem and illustrate the need for improved systems to manage the risks of prescription drugs," the authors said.

Use of Alternative Plus Conventional Medications May Put Elderly at Risk

Concurrent use of complementary/alternative medicines (CAM) and conventional medications is common in the Medicare population, yet little is known about potential interactions, according to a study published in the *Annals of Pharmacotherapy* (Ann Pharmacother 2007;41:1617-24). The study is considered to be the first population-based analysis of the prevalence of concurrent CAM products.

The elderly are of special concern, the authors note, because polypharmacy is well documented, sensitivity to some medications is greater, and the organs that process many drugs become less functional as people age. "These factors raise the likelihood that potentially toxic drug combinations will occur," the article says. In addition, about half of herbal product users do not discuss their use with a health care professional, creating a theoretically significant risk for adverse CMA product-drug interactions.

The authors performed a retrospective analysis on data from the Cardiovascular Health Study for four years: 1994, 1995, 1997, and 1999. Of 5,052 participants, the median age was 75, 60.2% were female, 16.6% were African-American, and 83.4% were white. The percent using CAM products during the four time periods was 6.3%, 6.7%, 12.8%, and 15.1%. The percent using both CAM products and conventional drugs was 6.0%, 6.2%, 11.7%, and 14.4%. Of these, 294 (5.8%) individuals took combi-

nations considered to have a significant risk for an adverse interaction. Combinations with risk were observed on 393 separate interviews.

Garlic, ginkgo, and ginseng are the top three CAM products used in this population. Most of these interactions (379) involved a risk of bleeding as a result of the use of ginkgo, garlic, or ginseng together with aspirin, warfarin, ticlopidine, or pentoxifylline. An additional 786 observations of combinations were considered to have some potential risk for an adverse interaction.

The authors noted that although participants presented all CAM products and conventional medications taken the previous two weeks to a study team member, other desirable information was limited. Researchers did not know the doses taken, the prevalence of use during the evaluation period, or whether the CAM and conventional medications were taken simultaneously each day.

The authors encourage further research to define the risks of combining these medications and the risk on the elderly population.

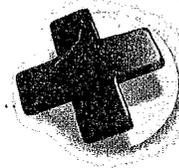
Being Overweight Does Not Cause Memory Problems

While obesity has been shown to contribute to high blood pressure, heart disease, and diabetes, being overweight in old age does not lead to memory problems, according to a study published in *Neurology* (published online before print September 19, 2007).

The study, conducted from 1993 to 2003, involved 3,885 community-dwelling people living in Chicago older than age 65. Of the participants, almost 25% were obese, with a body-mass index (BMI) more than 30, and 37% were overweight, with a BMI between 25 and 29.9. There was an average follow-up of 6.4 years.

Four cognitive tests were given at the beginning of the study and every three years over the six-year period. The study found no significant changes in memory or cognitive function throughout the study for overweight or obese participants. In fact, participants who were underweight had more cognitive decline over time.

"We do not know yet why being overweight or obese does not increase the risk for cognitive decline



Same Name Not Always Same Drug in Other Countries

The Institute for Safe Medication Practices has received a number of reports involving brand name medications that may contain different active ingredients in another country. In one report, a patient was prescribed Dilacor XR (diltiazem extended release) 120 mg daily for hypertension. While traveling to Serbia, he ran out of medication. A Serbian pharmacist filled the prescription, but he actually dispensed digoxin 0.25 mg because, in Serbia, Dilacor is a brand name for digoxin. The patient did not notice the change in tablet strength, so he continued to take the medication for three days upon return to the United States. However, he took extra doses each day (2–3 tablets) because he felt his blood pressure medication was not working. By the third day, the patient experienced signs of digoxin toxicity including nausea, vomiting, headaches, and chest pain worsened by exertion. He went to an emergency department and was admitted for monitoring and treatment with Digibind (digoxin immune FAB).

In another case, a hospitalized patient developed gastrointestinal (GI) bleeding and the medical team was trying to determine the cause. A pharmacy student on the team was asked to find out what "Cartia" was, since the patient had apparently been taking that medication prior to admission. The student found that several Web sites, as well as Micromedex, described Cartia as a 100 mg enteric-coated tablet of aspirin. When the student reported this information to the team, a decision was made to discontinue the drug as aspirin can cause GI bleeding. Fortunately, a medication error was averted when it was discovered that the patient was actually taking Cartia XT (diltiazem in the United States), which is bioequivalent to Cardizem CD, to treat hyperten-

sion and angina. Cartia is a trademark for enteric-coated aspirin in New Zealand and Australia. However, this product can be purchased over the Internet in the United States, and both products could be considered "heart" medications, increasing the risk of error. If a patient taking Cartia XT searches the Web and finds that "Cartia" is available without a prescription and inexpensive (one site advertised 28 tablets for \$1.94 in U.S. dollars), a medication error could occur. Confusion could also exist among physicians trained outside the United States or patients who travel between the United States and New Zealand or Australia.

Finally, the trademark Entex LA is used for two different products in the United States and Canada. In the United States, Andrx Pharmaceuticals markets a capsule formulation of Entex LA that contains phenylephrine hydrochloride (30 mg extended-release) and guaifenesin (400 mg immediate-release). In Canada, Purdue Pharma Canada supplies Entex LA as a tablet that contains pseudoephedrine (120 mg) and guaifenesin (600 mg). Compounding the confusion, the indicated adult dose for each product is one tablet every 12 hours.

ISMP recommendations being cautious of drug information only obtained from the Internet. Always question patients on the reason they are taking their medications so as not to rely solely on drug references. Remind patients when they travel to carry an adequate supply of medications and a list by generic and brand name. Those needing a temporary supply while overseas should confirm that the correct drug has been dispensed. *ap*

This article has been provided by the Institute for Safe Medication Practices (ISMP). The reports described in this column were received through the USP-ISMP Medication Errors Reporting Program (MERP). Errors, near misses, or hazardous conditions may be reported on the ISMP (www.ismp.org) or U.S. Pharmacopeia (www.usp.org) Web sites. ISMP can be reached at 215-947-7797 or isminfo@ismp.org.

**Kaiser Daily Health Policy Report****Monday, November 05, 2007****Prescription Drugs****Fewer U.S. Residents Purchase Prescription Drugs From Canada, In Part Because of Medicare Drug Benefit**

Online drug sales in 2006 from Canadian pharmacies to U.S. consumers dropped about 50%, from \$420 million Canadian dollars in 2005 to \$211 million Canadian dollars last year, according to data from IMS Health, the *Philadelphia Inquirer* reports. Drug sales across the border to U.S. patients -- once "a hot trend" -- have been suppressed by several factors, including threats from U.S. pharmaceutical companies to stop supplying drugs to Canadian firms, rising drug costs in Canada, a weaker U.S. dollar compared with the Canadian dollar and the 2006 introduction of the Medicare prescription drug benefit, the *Inquirer* reports.

Legislation (S 1082) introduced this year by Sens. Olympia Snowe (R-Maine) and Byron Dorgan (D-N.D.) would reduce restrictions on imports and enhance safety by calling for all exporters and importers to register with federal authorities. The Pharmaceutical Research and Manufacturers of America opposes prescription drug imports, citing the possibilities that counterfeiting could rise and existing safety regulations could be compromised. FDA has "conducted periodic sweeps against drugs delivered through the mail," but "its leaders admit they lack the staff to do a thorough job," the *Inquirer* reports.

Ilisa Bernstein, FDA's director of pharmacy affairs, said the agency does not know for certain whether online sales are increasing or decreasing. She said, "We really don't have the resources to quantify the number of products coming in," adding that FDA uses a "risk-based approach" to select the drugs that pose a high level of danger and need closer safety scrutiny. Bernstein said, "What's scary is, a lot of these online sellers will sell you drugs without a prescription."

Randall Lutter, FDA's deputy commissioner for policy, in a statement said, "The data lead us to believe that many people are buying drugs online not to save money but to bypass the need for a prescription from their doctor, since these Web sites typically do not require the purchaser to have a prescription" (Stark, *Philadelphia Inquirer*, 11/5).

November 3, 2007

Maker of Lipitor Digs In to Fight Generic Rival

By STEPHANIE SAUL and ALEX BERENSON

It is shaping up to be the biggest shift yet to a generic drug, potentially saving the nation \$2 billion a year or more in prescription costs.

And scientists and doctors say that for most of the 16 million people in America who take drugs to reduce cholesterol, the low-priced alternative will work as well as the name-brand medicine — Lipitor, which is made by Pfizer and is the nation's most widely prescribed drug.

While Lipitor itself is not available as a generic, a very similar drug made by Merck, Zocor, lost its patent protection last year. The generic version of Zocor, simvastatin, is now much cheaper than Lipitor, leading insurers to press doctors and patients to switch.

But Pfizer is not letting its flagship drug go down without a fight.

The company has mounted a campaign that includes advertisements, lobbying efforts and a paid speaking tour by a former secretary of the federal Department of Health and Human Services. Pfizer is also promoting a study — whose findings many experts are questioning — that concluded that British patients who switched to simvastatin had more heart attacks and deaths than those who remained on Lipitor.

The Lipitor battle has become a test of the pharmaceutical industry's ability to defend name brands, even as insurers, patients and doctors seek to whittle the nation's \$270 billion annual prescription drug bill by using generic alternatives whenever possible.

