PUBLICCITIZEN Health Letter

SIDNEY M. WOLFE, M.D., EDITOR APRIL 2010 – VOL. 26, No. 4

Misprescribing and Overprescribing of Drugs

The numbers are staggering: In 2008, an estimated 3.65 billion prescriptions were filled in retail drugstores and by mail order in the U.S. That averages out to 12 prescriptions filled for each of the 300 million people in this country. But many people do not get any prescriptions filled in a given year, so it is also important to find out how many prescriptions are filled by those who fill one or more prescriptions. In 2008, more than 2.5 times as many prescriptions were filled for those 65 and older (30.1 prescriptions per year) than for those 19-64 (11.6 prescriptions per year). Another way of looking at the high rate of prescriptions among older people is the government finding that although Medicare beneficiaries comprise only 14 percent of the community population, they account for more than 41 percent of prescription medicine expenses.

> More than 1.5 million people are hospitalized and more than 100,000 die each year from largely preventable adverse reactions to drugs, many of which should not have been prescribed in the first place.

There is no dispute that for many people, prescriptions are beneficial, even lifesaving in many instances. But hundreds of millions of these prescriptions are wrong, either entirely unnecessary or unnecessarily dangerous. Inappropriate prescribing is an academically gentle euphemism for prescriptions for which the risks outweigh the benefits, thus conferring a negative health impact on the patient. A recent comprehensive review of studies of such inappropriate prescribing in older patients found that 21.3 percent of community-dwelling patients 65 years or older were using at least one inappropriately prescribed drug. Much more so than age, per se, the total number of drugs being prescribed was an important predictor of inappropriate prescribing, as was female gender. Another study found that, conservatively — using very narrow criteria for inappropriate prescribing — elderly U.S. patients were prescribed at least one inappropriate drug at an estimated 16.7 million visits to physician offices or hospital outpatient departments in the year 2000. Examples of specific drugs that have been inappropriately prescribed, including studies involving younger adults and children, are given later in this article.

At the very least, misprescribing wastes tens of billions of dollars, barely affordable by many people who pay for their own prescriptions. But there are much more serious consequences. More than 1.5 million people are hospitalized and more than 100,000 die each year from largely preventable adverse reactions to drugs, many of which should not have been prescribed as they were in the first place. What follows is a summary of the seven all-too-often-deadly sins of prescribing.

First: The "disease" for which a drug is prescribed is actually an adverse reaction to another drug, masquerading as a disease but unfortunately not recognized by doctor and patient as a side effect. Instead of lowering the dose of the offending drug or replacing it with a safer alternative, the physician adds a second drug to the regimen to "treat" the adverse drug reaction caused by the first drug. Examples include drug-induced parkinsonism, depression, sexual dysfunction, insomnia, psychosis, constipation and many other problems.

Second: A drug is used to treat a problem that, although in some cases susceptible to a pharmaceutical solution, should first be treated with commonsense lifestyle changes. Problems such as insomnia and abdominal pain often have causes that respond very well to nondrug treatment, and often the physician can uncover these causes by taking a careful history. Other examples include medical problems such as high blood pressure, mild adult-onset diabetes, obesity, anxiety and situational depression. Doctors should recommend lifestyle changes as the first approach for these conditions, rather than automatically reaching for the prescription pad.

Third: The medical problem is both self-limited and completely unresponsive to treatments such as

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OVERPRESCRIBING from page 1

antibiotics or does not merit treatment with certain drugs. This is seen most clearly with viral infections such as colds and bronchitis in otherwise healthy children or adults.

Fourth: A drug is the preferred treatment for the medical problem, but instead of the safest, most effective — and often least expensive — treatment, the physician prescribes a much less preferable alternative (one of the drugs Public Citizen advises that consumers Do Not Use on its drug information Web site WorstPills.org). An example of a less preferable alternative would be to prescribe a drug to which the patient has a known allergy that the physician did not ask about.

Fifth: You are prescribed two drugs that can interact with each other. Each on its own may be safe and effective, but together they can cause serious injury or death.

Sixth: Two or more drugs in the same therapeutic category are used, the additional one(s) not adding to the effectiveness of the first but clearly increasing the risk to the patient. Sometimes the drugs come in a fixed combination pill, sometimes as two different pills. Often heart drugs or mind-affecting drugs are prescribed in this manner.