Lipitor and other cholesterol-lowering drugs, sometimes called statins, are the largest drug class, with spending of \$22 billion last year in the United States alone. And they have been researched more thoroughly than any other group of drugs, making head-to-head comparisons easier.

Many doctors have come to see simvastatin as a viable substitute for Lipitor. Studies show that at commonly prescribed doses Lipitor and simvastatin are equally effective at reducing LDL cholesterol, the so-called bad cholesterol.

A big difference is that Lipitor costs \$2.50 to \$3 a day, while simvastatin sells for 75 cents to \$1 a day at most retail pharmacies, and as little as 10 cents a day at discount pharmacies like Costco's.

Each month, doctors with patients on Lipitor are switching tens of thousands of them to simvastatin. And

simvastatin is also taking a growing share of the market for new patients who need a cholesterol drug. "Simvastatin is much less expensive to society over all and to patients," said Dr. Thomas H. Lee Jr., a prominent cardiologist. "If you put patients on generics," he said, "the chances that they're taking their medications six months later are higher than on a brand name drug. I think that a few hundred dollars a year does matter."

But Pfizer argues that Lipitor is the most effective statin and that patients who are having good results with it are not well-served by moving to another drug.

"The only reason one would want to switch from one drug to another is for the benefit of the patient's health," said Dr. Michael Berelowitz, senior vice president for worldwide medical affairs for Pfizer.

In September Pfizer began sounding safety alarms by citing an analysis of the medical histories of 2,500 people in Britain who switched to simvastatin from Lipitor, compared with 9,000 who did not make the change. The study concluded that patients who switched were more likely to have a heart attack or stroke than those who remained on Lipitor.

The results were presented on a poster at a European cardiology conference. And Dr. Berelowitz said the study had been accepted by the British Journal of Cardiology and would soon be published.

But independent researchers say that limitations in the study, which was conducted by Pfizer's own researchers, gives it little predictive power about what will happen to patients who take simvastatin instead of Lipitor. And they say the study is far less important than large clinical trials that have shown simvastatin's effectiveness at reducing cholesterol.

"It will run counter to everything that's been published to date if it's true," Dr. Lee said of the Pfizer study. He is president of the network of about 5,000 doctors in Partners HealthCare, the health system formed by Massachusetts General Hospital and Brigham and Women's Hospital in Boston.

Dr. Mark Fendrick, a professor of internal medicine at the University of Michigan and a specialist in health care economics, notes that for patients with extremely high cholesterol, Lipitor may be a better choice. An 80-milligram daily dose of Lipitor, the top dose, can reduce cholesterol by up to 60 percent, compared with about 50 percent for an 80-milligram dose of simvastatin, also the top dose.

But most patients with moderately high cholesterol take 10 or 20 milligrams of Lipitor a day, and can get comparable benefit from 40 or 80 milligrams of simvastatin, Dr. Fendrick said.

Dr. Robert O. Bonow, the chief of cardiology at Northwestern Memorial Hospital in Chicago and a past president of the American Heart Association, said patients' cholesterol levels should be monitored after the change, to make sure the simvastatin is having the desired effect.

"Switching itself is not a problem," Dr. Bonow said. "It's not that one drug has more risk or less risk."

Lipitor's share of the cholesterol-lowering drug market in this country has ebbed to 30 percent, down from 40 percent 18 months ago, when simvastatin was available only as name-brand Zocor — at prices that were higher than Lipitor's.

No generic version of Lipitor is in the offing because the Lipitor patent remains valid until at least March 2010. But the advent of generic Zocor has dented sales enough to hurt Pfizer's stock, which is trading near its lowest level in a decade.

In a recent conference call with Wall Street analysts, Pfizer vowed to step up its efforts to protect Lipitor. So far this year, the company has been spending more than 50 percent more on advertising the drug than it did in 2006, when its Lipitor ad spending for the year totaled \$142.7 million.

Lately, Pfizer has been running a print and broadcast advertising campaign that features Dr. Robert Jarvik, the inventor of the artificial heart, endorsing Lipitor.

"There's a common misconception that all cholesterol-lowering medications are the same," Dr. Jarvik says in a radio ad. "They're not. There is no generic version of Lipitor."

Despite Pfizer's efforts, analysts and physicians say they see little chance of the company's stemming the generic tide. After two decades of prescribing cholesterol-lowering drugs, doctors are comfortable with both Lipitor and simvastatin, said Dr. Jon LeCroy, who is an industry analyst at Natixis Bleichroeder and a physician.

Insurers and pharmacy benefits companies are spurring patients to switch mainly by raising their out-of-pocket co-payments if they choose Lipitor, while lowering them for generic drugs. On Oct. 1, for example, Blue Cross and Blue Shield of Illinois raised the average co-payment for Lipitor by \$10 to \$20 a month, said Bridget Houlihan, a Blue Cross spokeswoman.

This year, Blue Care Network, a health maintenance organization affiliated with Blue Cross and Blue Shield of Michigan, offered to pay \$100 to physicians for each patient who filled a prescription for a generic statin.

Pfizer is sponsoring a speaking tour by Dr. Louis W. Sullivan, a former secretary of Health and Human Services, who without citing Lipitor specifically is arguing against insurers' efforts to influence medical decisions.

The company has also been fighting the generics trend in the political arena. In a Sept. 10 letter to state lawmakers in Ohio, a Pfizer lobbyist cited the potential risks of switching to cheaper medicines.

That letter, from Linda Martens, Pfizer's assistant director of government relations in Ohio, noted the company's British study, saying it showed a 30 percent increase in cardiac risks "in patients who were switched from the leading cholesterol-lowering medicine, Lipitor, to another statin drug, simvastatin."

Independent researchers, however, say that the British study is of little value in comparing the two drugs, because it was not based on a clinical trial in which the two drugs were given to two randomly assigned groups of patients.

Instead, the Pfizer researchers simply compared the case histories of patients who had been switched with those who had not, regardless of the reasons they were taken off Lipitor. The results of the study are contradicted by a 9,000-patient clinical trial published in 2005, which found no statistically significant difference between Lipitor and Zocor.

Even a Pfizer doctor involved in the British study, Dr. Berkeley Phillips, said in an interview with the online publication [WebMD](#) that it did not prove that Lipitor worked better than simvastatin. "We can't say from this study that switching is bad or that one statin is better than another," Dr. Phillips said. "You would need a randomized clinical trial to say that."

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October 23, 2007

Sleep Drugs Found Only Mildly Effective, but Wildly Popular

By STEPHANIE SAUL

Your dreams miss you.

Or so says a television commercial for Rozerem, the sleeping pill. In the commercial, the dreams involve Abraham Lincoln, a beaver and a deep-sea diver.

Not the stuff most dreams are made of. But if the unusual pitch makes you want to try Rozerem, consider that it costs about \$3.50 a pill; gets you to sleep 7 to 16 minutes faster than a placebo, or fake pill; and increases total sleep time 11 to 19 minutes, according to an analysis last year.

If those numbers send you out to buy another brand, consider this, as well: Sleeping pills in general do not greatly improve sleep for the average person.

American consumers spend \$4.5 billion a year for sleep medications. Their popularity may lie in a mystery that confounds researchers. Many people who take them think they work far better than laboratory measurements show they do.

An analysis of sleeping pill studies found that when people were monitored in the lab, newer drugs like Ambien, Lunesta and Sonata worked better than fake pills. But the results were not overwhelming, said the analysis, which was published this year and financed by the National Institutes of Health.

The analysis said that viewed as a group, the pills reduced the average time to go to sleep 12.8 minutes compared with fake pills, and increased total sleep time 11.4 minutes. The drug makers point to individual studies with better results.

Subjects who took older drugs like Halcion and Restoril fell asleep 10 minutes faster and slept 32 minutes longer than the placebo group. Paradoxically, when subjects were asked how well they slept, they reported better results, 52 extra minutes of sleep with the older drugs and 32 minutes with the newer drugs.

“People seem to be getting a lot of relief from sleeping pills, but does getting 25 minutes of sleep really give you all that relief?” asked Dr. Wallace B. Mendelson, the former director of a sleep disorders unit at the University of Chicago. “A bigger aspect of this is that they change a person’s perception of their state of consciousness.”

Dr. Mendelson is semiretired and is a consultant for pharmaceutical companies.

Dr. Karl Doghramji, a sleep expert at Thomas Jefferson University in Philadelphia, agreed. “Sleeping pills do not increase sleep time dramatically, nor do they decrease wake time dramatically,” he said. “Despite those facts, we do find patients who, when they take them, have a high level of satisfaction.” Dr. Doghramji has disclosed in the past that he is a consultant to pharmaceutical companies.

Most sleeping pills work on the same brain receptors as drugs to treat anxiety. By reducing anxiety, the pills may make people worry less about not going to sleep. So they feel better.

Another theory about the discrepancy between measured sleep and perceived sleep involves

a condition called anterograde amnesia. While under the influence of most sleep medications, people have trouble forming memories. When they wake up, they may simply forget they had trouble sleeping.

“If you forget how long you lay in bed tossing and turning, in some ways that’s just as good as sleeping,” said Dr. Gary S. Richardson, a sleep disorders specialist at Henry Ford Hospital in Detroit who is a consultant and speaker for pharmaceutical companies and has conducted industry-sponsored research.

Sleep, after all, causes a natural state similar to amnesia, one reason toddlers often forget their violent nightmares by the next morning. If you stay in bed, as most people taking sleeping pills do, amnesia is not a bad thing.

Even some people who sleepwalked while taking Ambien, which was implicated in cases of odd, sometimes dangerous behavior while sleeping, believed they were having a good night’s sleep. Rosemary Eckley, a graphic artist in New London, Wis., said she thought she was sleeping well on Ambien but woke to find her wrist broken, apparently in a fall while sleepwalking, she wrote in an e-mail exchange.

Reports of sleep-eating and sleep-driving on Ambien are reminiscent of problems nearly 20 years ago with Halcion. Some people who took that drug to sleep on airplanes developed a condition known as traveler’s amnesia. They landed at their destinations, then got lost or forgot where they were, prompting the authorities in several countries to withdraw Halcion from the market.

Reports show that Ambien and similar drugs, advertised as safer than benzodiazepines like Halcion, can cause similar problems. The reports prompted the Food and Drug Administration to ask manufacturers to develop warning guides for distribution with virtually all sleep drugs. Despite such problems, most specialists say sleeping pills are generally safe. Dr. Mark W. Mahowald, director of the Minnesota Regional Sleep Disorders Center, which is involved in documenting cases of sleep-eating under the influence of Ambien, said serious side effects were rare and should not discourage the use of the pills.

The class of drugs known as nonbenzodiazepines, sometimes called “Z” drugs, includes Ambien, Lunesta and Sonata. Ambien and its generic equivalent, zolpidem, are the most widely used, together accounting for 40 percent of the market.

Newer drugs like Lunesta and Ambien CR, a controlled-release formula, cost about \$4 a pill. Zolpidem recently sold for \$2 a pill on [walgreens.com](http://www.walgreens.com).

Of the three drugs in the class, Sonata, which also retails for about \$3.50 a pill, remains in the body the shortest time and, therefore, is normally used by people who have trouble falling asleep but no problem staying asleep. The advocacy organization Public Citizen's Health Research Group says its benefits are so minimal it should not be used.

King Pharmaceuticals, the maker of Sonata, did not respond to several messages seeking comment.

A study by an [Oregon State University](http://www.oregonstate.edu) group that reviews the safety and effectiveness of drugs found that Lunesta offered little benefit over generic Ambien or older benzodiazepines, but cost more. Jonae Barnes, a spokeswoman for Lunesta's maker, Sepracor, said the company strongly disagreed and added that the Oregon group did not adequately consider waking time after falling asleep, an area in which Lunesta performed better.

Users also sometimes report that Lunesta leaves a bad taste in their mouths, according to studies of the drug.

Dr. Mahowald said the older drugs, including Halcion, also known as triazolam, offered better value than the newer ones.

"We tend to use the old benzodiazepines," he said of his practice. "They appear to be as effective as some of the newer ones, and they're infinitely less expensive." Dr. Mahowald said that his center participated in industry-sponsored clinical research, but that he did not personally work as a consultant or adviser to pharmaceutical companies.

Such drugs, which include flurazepam, brand name Dalmane, and temazepam, Restoril, sell in generic versions for 30 to 50 cents each.

Another inexpensive alternative, and one of the most widely used sleep medications in this country, is the antidepressant trazodone. It works well in many patients, but some people say it leaves them groggy the next day, according to Dr. Daniel Carlat, a psychiatrist in Newburyport, Mass., who publishes *The Carlat Psychiatry Report* and declines industry financing. In men, trazodone has been linked to rare cases of priapism, prolonged and

painful erections.

Some patients who fear using sleeping pills turn to over-the-counter remedies like Tylenol PM and Advil PM. Those contain the painkillers acetaminophen and ibuprofen combined with an antihistamine, diphenhydramine, the ingredient in the allergy medication Benadryl.

Antihistamines are known to make people sleepy, but there is little evidence that they improve sleep. They can also cause next-day sedation that impairs driving, as well as racing heartbeat and constipation. The Medical Letter, which reviews drugs, recommends against using antihistamines for sleep. Some doctors say users of Tylenol PM may be taking acetaminophen they do not need. Acetaminophen overdoses can cause liver failure.

Rozerem, with its unusual advertising campaign, has at least one benefit over other medications. Because it works by a different mechanism from the others, it is not a controlled substance and apparently does not affect the ability to form memories. It may be the sleeping pill of choice for elderly people who have trouble falling asleep, but suffer memory problems.

Still, researchers and drug companies have yet to find a holy grail. "The problem is, there is no ideal hypnotic," said Dr. Manisha Witmans, a sleep medicine specialist at the University of Alberta's Evidence-Based Practice Center. "The magic pill for sleep has not been invented yet."

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REPORT BRIEF • SEPTEMBER 2006

THE FUTURE OF DRUG SAFETY: ACTION STEPS FOR CONGRESS

The Institute of Medicine's Committee on the Assessment of the U.S. Drug Safety System intends that the 25 recommendations in its report will bring the strengths of the preapproval process (data, regulatory authority, organizational function and capabilities, and resources) to the postapproval phase in order to fulfill a lifecycle approach to the study, regulation, and communication about the risks and benefits of drugs.

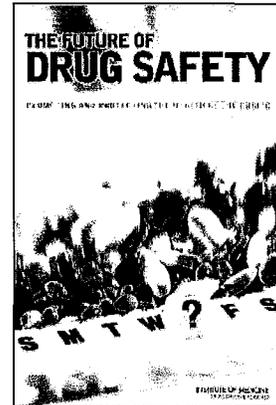
CLARIFY FDA'S REGULATORY AUTHORITY

The Food and Drug Administration's authorities must be clarified and strengthened to empower the agency to take rapid and decisive actions when necessary and appropriate. FDA lacks the clear, unambiguous authority needed to enforce sponsor compliance with regulatory requirements and instead relies on the prospect of productive negotiations with industry.

5.1 The committee recommends that Congress ensure that FDA has the ability to require such postmarketing risk assessment and risk management programs as are needed to monitor and ensure safe use of drug products. These conditions may be imposed both before and after approval of a new drug, new indication, or new dosage, as well as after identification of new contraindications or patterns of adverse events. The limitations imposed should match the specific safety concerns and benefits presented by the drug product. The risk assessment and risk management program may include:

- a) Distribution conditioned on compliance with agency-initiated changes in drug labels.
- b) Distribution conditioned on specific warnings to be incorporated into all promotional materials (including broadcast DTC advertising).
- c) Distribution conditioned on a moratorium on direct to consumer advertising.
- d) Distribution restricted to certain facilities, pharmacists, or physicians with special training or experience.
- e) Distribution conditioned on the performance of specified medical procedures.
- f) Distribution conditioned on the performance of specified additional clinical trials or other studies.
- g) Distribution conditioned on the maintenance of an active adverse event surveillance system.

5.2 The committee recommends that Congress provide oversight and enact any needed legislation to ensure compliance by both FDA and drug sponsors with the provisions listed above. FDA needs increased enforcement authority and better enforcement tools directed at drug sponsors, which should include fines, injunctions, and withdrawal of drug approval.



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REQUIRE SYMBOL TO ALERT CONSUMERS TO NEW PRODUCTS AND DENOTE HEIGHTENED REGULATORY ATTENTION

Marking the label and all promotional material for newly approved drugs or indications with a special symbol will help increase awareness of the nature of newly approved therapies (for example, the incompleteness of information on safety).

- 5.3 The committee recommends that Congress amend the Federal Food, Drug and Cosmetic Act to require that product labels carry a special symbol such as the black triangle used in the UK or an equivalent symbol for new drugs, new combinations of active substances, and new systems of delivery of existing drugs. FDA should restrict direct-to-consumer advertising during the period of time the special symbol is in effect. The symbol should remain on the drug label and related materials for 2 years unless FDA chooses to shorten or extend the period on a case by case basis.

ESTABLISH PERFORMANCE GOALS FOR SAFETY

The Prescription Drug User Fee Act mechanism that accounts for over half of the Center for Drug Evaluation and Research's funding and the reporting requirements associated with the user-fee program are excessively oriented toward supporting speed of approval and insufficiently attentive to safety.

- 3.5 To restore appropriate balance between the FDA's dual goals of speeding access to innovative drugs and ensuring drug safety over the product's lifecycle, the committee recommends that Congress should introduce specific safety-related performance goals in the Prescription Drug User Fee Act IV in 2007.

HOLD INDUSTRY AND RESEARCHERS ACCOUNTABLE FOR MAKING DRUG SAFETY STUDY RESULTS PUBLIC

The committee believes strongly in the importance of increasing the availability of information to the public and to researchers about risks and benefits, whether specific study results or CDER staff analyses of concerns. The National Library of Medicine hosts a website for registration of clinical trials, but with few exceptions, this is voluntary and does not include a summary of results.

- 4.11 To ensure that trial registration is mandatory, systematic, standardized, and complete, and that the registration site is able to accommodate the reporting of trial results, the committee recommends that Congress require industry sponsors to register in a timely manner at clinicaltrials.gov, at a minimum, all Phase 2 through 4 clinical trials, wherever they may have been conducted, if data from the trials are intended to be submitted to the FDA as part of a new drug application, supplemental new drug application, or to fulfill a post market commitment. The committee further recommends that this requirement include the posting of a structured field summary of the efficacy and safety results of the studies.