Seventh: The right drug is prescribed, but the dose is dangerously high. This problem is seen most often in older adults, who cannot metabolize or excrete drugs as rapidly as younger people. This problem is also seen in small people who are usually prescribed the same dose as that prescribed to people weighing two to three times as much as they do. Thus, per pound, they are getting two to three times as much medicine as the larger person.

Evidence of misprescribing and overprescribing

The following are examples from recent studies by a growing number of medical researchers documenting misprescribing and overprescribing of specific types of drugs.

Treating adverse drug reactions with more drugs

Researchers at the University of Toronto and at Harvard have clearly documented and articulated what they call the prescribing cascade. It begins when an adverse drug reaction is misinterpreted as a new medical condition. Another drug is then prescribed, and the patient is placed at risk of developing additional adverse effects relating to this potentially unnecessary treatment. To prevent this prescribing cascade, doctors — and patients — should follow Rule 7 of the *Ten Rules for Safer Drug Use* (see "Ten Rules for Safer Drug Use," page 6): Assume that any new symptom you develop after starting a new drug might be caused by the drug. If you have a new symptom, report it to your doctor.

Some of the instances of the prescribing cascade that these and other researchers have documented include:

- The increased use of anti-Parkinson's drugs to treat drug-induced parkinsonism caused by the heartburn drug metoclopramide (Reglan) or by some of the older antipsychotic drugs.
- A sharply increased use of laxatives in people with decreased bowel activity that has been caused by antihistamines such as diphenhydramine (Benadryl), antidepressants such as amitriptyline (Elavil) or some antipsychotic drugs such as thioridazine (Mellaril).
- An increased use of antihypertensive drugs in people with high blood pressure that was caused or increased by very high doses of nonsteroidal anti-inflammatory drugs (NSAIDs), used as painkillers or for arthritis.

Failing to treat certain problems with nondrug treatments

Research has shown that many doctors are too quick to pull the prescription trigger. In one study, in which doctors and nurse practitioners were presented with part of a clinical scenario — as would occur when first seeing a patient with a medical problem — and then encouraged to ask to find out more

about the source of the problem, 65 percent of doctors recommended that a patient complaining of insomnia be treated with sleeping pills even though, had they asked more questions about the patient, they would have found that the patient was not exercising, was drinking coffee in the evening, and, although awakening at 4 a.m., was actually getting seven hours of sleep by then.

In a similar study, doctors were presented with a patient who complained of abdominal pain and whose endoscopy showed diffuse irritation in the stomach. Sixty-five percent of the doctors recommended treating the problem with a drug — a histamine antagonist (such as Zantac, Pepcid or Tagamet). Had they asked more questions, they would have discovered that the patient was using aspirin, drinking a lot of coffee, smoking cigarettes and was under considerable emotional stress — all potential contributing factors to abdominal pain and stomach irritation.

In summarizing the origin of this overprescribing problem, the authors stated: "Apparently quite early in the formulation of the problem, the conceptual focus [of the doctor] appears to shift from broader questions like 'What is wrong with this patient?'or 'What can I do to help?' to the much narrower concern, 'Which prescription shall I write?'" They argued that this approach was supported by the "barrage" of promotional materials that only address drug treatment, not the more sensible lifestyle changes to prevent the problem.

In both of the above scenarios, nurse practitioners were much more likely than doctors to take an adequate history that elicited the causes of the problems and, not surprisingly, were only one-third as likely as the doctors to decide on a prescription as the remedy instead of suggesting changes in the patient's habits.

Treating viral infections with antibiotics or treating other diseases with drugs that are not effective for those problems

Two studies based on nationwide data from office visits for children and adults have decisively documented the expensive and dangerous massive overprescribing of antibiotics for conditions that, because of their viral origin, do not respond to these drugs. Forty-four percent of children under 18 years old were given antibiotics for treatment of a cold and 75 percent for treatment of bronchitis. Similarly, 51 percent of people 18 or older were treated with antibiotics for colds and 66 percent for bronchitis. Despite the lack of evidence of any benefit for most people from these treatments, more than 23 million prescriptions a year were written for colds, bronchitis and upper respiratory infections. This accounted for approximately one-fifth of all prescriptions for antibiotics written for children or adults. An accompanying editorial warned of "increased costs from unnecessary prescriptions, adverse drug reactions, and [subsequent] treatment failures in patients with antibiotic-resistant infections" as the reasons to try to reduce this epidemic of unnecessary antibiotic prescribing.