APPROPRIATE ADEQUATE RESOURCES FOR DRUG SAFETY

An agency whose crucial mission is to protect and advance the public's health should have adequate resources to do its job. Also, the effect on CDER's work of CDER's overdependence on PDUFA funding with restrictions on how FDA can use the money from user fees hurts FDA's credibility and may affect the agency's effectiveness.

- 7.1 To support improvements in drug safety and efficacy activities over a product's lifecycle,

the committee recommends that the Administration should request and Congress should approve substantially increased resources in both funds and personnel for FDA. The committee favors appropriations from general revenues, rather than user fees, to support the full spectrum of new drug safety responsibilities proposed in this report.

STABILIZE THE LEADERSHIP OF FDA

Instability in the Office of the Commissioner has been a serious problem for FDA and CDER in particular. A large, complex, science-based regulatory agency cannot perform optimally in the absence of stable, capable leadership, and clear, consistent direction.

- 3.1 The committee recommends that the Federal Food, Drug, and Cosmetic Act be amended to require that the FDA Commissioner currently appointed by the President with the advice and consent of the Senate also be appointed for a 6-year term of office. The Commissioner should be an individual with appropriate expertise to head a science-based agency, demonstrated capacity to lead and inspire, and a proven commitment to public health, scientific integrity, transparency, and communication. The President may remove the Commissioner from office only for reasons of inefficiency, neglect of duty, or malfeasance in office.

IMPROVE FDA'S COMMUNICATION TO THE PUBLIC

The public would benefit from more information about how drugs are studied before FDA approval, how drugs' risks and benefits are assessed, and what FDA review entails. Patients also need timely information about emerging safety concerns or about a drug's effectiveness in order to make better decisions in collaboration with their health care providers. FDA does not have an adequate mechanism for seeking and receiving specific scientific and patient/consumer advice on communication matters.

- 6.1 The committee recommends that Congress enact legislation establishing a new FDA advisory committee on communication with patients and consumers. The committee would be composed of members who represent consumer and patient perspectives and organizations. The advisory committee would advise CDER and other centers on communication issues related to efficacy, safety, and use during the lifecycle of drugs and other medical products, and it would support the centers in their mission to "help the public get the accurate, science-based information they need to use medicines and foods to improve their health."

OTHER RECOMMENDATIONS OF PARTICULAR INTEREST TO CONGRESS

- 3.4 The committee recommends that CDER appoint an Office of Surveillance and Epidemiology staff member to each New Drug Application review team and assign joint authority to Office of New Drugs and OSE for postapproval regulatory actions related to safety.
- 4.10 The committee recommends FDA establish a requirement that a substantial majority of the members of each advisory committee be free of significant financial involvement with companies whose interests may be affected by the committee's deliberations.
- 5.4 The committee recommends that FDA evaluate all new data on new molecular entities no later than 5 years after approval. Sponsors will submit a report of accumulated data relevant to drug safety and efficacy, including any additional data published in a peer reviewed journal, and will report on the status of any applicable conditions imposed on the distribution of the drug called for at or after the time of approval.

FOR MORE INFORMATION...

Copies of *The Future of Drug Safety: Promoting and Protecting the Health of the Public* are available from the National Academies Press, 500 Fifth Street, N.W., Lockbox 285, Washington, DC 20055; (800) 624-6242 or (202) 334-3313 (in the Washington Metropolitan area); Internet, <http://www.nap.edu>. The full text of this report is available at <http://www.nap.edu>.

This study was supported by funds from the Food and Drug Administration, the Agency for Healthcare Research and Quality, the Centers for Medicare and Medicaid Services, the U.S. Department of Veterans Affairs, and the National Institutes of Health. Any opinions, findings, conclusions, or recommendations expressed in this publication are those of the author(s) and do not necessarily reflect the views of the organizations or agencies that provided support for the project.

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COMMITTEE ON THE ASSESSMENT OF THE U.S. DRUG SAFETY SYSTEM

SHEILA P. BURKE, M.P.A., R.N. (*Chair*), Deputy Secretary and Chief Operating Officer, Smithsonian Institution; **DAVID BLUMENTHAL, M.D., M.P.P.**, Samuel O. Thier Professor of Medicine and Health Policy, Harvard Medical School; Director, Institute for Health Policy, Massachusetts General Hospital/Partners Health Care System; **SIR ALASDAIR BRECKENRIDGE, C.B.E.**, Chairman, Medicines and Healthcare products Regulatory Agency (United Kingdom); **R. ALTA CHARO, J.D.**, Warren P. Knowles Professor of Law & Bioethics, University of Wisconsin-Madison; Visiting Professor of Law, University of California, Berkeley; **SUSAN EDGMAN-LEVITAN, P.A.**, Executive Director, John D. Stoeckle Center for Primary Care Innovation, Massachusetts General Hospital; **SUSAN S. ELLENBERG, Ph.D.**, Department of Biostatistics and Epidemiology, Center for Clinical Epidemiology and Biostatistics, University of Pennsylvania School of Medicine; **ROBERT D. GIBBONS, Ph.D.**, Director, Center for Health Statistics, University of Illinois at Chicago; **GEORGE HRIPCSAK, M.D., M.S.**, Professor of Biomedical Informatics, Vice Chair, Department of Biomedical Informatics, Columbia University; **DAVID KORN, M.D.**, Senior Vice President, Division of Biomedical and Health Sciences Research, Association of American Medical Colleges; **DAVID MELTZER, M.D., Ph.D.**, Section of General Internal Medicine, University of Chicago; **WOODROW A. MYERS, JR., M.D., M.B.A.**; Former Executive Vice President and Chief Medical Officer, WellPoint Inc.; **MARY OLSON, Ph.D.**, Associate Professor of Economics and Political Economy, Tulane University; **BRUCE M. PSATY, M.D., Ph.D.**, Professor, Medicine & Epidemiology, Co-director, Cardiovascular Health Research Unit, University of Washington; **CHRISTOPHER SCHROEDER, J.D.**, Charles S. Murphy Professor of Law, Public Policy Studies Director, Program in Public Law, Duke Law School; **ANDY STERGACHIS, Ph.D., R.Ph.**, Professor of Epidemiology & Adjunct Professor of Pharmacy, Interim Chair, Pathobiology, Northwest Center for Public Health Practice, School of Public Health & Community Medicine, University of Washington.

IOM STAFF

KATHLEEN STRATTON, Ph.D., Study Director; **ALINA BACIU, M.P.H.**, Program Officer; **AMY GROSSMAN, M.P.H.**, Senior Health Policy Associate; **RUTH KANTHULA, M.P.H.**, Senior Project Assistant; **ROSE MARIE MARTINEZ, Sc.D.**, Board Director, Board on Population Health and Public Health Practice; **GEORGE ISHAM, M.D., M.S.**, Liaison, Board on Population Health and Public Health Practice.

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Public Health Advisory

Nonprescription Cough and Cold Medicine Use in Children

August 15, 2007

1/2008: Please see the updated Public Health Advisory on Nonprescription Cough and Cold Medicine Use in Children at: http://www.fda.gov/cder/drug/advisory/cough_cold_2008.htm

[Federal Register Meeting Notice](#)

FDA announced today that, in October, the Nonprescription Drugs Advisory Committee will discuss the safety and effectiveness of cough and cold drug product use in children. Questions have been raised about the safety of these products and whether the benefits justify any potential risks from the use of these products in children, especially in children under 2 years of age. In preparation for the meeting, FDA is reviewing safety and efficacy data for the ingredients of these products.

Some reports of serious adverse events associated with the use of these products appear to be the result of giving too much of these medicines to children. An over-the-counter cough and cold medicine can be harmful if more than the recommended amount is used, if it is given too often, or if more than one cough and cold medicine containing the same active ingredient are being used. To avoid giving a child too much medicine, parents must carefully follow the directions for use of the product in the "Drug Facts" box on the package label.

What should parents know about using cough and cold products in children?

- Do **not** use cough and cold products in children under 2 years of age UNLESS given specific directions to do so by a healthcare provider.
- Do not give children medicine that is packaged and made for adults. Use only products marked for use in babies, infants or children (sometimes called "pediatric" use).
- Cough and cold medicines come in many different strengths. If you are unsure about the right product for your child, ask a healthcare provider.
- If other medicines (over-the-counter or prescription) are being given to a child, the child's healthcare provider should review and approve their combined use.
- Read all of the information in the "Drug Facts" box on the package label so that you know the **active ingredients** and the **warnings**.
- Follow the **directions** in the "Drug Facts" box. Do not give a child medicine more often or in greater amounts than is stated on the package.
- Too much medicine may lead to serious and life-threatening side effects, particularly in children aged 2 years and younger.
- For liquid products, parents should use the measuring device (dropper, dosing cup or dosing spoon) that is packaged with each different medicine formulation and that is marked to deliver the recommended dose. A kitchen teaspoon or tablespoon is not an appropriate measuring device for giving medicines to children.
- If a measuring device is not included with the product, parents should purchase one at the pharmacy. Make sure that the dropper, dosing cup or dosing spoon has markings on it that match the dosing that is in the **directions** in the "Drug Facts" box on the package label, or is recommended by the child's health care provider.
- If you DO NOT UNDERSTAND the instructions on the product, or how to use the dosing device (dropper, dosing cup or dosing spoon), DO NOT USE the medicine. Consult your healthcare provider if you have questions or are confused.
- Cough and cold medicines only treat the symptoms of the common cold such as runny nose, congestion, fever, aches, and irritability. They do not cure the common cold. Children get better with time.
- If a child's condition worsens or does not improve, stop using the product and immediately take the child to a health care provider for evaluation.

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Date created: August 15, 2007

FDA Urges Caution on Giving Cough and Cold Medicines to Children

FDA Patient Safety News: Show #68, October 2007

file Public

FDA is urging parents to be careful when giving cough and cold medications to children, especially those younger than two. Serious and even fatal adverse events can occur if a child is given too much medicine, or it is given too often, or if the child is given more than one medicine that contains the same active ingredient.

Here are some recommendations for parents from the FDA:

- Do not give cough and cold products to children under 2 years old unless specifically directed to do so by a healthcare provider.
- Do not give children medicine that's made for adults. Only use products marked for babies, infants or children, which are sometimes labeled as "pediatric". Caregivers should be sure to read the "Drug Facts" box on the label to understand how to use the product and know the active ingredients and warnings.
- Do not give your child other prescription or non-prescription medicines at the same time as cough and cold medicines without first checking with your child's healthcare provider.
- Do not use kitchen utensils like a teaspoon or tablespoon to measure out liquid medicines. Instead, use the dropper, dosing cup or dosing spoon that comes with the medicine. If a measuring device is not included, buy one at a pharmacy and be sure it has markings that match the dosing recommendations on the drug label or given by your child's healthcare provider.

FDA will hold a public meeting in October to discuss the safety and effectiveness of cough and cold products for children.

Additional Information:

FDA MedWatch Safety Alert. Nonprescription Cough and Cold Medicine Use in Children. August 16, 2007.
<http://www.fda.gov/medwatch/safety/2007/safety07.htm#Cough>

FDA MedWatch Safety Alert. Cough and Cold Medications in Children Less Than Two Years of Age. January 12, 2007.
<http://www.fda.gov/medwatch/safety/2007/safety07.htm#coughcold>

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September 10, 2007 5:28 p.m. EDT

Study Shows Steep Rise In Adverse Drug Reactions

By JENNIFER CORBETT DOOREN
September 10, 2007 5:28 p.m.

WASHINGTON -- The number of serious drug side effects and deaths reported to the U.S. Food and Drug Administration more than doubled over an eight-year period, according to an analysis of adverse-drug events reported to the agency.

As part of the agency's so-called MedWatch reporting system, drug companies, health-care professionals and the public can file reports when they think a drug is connected to a side-effect or fatality. Drug companies are required to file such reports while they are voluntary for health-care professionals.

A study, published in Monday's Archives of Internal Medicine, looked at reports that are considered serious from 1998 to 2005. The study was conducted by researchers at the Institute for Safe Medication Practices in Huntingdon Valley, Pa., and Wake-Forest University School of Medicine in Winston-Salem, N.C.

Such reports also included reports of deaths in which people believe a particular drug might have contributed to, or caused, the death. Adverse-event reports have to be investigated by the FDA as the reports themselves don't necessarily mean a particular drug or drugs caused a problem.

A serious adverse drug event, defined by the FDA, means an event that resulted in death, a birth defect, disability, hospitalization, was life-threatening or required medical intervention to prevent harm.

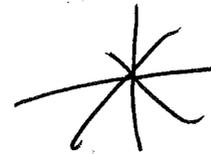
From 1998 to 2005, there were 467,809 serious adverse events reported. The annual number of reports rose from 34,966 in 1998 to 89,842 in 2005 while the number of fatal adverse drug events increased from 5,519 to 15,107 in the same time frame.

The study noted that, overall, the relative increase in serious reports was four times faster than the growth in total U.S. outpatient prescriptions, which grew in the same period from 2.7 billion to 3.8 billion.

One of the study's authors, Thomas J. Moore, senior scientist, drug safety and policy at the Institute for Safe Medication Practices, said one of the surprises in the study was that drugs withdrawn from the market, such as Merck & Co.'s Vioxx, were a "modest" share of the serious event reports.

The study found the two top drugs listed in fatal reports were powerful painkillers oxycodone and fentanyl and were attributed to about 9,000 deaths. Other drugs in a list of top 15 drugs cited in death reports included anti-psychotics and acetaminophen, the active ingredient in over-the-counter pain drugs like Tylenol as well as prescription drugs.

Moore also said newer so-called biotech drugs that modify the immune system to diseases like multiple sclerosis, rheumatoid arthritis and Crohn's disease were associated with about 10,000 serious adverse reports, and accounted for about 15% of the rise in overall adverse event reports over the eight-year study period. Most of the drugs carry black-box warnings discussing serious side effects and the possibility of death.



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The top two drugs with the most reports of non-fatal serious side effects were estrogen-containing products, used in birth-control pills and hormone-replacement therapy, and insulin, a drug used to treat diabetes, the study said.

"These data show a marked increase in reported deaths and serious injuries associated with drug therapy over the study period," the study's authors wrote. "The results highlight the importance of this public-health problem and illustrate the need for improved systems to manage the risks of prescription drugs."

Write to Jennifer Corbett Dooren at jennifer.corbett-dooren@dowjones.com¹

URL for this article:

<http://online.wsj.com/article/SB118945426353322894.html>

Hyperlinks in this Article:

(1) <mailto:jennifer.corbett-dooren@dowjones.com>

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Attachment 7

Public Outreach Activities



California State Board of Pharmacy

1625 N. Market Blvd, Suite N 219, Sacramento, CA 95834
Phone (916) 574-7900
Fax (916) 574-8618
www.pharmacy.ca.gov

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

Date: January 2, 2008

To: Board Members

Subject: Update on the Board's Public Outreach Activities

Public and licensee outreach activities performed since the September report to the committee include:

- Supervising Inspector Ming provided information about pharmacy law to the Indian Pharmacist Association on September 15.
- Supervising Inspector Nurse spoke about California's pedigree requirements at LogiPharma's annual conference in Philadelphia on September 17.
- Analyst Sue Durst staffed an information booth on September 17 at the Senior Fraud Fest event at the South San Francisco Conference Center.
- The board hosted an information booth at a health fair at the Siskiyou County Fairgrounds on September 22.
- Executive Officer Herold and AG Liaison Room spoke at the Healthcare Distribution Management Association's two-day conference, California Pedigree: Preparing for Implementation on September 27.
- Executive Officer Herold and Supervising Inspector Nurse spoke at EPCglobal's annual US Exposition on California's pedigree requirements in Chicago on October 3.
- President Powers spoke to the Renaissance Society (a group of seniors) on October 5 about purchasing drugs online and other consumer issues involving pharmacy.
- Public Outreach Coordinator Abbe and Analyst Durst staffed a booth at the 22nd Annual Marin County Senior Information Fair on October 10.
- Executive Officer Herold and Supervising Inspector Nurse spoke about California's electronic pedigree requirements along with EPCglobal at CSHP's Seminar on October 20 in Palm Springs.
- The board staffed an information booth at the CSHP's Seminar on October 19 and 20.
- Executive Officer Herold provided information about the board's emergency response activities at CPhA's Synergy Conference on November 10.
- Supervising Inspector Ratcliff provided information about pharmacy law in a CE presentation to the Sacramento Valley Society of Health-System Pharmacists on December 12.

Attachment A

*Minutes of the Communication and
Public Education Committee Meeting
of January 8, 2008*



California State Board of Pharmacy
1625 N. Market Blvd, Suite N219, Sacramento, CA 95834
Phone (916) 574-7900
Fax (916) 574-8618
www.pharmacy.ca.gov

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

**STATE BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
COMMUNICATION AND PUBLIC EDUCATION COMMITTEE
MINUTES**

DATE: January 8, 2008

LOCATION: Department of Consumer Affairs
Santa Barbara Conference Room
1625 N. Market Boulevard, N-118
Sacramento, CA 95834

**BOARD MEMBERS
PRESENT:** Kenneth H. Schell, PharmD, Chairperson
Susan L. Ravnar, PharmD
Hank Hough, Public Member

STAFF PRESENT: Virginia Herold, Executive Officer
Anne Sodergren, Legislation and Regulation Manager
Karen Abbe, Public and Licensee Education Analyst

Call to Order

Chairperson Schell called the meeting to order at 1:04 p.m.

1. Consumer Fact Sheet Series

Dr. Schell summarized information provided in the meeting materials regarding the Consumer Fact Sheet project. The purpose of the project is to integrate pharmacy students into public outreach activities promoting consumer education.