Another study highlights cases of misprescribing of drugs that are useful and important for certain problems, but not necessary or effective (and often dangerous) for other problems. In this case, 47 percent of the people admitted to a nursing home who were taking digoxin, an important drug for treating abnormal heart rhythm or severe congestive heart failure, did not have either of these medical problems and were thereby being put at risk for life-threatening digitalis toxicity without the possibility of any benefit.

A final example in this category involves the overuse of a certain class of drugs, in this case calcium channel blockers, which have not been established as effective for treating people who have had a recent heart attack. The study shows that this prescribing pattern actually did indirect damage to patients because their use was replacing the use of beta-blockers, drugs shown to be very effective for reducing the subsequent risk of death or hospitalization following a heart attack. Use of a calcium channel blocker instead of a beta-blocker was associated with a doubled risk of death, and beta-blocker recipients were hospitalized 22 percent less often than nonrecipients.

The prescribing of more dangerous and/or less effective drugs instead of safer alternatives

On our drug safety information Web site WorstPills.org, we list nearly 200 drugs that we advise consumers against using (called Do Not Use drugs), and we recommend safer alternatives for every Do Not Use drug.

These Do Not Use drugs are for heart disease or high blood pressure, insomnia, anxiety, depression and other mental problems, pain, gastrointestinal problems, coughs, colds, allergies, asthma and infections and other commonly used categories of drugs. Although the original determinations for these Do Not Use drugs were based on their use by older adults, we have concluded that the same warnings apply to use by anyone and now include drugs, such as contraceptives, not used by older adults.

On WorstPills.org, we also label some drugs Do Not Use Until Seven Years After Release. We have applied this warning to drugs that have only recently appeared on the market, for which there is no evidence of their superiority over older drugs about which we have much more information as to long-term safety and effectiveness. Because of incomplete and worrisome safety information, there is a risk that some of these newer drugs will have to be banned. But by the time they have been on the market for seven years, it is much less likely that they will be banned, and it is much more likely

that, if they are still being used, there will be much better information about their safety and effectiveness, such as a new black-box warning not present when the drugs were first marketed.

Another avoidable category of misprescribed drugs are those to which patients are known to be allergic, but about which their physicians have not taken a careful medical history.

The Causes of Misprescribing and Overprescribing

The Drug Industry

The primary culprit in promoting the misprescribing and overprescribing of drugs is the pharmaceutical industry, which now sells about $216 billion worth of drugs per year in the U.S. alone. The industry uses loopholes in the law not requiring proof of superiority over existing drugs for approval, and otherwise intimidates the Food and Drug Administration (FDA) into approving record numbers of "me-too" drugs (drugs that offer no significant benefit over drugs already on the market) that often have dangerous adverse effects. In addition, the industry spends well in excess of $21 billion a year to promote drugs using advertising and promotional tricks that push at or through the envelope of being false and misleading. This industry has been extremely successful in distorting, in a profitable but dangerous way, the rational processes for approving and prescribing drugs. Two studies of the accuracy of ads for prescription drugs widely circulated to doctors both concluded that a substantial proportion of these ads contained information that was false or misleading and violated FDA laws and regulations concerning advertising.

The fastest-growing segment of drug advertising is directed not at doctors but at patients. It has been estimated that from 1991 to 2002 direct-to-consumer (DTC) advertising expenditures in the U.S. grew from about $60 million a year to $3 billion a year, an increase of 50-fold in just 11 years, employing misleading advertising campaigns similar to those used for doctors.

A study by Consumer Reports of 28 such ads found that "only half were judged to convey important information on side effects in the main promotional text," only 40 percent were "honest about efficacy and fairly described the benefits and risks in the main text," and 39 percent of the ads were considered "more harmful than helpful" by at least one reviewer. This campaign has been extremely successful. According to a drug industry spokesman, "There's a strong correlation between the amount of money pharmaceutical companies spend on DTC advertising and what drugs patients are most often requesting from physicians." The advertising "is definitely driving patients to the doctor's office, and in many cases, leading patients to request the drugs by name."

The problems with DTC advertising are best summed up in an article written by a physician more than 15 years ago in *The New England Journal of Medicine*, before the current binge had really begun: "If direct [to consumer] advertising should prevail, the use of prescription medication would be warped by misleading commercials and hucksterism. The choice of a patient's medication, even of his or her physician, could then come to depend more on the attractiveness of a full-page spread or prime-time commercial than on medical merit...such advertising would serve only the ad-makers and the media, and might well harm our patients."