The committee and board staff had been working with the UCSF Center for Consumer Self Care developing consumer fact sheets. During the fall of 2007, UCSF advised they could no longer perform these duties without a stipend to offset their expenses. At the October 2007 Board Meeting, the board accepted the committee's recommendations to offer other schools of pharmacy the opportunity to have their students develop consumer fact sheets. A template was developed for future one-page fact sheets with the following points:

- Title
- Issue/Why Important/Facts/Myths
- Patients Need to Ask/Understand
- What Patients Should Do/Questions to Ask
- Contacts For More Information

A draft letter to deans of potential schools of pharmacy was also provided in the meeting materials. The letter invited participation in the project, emphasizing the benefits and experience to be gained by the students in researching health care topics. The letter also provided guidance about the role that the school's faculty would serve, and the need to provide annotated copies reflecting the origin of information referenced on each fact sheet.

Ms. Herold spoke about the skill set involved in relaying information to consumers in a concise manner. She provided a draft created by the board's graphic artist Victor Perez, demonstrating relevant consumer information in a colorful user-friendly format.

Ms. Herold stated that the template would be sent to schools of pharmacy soon, to get students involved in the project as soon as possible. She further stated that the board approved the committee's recommendation to host a competition to acknowledge the best fact sheets developed. The board will acknowledge the winners of competitions at regular intervals (i.e., yearly or coinciding with quarterly school sessions).

Ms. Herold also referred to a list of potential consumer fact sheet topics provided in the meeting materials. She emphasized that the committee will guide the schools of pharmacy that want to participate in the project, but should also leave the topics open for diversity.

Mr. Hough stated that this project provides a wonderful opportunity for aspiring pharmacists to get experience while writing the fact sheets. He also supported a competition and award program to acknowledge the students and schools.

Michael Negrete, from CSHP, suggested that an RFP be used for open-ended solicitation of topics and material.

Dr. Schell suggested that the list of consumer fact sheet topics be prioritized into high, low, and medium topics.

Ms. Herold stated that the committee had developed a list of priority subjects. These would be referenced.

Dr. Ravnan spoke about faculty from schools of pharmacy having oversight in the initial review of each fact sheet. She suggested that faculty work directly with board staff to prevent duplication of efforts on any particular topics.

Ms. Herold asked Dr. Ravnan if she would serve as one of the faculty advisors on the project.

Dr. Ravnan said she would be willing to do this. She offered to approach UOP with the suggestion that students who participate in the project would earn one unit in an elective class during a semester. She said there are three months in each semester.

Dr. Schell added that the project should be open to residency programs as well.

2. Update Report on *The Script*

Dr. Schell said that the next issue of *The Script* was being finalized for publication and distribution later in January. The focus of the issue would be on new laws, questions and answers about pharmacy practice asked of the board, and new regulation requirements. The issue of *The Script* is planned for July 2008.

Dr. Ravnan suggested that the future issue of *The Script* include steps on how to prevent medication errors. She referred to look-alike and sound-alike medications. It would benefit pharmacists to be reminded when to stop and check for things they may take for granted, and when to call the prescribing physicians for clarification.

Dr. Negrete referred to a keynote address by Mike Cohen relating to 10 things you can do in a pharmacy to reduce medication errors. He noted that Mr. Cohen is speaking at CPhA's annual meeting in February.

Dr. Schell referred to new "mini-clinics" and suggested Q&As for their pharmacists.

Dr. Ravnan noted that one of the questions that arises is whether legitimate prescriptions for medical marijuana can be filled in any pharmacy.

Ms. Herold responded that prescriptions for medical marijuana cannot be filled. Pharmacies can fill a prescription for Marinol. Pharmacies can only buy drugs from licensed manufacturers or wholesalers, so there is no way for a pharmacy to obtain legally medical marijuana.

Dr. Negrete spoke about the SCR 49 Medication Errors Report and recommendations for new labeling.

Ms. Herold asked Dr. Negrete if he would be interested in drafting an article on that topic for *The Script*.

Dr. Negrete said he would consider drafting an article, though he has a fourth-year school of pharmacy student that may also be interested.

Dr. Schell also recommended that the next issue of *The Script* contain information about the licensing exam and how applicants can get licensed timely.

Ms. Herold also noted that a future issue of *The Script* will contain a chart that runs across two pages listing legal requirements for pharmacies to fill (or not fill) a prescription.

3. Development of New Consumer Brochures

Dr. Schell referred to information about the board's brochures provided in the meeting materials. He noted that both the overview brochure and the Prescription Drug Program brochure were bright and colorful.

Mr. Hough gave his support of the brochures provided in the meeting materials.

Dr. Schell raised questions regarding the board's complaint brochure. He was uneasy about the emphasis on soliciting complaints about pharmacists. Dr. Schell also questioned the brochure's title, "Do You Have A Complaint?" and its stark color.

Dr. Ravnan asked whether information in the brochure could be balanced by asking consumers if they want to call attention to an outstanding pharmacist in their community doing great things.

Dr. Negrete suggested that the brochure solicit personal stories about pharmacists. He said that patients should be told why it's great to interact with pharmacists.

Ms. Herold noted that the brochure was intended to accompany the board's complaint form and to advise the public about the board's jurisdiction in resolving complaints involving pharmacists. She stated that CPhA had a brochure describing the profession of pharmacy. She also suggested that Mr. Negrete's "Priceless" video be shown again, perhaps at the January 2008 Board Meeting. The video emphasizes pharmacists' contributions to the public by quality pharmacist care.

Mr. Hough suggested that the title of the complaint brochure be revised to include asking consumers, "Have We Heard From You?"

Ms. Herold noted that additional modifications to the complaint brochure will be considered.

Dr. Schell stated that the language in the "What You Need To Know Before Buying Drugs From Foreign Countries" brochure is being updated to reflect the current market.

Ms. Herold noted that the original language in that brochure served to answer questions about buying drugs from Canada and Mexico, from the Internet, and how to save money on prescription drugs.

Dr. Schell advised that a brochure or fact sheet will be developed with information about the pharmacist exam. He noted that applicants generally do not read or retain the information provided in the board's Web site regarding the pharmacist exam.

4. Notice to Consumers

Dr. Schell summarized information contained in the meeting materials regarding the Notice to Consumers posters required by 16 CCR Section 1707.2. Amendments to 16 CCR Section 1707.2(g) created additional requirements for a Notice to Consumers poster regarding patients' rights to obtain lawfully prescribed medicine from a pharmacy.

Ms. Herold provided several full-color mock-ups of posters for the committee's comments. She said that a lot of information is now required to be posted, and it will be difficult to place all required information onto one poster. She noted that pharmacies have limited wall space, so this will be taken into consideration as well.

Ms. Herold advised that the Department's graphic artist created a mock-up, as well as board staffer Victor Perez. The state's printing plant will also be asked to create a mock-up for consideration.

Ms. Herold emphasized that if two posters are used, they should have a consistent theme and need to be "related" to each other. She also noted that two posters could result in some duplication of information on each poster. Name recognition of the board is important as well, and the posters should emphasize patients' rights to get medicines prescribed to them.

There was a discussion during the meeting about font sizes and colors, and which mock-ups provided the most readable information for consumers.

Dr. Negrete asked whether the wording on the posters could be changed.

Ms. Herold responded, no. The regulation specifies the wording on the poster(s); however, the order of the text could be shifted from one area to another.

Mr. Hough supported a one-poster concept, highlighting essential points in an outline form.

Ms. Herold noted that the posters create an opportunity to encourage patient consultations.

A member of the audience suggested that the posters be reviewed by an optometrist. She also noted that some states require a one-inch minimum font size.

Dr. Schell reminded the committee that pharmacies with wall space constraints also have the option of printing the added information onto a receipt.

Dr. Negrete suggested having the final choices reviewed by consumers as a target audience, such as the Gray Panthers.

Ms. Herold stated that consumer hearings will be held statewide regarding new labeling, and the board could display the posters at that time and ask for input.

Dr. Schell also noted that due to recent appointments by the Governor, the board now has a full complement of board members who can give input on this issue.

Russ Heimerich, Public Information Officer for the Office of Public Affairs, suggested the posters be brought to DCA outreach events. He said that Michael Lafferty could provide information about different events.

5. Establishment of Public Hearing Schedule to Implement Senate Bill 472, Standardized, Patient-Centered Prescription Labels by 2011

Dr. Schell summarized information from the meeting materials regarding the establishment of a hearing schedule to implement Senate Bill 472. The new legislation requires standardized, patient-centered prescription labels by 2011.

Dr. Schell noted that the public will be given free reign to comment at the meetings. He said the committee is taking the matter seriously, and the public's input is critical. Dr. Schell added that he is looking forward to the process of getting new labels out to consumers.

Mr. Hough said that consumers, particularly seniors, need to take responsibility for taking medications as directed. He said you can only do so much hand-feeding to consumers. He emphasized that patients can choose to either live well or not, and that there are consequences to their actions. Prescription drugs allow seniors to live better, longer, and stay out of hospitals.

Dr. Schell agreed that patient adherence is a problem, but there is a perception that the current labels engender confusion for patients. Improved labeling should help eliminate some of that confusion.

Dr. Negrete spoke about root causes and patient motivations. He offered to send information to the committee regarding that issue.

Philip Swanger, CSHP, noted that it is good to get feedback from the public, and he asked about a plan for outreach opportunities.

Ms. Herold said that sponsors of the legislation will be providing a mailing list. The Department's mailing list, as well as the Gray Panthers' and CSHP mailing lists, will be used as well. She emphasized the need to set the public hearing dates so people could plan ahead to attend.

Mr. Swanger suggested noticing the hearings in *The Sacramento Bee*.

Ms. Herold noted that the Latino Coalition for Health Care, the Gray Panthers, and a third sponsor affiliated with health literacy would be participating. The board will also invite the California Medical Association to give input as well. She said the sponsors want to attain the printing of labels in languages other than English.

Ms. Herold noted that the wording on auxiliary labels (i.e., warnings about sunlight or taking a medicine with grapefruit juice) could be standardized.

6. Board of Pharmacy Web Site Redesign

Dr. Schell noted that the Governor's Office directed all state agencies to develop a state-standardized Web site by November 1, 2007, and the board met this deadline. Board staffers Kim de Long and Victor Perez worked on this project.

The board will be adding a web page devoted to locating information on electronic pedigree requirements in California.

A full color copy of one of the board's Web pages and one page of the Department of Consumer Affairs site were provided in the meeting materials.

Dr. Schell advised that he received positive feedback on the board's new Web site from a board critic. The tabs at the top of each page were particularly helpful.

7. Miscellaneous Consumer Issues/Articles in the Media

Dr. Schell referred to copies of articles in the news provided in the meeting materials. He noted an article about a survey of parents' views of over-the-counter cold and cough medications for children under age six. The survey was conducted after the FDA noted safety concerns. The survey highlighted parents' confusion about whether to continue using the medications.

Mr. Hough noted that the information provided regarding buying prescriptions drugs on-line was also helpful.

Dr. Schell also noted the article in U.S. News & World Report entitled, "Drugs That Go Untaken." The article highlighted the medication adherence issue.

8. Update on the Board's Public Outreach Activities

Dr. Schell referred to a list provided in the meeting materials. He stated that board staff have done a good job of doing outreach to community groups, and he commended their efforts. He noted 12 public outreach events that the board participated in between September and December 2007. He said the board is active and takes consumer protection seriously.

Adjournment

There being no additional business, Chairperson Schell adjourned the meeting at 3:24 p.m.

COMMUNICATION AND PUBLIC EDUCATION COMMITTEE

Goal 4: Provide relevant information to consumers and licensees.

Outcome: Improved consumer awareness and licensee knowledge.

Objective 4.1	Develop a minimum of 10 communication venues to the public by June 30, 2011.
Measure:	Number of communication venues developed to the public.
Tasks:	<ol style="list-style-type: none"> <li data-bbox="370 480 1461 585">1. Assess the effectiveness of the board's educational materials and outreach: survey consumers to identify whether board-produced materials are valued and what new materials are desired. <ul style="list-style-type: none"> <li data-bbox="440 590 1159 621"><i>Sept. 2006: Committee begins review of consumer outreach.</i> <li data-bbox="440 625 1471 730"><i>Dec. 2006: Staff conducts assessment of the board's consumer outreach written materials. Material is identified for revision and update, future development, or evaluation for continued need.</i> <li data-bbox="440 735 1438 808"><i>Jan. 2007: Drafts of board informational brochure and complaint process brochures are updated; brochures will undergo review.</i> <li data-bbox="440 812 1438 886"><i>April 2007: Drafts of board informational brochure and complaint process brochures are provided to the Department of Consumer Affairs for review.</i> <li data-bbox="440 890 1479 963"><i>June 2007: Committee reviews Department of Consumer Affairs prepared brochures and recommends board produce its own versions.</i> <li data-bbox="440 968 1317 999"><i>Sept. 2007: Board publishes new board brochure and complaint brochure.</i> <li data-bbox="440 1003 987 1035"><i>Jan. 2008: Reformatted complaint brochure.</i> <li data-bbox="370 1039 1211 1071">2. Restructure the board's Web site to make it more user friendly. <ul style="list-style-type: none"> <li data-bbox="440 1075 1414 1180"><i>July 2006: Web site modified to contain lists of disciplinary actions finalized each quarter and permit online access to public documents regarding board disciplinary actions taken against a licensee.</i> <li data-bbox="440 1184 1487 1331"><i>March 2007: Web site modified by adding 14 links to obtain various information regarding Medication Safety and Drug Interactions. Web site modified by adding 7 links to obtain information from FDA regarding Medications and Medical Devices.</i> <li data-bbox="440 1335 1484 1398"><i>March 2007: Work initiated on the latest State Web site design to be in place by November 2007.</i> <li data-bbox="440 1402 1305 1434"><i>June 2007: Work progressing for timely completion by November 1, 2007.</i> <li data-bbox="440 1438 1008 1470"><i>Oct. 2007: Work nearly completed on Website.</i> <li data-bbox="440 1474 967 1505"><i>Nov. 2007: New Website design completed.</i> <li data-bbox="440 1509 1325 1541"><i>Jan. 2008: Web page created consolidating all information on e-pedigree.</i> <li data-bbox="370 1556 1443 1629">3. Work with the California Health Communication Partnership on integrated public information campaigns on health-care topics. <ul style="list-style-type: none"> <li data-bbox="440 1633 1435 1738"><i>Sept. 2006: Committee continues collaboration with the partnership whose fall campaign is screening for prostate and breast cancer. Plans underway to work to promote generic drugs in the future.</i> <li data-bbox="440 1743 1495 1848"><i>April 2007: Summary provided of the Fall 2006 campaign to raise awareness about breast cancer screening and prostate cancer screening. No recent meetings of the partnership have occurred.</i>

4. Continue collaboration with UCSF's Center for Consumer Self Care for pharmacist interns to develop consumer fact sheets on health topics.
 - Sept. 2006: Nine previously developed fact sheets are sent to a translation service to develop Spanish, Chinese, and Vietnamese versions of these materials. Four new fact sheets developed and undergoing review by the board.*
 - April 2007: Four draft fact sheets are still under review and the committee receives three new fact sheets. The committee determines that the board will expand the project beyond the Center for Consumer Self Care to include students from other Schools of Pharmacy.*
 - Sept. 2007: Discussion with UCSF lead to request for funding to continue project. Meanwhile board seeks to establish intern projects with other schools of pharmacy.*
 - Oct. 2007: Board agrees to offer intern fact sheet program to all California schools of pharmacy.*
 - Jan. 2008: Committee prepares scope for program.*
5. Develop a Notice to Consumers to comply with requirements of AB 2583 (Nation, Chapter 487, Statutes of 2006) on patients' rights to secure legitimately prescribed medication from pharmacies.
 - Sept. 2006: Governor signs AB 2583.*
 - Oct. 2006: Committee advances draft regulation text for comment at the October Board Meeting. Board votes to create a second Notice to Consumers poster vs. adding additional language to current poster.*
 - Jan. 2007: Committee refines language to be advanced to the board. Board reviews, modifies, and sets for regulation notice the proposed language for a second Notice to Consumers poster.*
 - April 2007: Board reviews comments submitted in rulemaking process to adopt this regulation change, and plans to renote amended language for a new rulemaking process.*
 - July 2007: New "Notice to Consumers" approved by board; rulemaking file submitted to Administration for approval.*
 - Nov. 2007: Office of Administrative Law approves "Notice to Consumers" rulemaking. Work on drafting new poster design initiated by board staff at DCA design staff.*
 - Jan. 2008: Committee reviews draft concepts for new poster: additional work by board staff and the Office of State Publishing artists will continue to generate concept designs for the poster.*
6. Evaluate the practice of pill splitting as a consumer protection issue.
 - Jan. 2007: Board holds discussion of pill splitting issues during Board Meeting.*
 - March 2007: Legislation and Regulation Committee and Communication and Public Education Committee continue discussion of pill splitting.*
 - April 2007: Board hears discussion of pill splitting.*
 - June 2007: Communication and Public Education Committee discussed proposed consumer fact sheet on pill splitting.*
 - July 2007: The Script newsletter contains an article for pharmacists on pill splitting.*
 - Sept. 2007: Consumer Fact Sheet completed.*