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FDA

Attempting to fend off FDA-weakening legislation even worse than that which was signed into law in 1997, the FDA has bent over backwards to approve more drugs, culminating in 1996 and 1997 when the agency approved a larger number than had ever been approved in any two-year period. Thousands of people were injured or killed after taking one of three such recently approved drugs (which have subsequently been recalled from the market). These drugs were the weight-loss drug dexfenfluramine (Redux), the heart drug mibefradil (Posicor) and the painkiller bromfenac (Duract). Other drugs that would not have gotten approved in a more cautious era at the FDA have also been approved, but are likely either to be banned or to be forced to carry severe warnings that will substantially reduce their use.

In the more than 30 years since Public Citizen started monitoring the FDA and the drug industry, the current pro-industry attitude at the FDA is as bad and dangerous as it has ever been. In addition to record numbers of approvals of questionable drugs, FDA enforcement over advertising has all but disappeared. From a peak number of 157 enforcement actions to stop illegal prescription drug ads that understate risks and/or overstate benefits in 1998, the number has decreased to only 24 — an 85 percent decrease — in 2003. There is no evidence that the accuracy or legality of these ads has increased during this interval, and the amount of such advertising has clearly increased. The division at FDA responsible for policing prescription drug advertising has never been given adequate resources to keep up with the torrent of newly approved drugs. More recently, however, it has also been thwarted by marching orders from higher up in the agency to, effectively, go easy on prescription drug advertising. As a result, the drug industry correctly believes it can get away with more violative advertising than in the past. The role of the U.S. Congress in pushing the FDA into approving more drugs, and passing, with the FDA's reluctant approval, legislation to further weaken the FDA's ability to protect the public, cannot be overlooked.

Physicians

The well-financed promotional campaigns by drug companies would not have as much of an impact as they do were there not such an educational vacuum about proper prescribing of drugs. This is a serious problem that must be laid at the feet of medical school and residency training. The varieties of overprescribing and misprescribing of drugs by doctors are all strongly enhanced by the mind-altering properties of drug promotion. The best doctors do not waste their time talking to drug salespeople, toss promotional materials away and ignore drug ads in medical journals. Too many doctors, however, are heavily influenced by drug companies, accepting free meals, drinks and medical books in exchange for letting the drug companies "educate" them at symposia in which the virtues of certain drugs are extolled. Unfortunately, many of these doctors are too arrogant to realize that there is no such thing as a free lunch. The majority of doctors attending such functions have been found to increase their prescriptions for the targeted drugs following attendance at the "teach-in."

Beyond traditional advertising and promotion and their influence, bias of drug company-sponsored research, as published in medical journals, also can sway doctors toward more favorable impressions about drugs. An analysis was done of 56 trials that were paid for by drug companies and reported in 52 medical journals about drugs for arthritis and pain — NSAIDs. (These drug company-sponsored studies represented 85 percent of those that the researchers originally reviewed.) In barely one-half of the studies identifying the company's drug as less toxic than another drug was there justification for the finding of less toxicity. This certainly explains why, contrary to fact, newer arthritis drugs almost always seem safer than older, usually much less expensive ones.

A final example demonstrates the ignorance of many physicians, especially in dealing with prescribing drugs to older adults. A study of physicians who treat Medicare patients found that 70 percent of the doctors who took an examination concerning their knowledge of prescribing for older adults failed to pass the test. The majority of physicians who were contacted for participation in the study refused to take the test, often giving as their reason that they had a "lack of interest in the subject." The authors concluded "many of [the] physicians [who failed the exam] had ... not made good use of the best information on prescribing for the elderly."

Pharmacists

A small fraction of pharmacists have, in our view, betrayed their professional ethics and are working for drug companies, engaging in such activities as calling doctors to get them to switch patients from drugs made by a company other than the one the pharmacist works for to the pharmacist's employer's drugs. In addition, pharmacy organizations such as the American Pharmaceutical Association and others have fought hard to prevent the FDA from requiring accurate patient package information to be dispensed with each prescription filled.

Too many pharmacists, despite having computers to aid them, have been willing to fill prescriptions for pairs of drugs that should never be dispensed to the same person because of life-threatening interactions that can occur if they are used at the same time.

- Sixteen (32 percent) of 50 pharmacies in Washington, D.C., filled prescriptions for erythromycin and the now-banned terfenadine (Seldane) without comment. These two drugs, if used in combination, can cause fatal heart arrhythmias.

- In another study, of 245 pharmacists in seven cities, about one-third of pharmacists did not alert consumers to the potentially fatal and widely publicized interaction between astemizole (Hismanal), a commonly used but now banned antihistamine, and ketoconazole (Nizoral), an often-prescribed antifungal drug. Only four out of 17 pharmacists warned of the interaction between oral contraceptives and Rimactane, an antibiotic that could decrease the effectiveness of the oral contraceptive. Only three out of 61 pharmacists issued any verbal warnings about the interaction between enalapril (Vasotec) and triamterene and hydrochlorothiazide (Dyazide) — two drugs for treating hypertension — which may lead to dangerously high levels of potassium in the blood.

- In yet another study, concurrent use of terfenadine (Seldane) and contraindicated drugs declined over time. The rate of same-day dispensing declined by 84 percent, from an average of 2.5 per 100 persons receiving terfenadine in 1990 to 0.4 per 100 persons during the first six months of 1994, while the rate of overlapping use declined by 57 percent (from 5.4 to 2.3 per 100 persons). Most cases involved erythromycin. Despite substantial declines following reports of serious drug interactions and changes in product labeling, concurrent use of terfenadine and contraindicated antibiotics such as erythromycin and clarithromycin (Biaxin) and antifungals such as ketoconazole continued to occur.

Patients

For too many patients, the system is stacked against you. Drug companies, doctors and pharmacists are too often making decisions that ultimately derive from what is best for the drug companies, doctors and pharmacists, and not necessarily from what is best for you. Use WorstPills.org to learn about adverse drug reactions, drug-induced diseases, dangerous drugs and safer alternatives to these drugs, and ways to save money on your prescription drug bills. ✦

Ten Rules for Safer Drug Use

Rule 1: Have 'brown bag sessions' with your primary doctor; fill out a Drug Worksheet.

It is impossible to overemphasize the importance of this first and most crucial step in preventing adverse drug reactions. Whenever you go to a doctor you have not previously seen or to one with whom you have never discussed your full drug regimen, start with a "brown bag session": Gather all prescription and over-the-counter drugs and dietary supplements that you take both on an irregular and infrequent basis and bring them to the doctor so that together you can make a list and start to fill out a Drug Worksheet.

The purpose of a Drug Worksheet is for you and your doctor (or doctors) to keep an ongoing record of all drugs you are using, the purposes for which they are being used, adverse reactions, whether the drug is working, and other information essential to the safest and most effective use of these products.

Doctors should never prescribe a drug or renew a prescription, nor should you be willing to get a new prescription, without full, up-to-date knowledge of all drugs already being taken or likely to be taken.

Before your brown-bag session with the doctor, your pharmacist may help you to fill out some of the blanks on your Drug Worksheet, included in this issue on page 8.

Once you have brought in all the drugs you are taking, ask your doctor to help you fill out the information concerning prescription drugs on the Drug Worksheet. While you may be able to answer many questions about the over-the-counter drugs or dietary supplements on your own, your doctor may be better able to answer questions about the meds that he or she has prescribed for you.

Rule 2: Make sure drug therapy is really needed.

Often, drugs are prescribed to treat situational problems such as loneliness, isolation and confusion. Whenever possible, nondrug approaches to these problems should be tried. These include hobbies, socializing with others and getting out of the house. When a person is suffering from an understandable depression after losing a loved one, for example, support from friends, relatives or a psychotherapist is often preferable to drugs such as antidepressants.

Nondrug therapy, such as weight loss and exercise, is preferable to drug therapy for such problems as mild high blood pressure and mild adult-onset diabetes. Increasing fiber and liquid in the diet is preferable to using laxatives. For swollen legs due to "bad" veins in the legs (not due to heart disease), wearing support hose is less expensive, safer and probably more effective than taking heart pills or water pills.

Drugs should rarely be prescribed for anxiety or difficulty sleeping, particularly in older adults.

A last category of "disease" for which drug therapy is rarely, if ever, appropriate is drug-induced disease (or adverse drug reactions). The proper treatment for drug-induced parkinsonism is not a second drug to treat the problem caused by the first drug, but, rather, stopping the use of the first drug.