	<p>7. Evaluate the SCR 49 Medication Errors Report for implementation. <i>March 2007: Communication and Public Education Committee reviews SCR 49 report.</i> <i>April 2007: Board presentation of the SCR 49 report by former board member Sandra Bauer.</i> <i>Oct. 2007: SB 472 enacted to require the board to standardize container labels into a patient friendly format by 2011.</i></p> <p>8. Develop patient-centered standardized prescription container labels by 2011 pursuant to SB 472 (Corbett, Chapter 470, Statutes of 2007). <i>Oct. 2007: Board president appoints members to subcommittee.</i> <i>Jan 2008: Board readies plans for six public hearings statewide during 2008</i></p>
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Objective 4.2	Develop 10 communication venues to licensees by June 30, 2011.
Measure:	Number of communication venues developed to licensees.
Tasks:	<ol style="list-style-type: none"> <li data-bbox="367 199 1495 525"> <p>1. Publish <i>The Script</i> two times annually.</p> <p><i>Sept. 2006: The Script published, placed online and mailed to pharmacies and wholesalers.</i></p> <p><i>Jan. 2007: The Script published, placed online and mailed to pharmacies and wholesalers.</i></p> <p><i>July 2007: The Script published, placed online and mailed to pharmacies and wholesalers.</i></p> <p><i>Jan 2008: The Script published, placed online and mailed to pharmacies and wholesalers.</i></p> <li data-bbox="367 535 1495 1923"> <p>2. Develop board-sponsored continuing education programs in pharmacy law and coordinate presentation at local and annual professional association meetings throughout California.</p> <p><i>1st Qtr 06/07: Board supervising inspectors present five CE programs on pharmacy law and the Board of Pharmacy to pharmacist associations statewide.</i></p> <p><i>Sept. 2006: Supervising Inspector Ming provides information on pharmacy law to 80 pharmacists and pharmacy technicians at a San Mateo Pharmacist Association.</i></p> <p><i>Supervising Inspector Ratcliff provides information on pharmacy law to the Sacramento Valley Society of Health System Pharmacists.</i></p> <p><i>Oct. 2006: Interim Executive Officer Herold presents Legislation and Regulation update at CSHP's Annual Seminar. Board also staffs information booth for licensees.</i></p> <p><i>Nov. 2006: Board Member Goldenberg speaks at the California Association of Health Facilities Convention in Palm Springs.</i></p> <p><i>Supervising Inspector Ming provides information on pharmacy law to UCSD students.</i></p> <p><i>Jan. 2007: Supervising Inspector Ming provides information on pharmacy law to the Indian Pharmacist Association.</i></p> <p><i>Feb. 2007: Executive Officer Herold provides information about the board at the CPhA's annual meeting.</i></p> <p><i>Feb. 2007: Board Member Hiura provides information about pharmacy law to pharmacists at a Korean pharmacist association meeting.</i></p> <p><i>March 2007: Supervising Inspector Nurse presents California's Electronic Pedigree requirements to the Generic Pharmaceutical Manufacturers Association annual meeting in Phoenix.</i></p> <p><i>March 2007: Supervising Inspector Ratcliff provides information about pharmacy law and the board to 80 UCSF students.</i></p> <p><i>March 2007: Former Board Member John Jones provides a law update to Western University students.</i></p> <p><i>April 2007: Supervising inspectors and board members provide information about pharmacy law and board programs to pharmacists at Anaheim Memorial Hospital, to the Diablo Valley Pharmacists Association Meeting and the San Diego Pharmacists Association.</i></p> <p><i>May 2007: Staff and board members provide information about pharmacy law and board programs to Loma Linda and University of the Pacific School of Pharmacy graduating students, and to Sutter Hospitals' pharmacists.</i></p> <p><i>June 2007: Board member provides information about the board's citation and fine program to the Pharmacists Professional Society of San Fernando Valley.</i></p>

Aug. 2007: Staff provide information about the Veterinary Food Animal Drug Retailer program to a group of food animal veterinarians.

Sept. 2007: Supervising Inspector Ming provides information about pharmacy law to the Indian Pharmacists Association.

Dec. 2007: Supervising Inspector Ratcliff provided information about pharmacy law in a CE presentation to the Sacramento Valley Society of Health-System Pharmacists.

3. Maintain important and timely licensee information on Web site.

1st Qtr 06/07: Added 50-year pharmacist recognition pages as a special feature. Updated license totals. Added enforcement actions for effective dates between April 1 and June 30, 2005. Changed definitions on license lookup to clarify license status. Posted board and committee meeting agendas and materials. Sent out subscriber alert notifications to the board's e-mail notification list, including two drug recalls.

2nd Qtr 06/07: Unveiled new Web site of the board, and created new Web links. Revised and added new fax and contact information to speed communication with appropriate enforcement and licensing staff. Updated listing of 50 year pharmacists. Added frequently asked questions on emerging contraception. Updated listing of enforcement actions taken. Reviewed and updated board member biographies. Made corrections to the board's online lawbook. Added all agendas, meeting packets and minutes for board and committee meetings. Sent out nine subscriber alerts for important information added to the board's Web site.

3rd Qtr 06/07: Completed updates to website to comply with SB 796. Updated copyright year. Updated links referring to California's and the governor's web pages. Added information about the denial of a registration or license. Added information about the new CPJE vendor. Added inspector and supervising inspector exam information. Revised information on our Contact Us page. Updated applications on the website to include mandatory reporting information. Updated public disclosure through Web Lookup to include discipline taken after January 2002. Updated listing of 50-year pharmacists. Added enforcement actions for effective dates between January 1 and March 30, 2007. Posted board and committee meeting agendas and materials. Sent out 19 subscriber alert notifications to the board's e-mail notification list.

4th Qtr 06/07: *Created a page dedicated to drug alerts and recalls.
Updated exam information to reflect the new vendor.
Added the new self-assessment forms for Community and Hospital Pharmacies.
Added the self-assessment form for Wholesalers.
Updated the lawbook with an updated, book marked version for easier usability.
Updated DEA links.
Added enforcement actions for the effective dates between April 1 and June 30, 2007.
Posted board and committee meeting agendas and materials.
Sent out 20 subscriber alert notifications to the board's email notification list.*

1st Qtr 07/08: *Added information about NAPLEX being suspended.
Added the latest issue of The Script.
Added information about Heat Preparedness.
Updated fingerprint fees.
Updated regrade information.
Updated information about the release of CPJE results.
Added information about pill-splitting.
Updated information on our Contact Us page.
Sent out 8 subscriber alert notifications to the board's e-mail notification list.
Posted board and committee meeting agendas and materials.
Verified that minutes are included for each of the past meetings listed on the website.*

2nd Qtr 07/08: *Website reflecting the New State Redesign launched.
Updated applications and application information to reflect the Board's new application fees.
Updated the fee schedule page to reflect the Board's new application and renewal fees.
Updated pages which include fingerprint fees to reflect new costs.
Sent out three disaster response subscriber alerts regarding the Southern California wildfires to the board's e-mail notification list.
Updated number of current licenses by license types.
Added enforcement actions for the effective dates between October 1 and December 31, 2007.
Posted board and committee meeting agendas and materials.
Sent out nine subscriber alert notifications to the board's e-mail notification list.*

Objective 4.3	Participate in 12 forums, conferences and public education events annually.
Measure:	Number of forums participated.
Tasks:	<p>1. Participate in forums, conferences and educational fairs.</p> <p><i>Sept. 2006: Supervising Inspector Nurse provides presentation on California's e-pedigree requirements at Logi-Pharma's Annual Convention in Austin TX.</i></p> <p><i>Oct. 2006: Board hosts the three-day NABP Districts 7 & 8 Meeting. Topics include the FDA's pedigree requirements, the DEA's pseudoephedrine requirements, divergent intern requirements from state to state, and development of ethics programs for health professionals.</i></p> <p><i>Supervising Inspector Nurse provides presentations to national EPCglobal Convention (a standards setting organization) in Los Angeles on California's e-pedigree requirements for prescription drugs.</i></p> <p><i>Board staffs information booth at San Mateo Senior Fest where 600 people attend.</i></p> <p><i>Dec. 2006: Inspector Barnard and Public and Licensee Education Analyst Abbe staff information booth at the Sacramento AARP-sponsored Ask A Pharmacist event.</i></p> <p><i>Jan. 2007: Supervising Inspector Nurse provides presentation on California's e-pedigree requirements at Secure Pharma 2007, the supply chain security conference in Philadelphia.</i></p> <p><i>Feb. 2007: The board hosts an information booth for two days at CPhA's annual meeting.</i></p> <p><i>March 2007: Inspector Wong and Analyst Abbe staff information booth at the 2007 Consumer Protection Day forum in San Diego.</i></p> <p><i>April 2007: Presentation on being a pharmacist at a career day presentation in Southern California.</i></p> <p><i>May 2007: The board staffed a public information booth at the Family Safety and Health Expo at Safetyville in Sacramento, at the Sacramento Chapter of the American Diabetes Association Health Fair. Also provided information about California's electronic pedigree requirements for prescription medicine to a full session at the National Association of Boards of Pharmacy annual meeting.</i></p> <p><i>June 2007: Board Member participated in panel discussion that will be released as a web cast on prescription errors with Lyle Bootman and Michael Cohen, hosted by Drug Topics.</i></p> <p><i>July 2007: Staff met with visiting dignitaries from Australia who were interested in learning about California's controlled substances requirements.</i></p> <p><i>Aug. 2007: The board staffed a public information booth at the California State Fair.</i></p> <p><i>Sept. 2007: Major presentation made on California's standards to LogiPharma in Philadelphia.</i></p> <p><i>The board staffed a public information booth at the Senior Fraud Fest event.</i></p> <p><i>The board staffed a public information booth at the Siskiyou County Fairgrounds.</i></p> <p><i>Major presentation made on California's standards at HDMA's conference in Berkeley.</i></p>

	<p>Oct. 2007: Executive Officer Herold and Supervising Inspector Nurse speak at EPCglobal's annual U.S. Exposition on California's pedigree requirements. Executive Officer Herold and Supervising Inspector Nurse speak about California's electronic pedigree requirements at CSHP's Seminar. President Powers speaks to the Renaissance Society about pedigree issues, purchasing drugs online and other consumer issues involving pharmacy. The board staffed a public information booth at the Annual Marin County Senior Information Fair and at the CSHP's Seminar.</p> <p>Nov. 2007: Executive Officer Herold provides information about the board's emergency response activities at CPhA's Synergy Conference. Executive Officer Herold and Supervising Inspector Nurse speak at the NACDS/HDMA conference on California's e-pedigree requirements.</p>
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