For any condition, always consider the seriousness of the condition that your doctor is considering treating and try to make sure that the treatment is not worse than the disease. A common example of this is the overtreatment of older people with slightly high blood pressure but without any symptoms of or problems caused by high blood pressure. In most cases, treatment will make the person feel worse with no evidence of any benefit.

The guiding principle is to use as few drugs as possible in order to reduce side effects, including interactions between the larger number of drugs, and increase the odds of properly taking the drugs that are really necessary.

Rule 3: If drug therapy is needed, it is usually safer in older adults to start with a dose that is lower than the usual adult dose.

More generally, start with as low a dose as possible. In other words, "Start low, go slow." A lower dose will cause fewer side effects, which are almost always related to dose. In the elderly, some experts suggest starting with one-third to one-half the usual adult dose for most drugs and watching for side effects, increasing the dose slowly and only if necessary to get the desired effect.

Rule 4: When adding a new drug, see if it is possible to stop taking another drug.

If your doctor is considering adding a new drug, this is an opportunity to reevaluate existing drugs and eliminate those that are not absolutely essential. The possibility of an adverse drug interaction between the new drug and one of the old ones may lead to discontinuing or changing the use of a drug.

Rule 5: Stopping a drug is as important as starting it.

At least every three to six months, regularly review with your doctor the need to continue each drug being taken. For many mind-affecting drugs, such as sleeping pills, tranquilizers and antidepressants, and for antibiotics, this re-evaluation should be more frequent and sooner. The prevailing principle for doctors and patients should be to discontinue any drug unless it is essential. Many side effects have been caused by continuing to use drugs long after they are needed.

Many drugs such as antidepressants, sleeping pills, tranquilizers and others that are prescribed for an acute problem are not needed beyond a short period and cause risks without providing benefits. Slow and careful weaning off these drugs may significantly improve the user's health.

In addition to considering whether

to stop the drug, you and your doctor should discuss the possibility of lowering the dose. As mentioned, an exception to this is the use of antibiotics for the prescribed period of time, even if you are feeling better before having finished the prescribed dosage.

Rule 6: Find out if you are having any adverse drug reactions.

If you develop any of the following reactions after beginning to use any drug, contact your doctor. Ask if you really need a drug in the first place and, if you do, whether a safer drug can be substituted or whether a lower dose could be used to reduce or eliminate the adverse effect.

- *Mental adverse drug reactions:* depression, hallucinations, confusion, delirium, memory loss, impaired thinking and insomnia
- *Nervous system adverse drug reactions:* parkinsonism, involuntary movements of the face, arms and legs (tardive dyskinesia), dizziness on standing, falls (which can sometimes result in hip fractures), automobile accidents that result in injury because of sedation, and sexual dysfunction
- *Gastrointestinal adverse drug reactions:* loss of appetite, nausea, vomiting, abdominal pain, bleeding, constipation and diarrhea
- *Urinary tract adverse drug reactions:* difficulty urinating or loss of bladder control (incontinence)

If you or someone you know has any of the above problems or develops other problems after starting a new drug, notify your doctor or tell that person to notify his or hers.

Public Citizen's drug safety information Web site WorstPills.org is an excellent source of information about your drugs' side effects. Subscribers to the site may look up information about side effects and interactions of more than 500 popular drugs.

Rule 7: Assume that any new symptom you develop after starting a new drug might be caused by the drug.

If you have a new symptom, report it to your doctor.

Rule 8: Before leaving your doctor's office or pharmacy, make sure the instructions for taking your medicine are clear to you and a family member or friend.

Regardless of how old someone is, the chance of adverse reactions is high enough that at least one other person — a spouse, child or friend — should know about these possibilities. This is especially critical if the drug has side effects such as confusion and memory. For older adults, the complexities of drug use may be greater, especially for people taking more than one drug and people with physical or mental disabilities. In these cases, it is even more important to inform another person about possible adverse drug reactions.

Ask your doctor to make sure that the label on the drug states, if at all possible, the purpose for which the drug is being used. This is especially important when you are using multiple drugs but is always important as a way of increasing your and your family's or friend's participation. All information concerning the proper use of the drug should also be on the label. In addition to the label, you should get a separate instruction sheet and have it explained to you.

Rule 9: Discard all old drugs carefully.

Many people are tempted to keep and reuse drugs obtained in the past, even though their condition has changed. Additional drugs used may make the earlier drugs much more dangerous. In addition, you may be tempted to give drugs, such as antibiotics, to a friend or relative who you believe may benefit from them. Resist these temptations and avoid further problems caused by using outdated drugs by throwing them away when you are done with your course of therapy.

Rule 10: Ask your primary doctor to coordinate your care and drug use.

If you see a specialist and he or she wants to start you on new medicines in addition to the ones you are on, check with your primary doctor first — usually an internist or general or family practitioner. It is equally important to use one pharmacist, if possible.

See Drug Worksheet on page 8

Drug Worksheet for Patients, Family, Doctor and Pharmacist

Name _____ **Page** _____

Primary Doctor's Name _____ **Doctor's Telephone** _____

Generic Name of Drug / Brand Name of Drug	Doctor, date started & changes	Reason why prescribed or changed?	Dose? (Each time)	Times per day	What time of day?	How long should you take drug? days/ weeks/ months	Problems to watch out for which this drug can cause	Interactions of this drug with other drugs or food; diet recommendations	How are you actually taking the drug?	New problems or complaints since drug started (Date it began?)	Is drug working?

Instructions:

1. Include all drugs you take including aspirin, herbs, vitamins and other nonprescription products as well as prescription drugs.
2. When you change doses draw a single line through the old dose.
3. Bring this with you every time you go to a doctor or pharmacist.
4. Be straightforward with your doctor and yourself about how often you take medicine and why.

Product Recalls

February 13, 2010 - March 15, 2010

This chart includes recalls from the Food and Drug Administration (FDA) Enforcement Report for drugs and dietary supplements, and Consumer Product Safety Commission (CPSC) recalls of consumer products.

DRUGS AND DIETARY SUPPLEMENTS

The recalls noted here reflect actions taken by a firm to remove a product from the market. Recalls may be conducted on a firm's own initiative, by FDA request or by FDA order under statutory authority. If you have any of the drugs noted here, label them "Do Not Use" and put them in a secure place until you can return them to the place of purchase for a full refund. You can also contact the manufacturer. If you want to report an adverse drug reaction to the FDA, call (800) FDA-1088. The FDA Web site is www.fda.gov. Visit www.recalls.gov for information about FDA recalls and recalls issued by other government agencies.

Recalls and Field Corrections: Drugs – Class I

Indicates a problem that may cause serious injury or death

Name of Drug or Supplement; Problem; Recall Information

Vicks Sinex Vapo Spray (Oxymetazoline HCl) Nasal Spray 0.05%, 15 mL bottle, OTC, UPC 3 23900 01253 0. 44,352 bottles. Microbial Contamination of Non-Sterile Product: Product may be contaminated with bacteria Burkholderia cepecia. A stability sample had failed microbial content testing. The microbial content was 8560 cfu/ml for total aerobic count (specification maximum is <100 cfu/ml). Lot #: 9239028831; Procter & Gamble Co.

Recalls and Field Corrections: Drugs – Class II

Indicates a problem that may cause temporary or reversible health effects; unlikely to cause serious injury or death

Alka-Seltzer Plus Day & Night Cold Formulas Liquid Gels is an OTC product. The Alka-Seltzer Plus Day & Night Cold Formulas (combination pack only) contains 20 capsules per carton (12 day formulation capsules and 8 night formulation capsules) with NDC number is 0280-115--20, and the UPC number is 0-16500-53777-9. 107,520 boxes. Labeling: Label Mix-Up: Firm is recalling one lot of Alka Seltzer Plus Day & Night Cold Formulas Liquid Gels (combination pack only) after identifying that the label on the foil blister card of certain packages were printed with the label reversed. Therefore, the label for the green Night product appears under some of the blue Day product and vice versa. All individual liquid filled capsules are imprinted correctly. Lot #: 296939L, exp. date 05/2011; Bayer Healthcare, LLC.

Allergy relief (diphenhydramine HCL) capsules, 25mg, 100-count bottle, OTC; Distributed under the brand names: 1) Target, NDC 11673-310-13, UPC 8 97882 00105 4; Allergy (Diphenhydramine Hydrochloride) capsules, 25 mg, 24-count blisters in a box, OTC; Today's Health, NDC 65905-310-31, UPC 8 43072 00353 7 Multi-Symptom Complete Allergy (Diphenhydramine HCL) capsules, 25 mg, 24-count blisters in a box, OTC; UPC 8 97882 00109 2. The product was distributed under the brand names Target, Diphendryl Allergy; Dollar General, DG Allergy; and Today's Health, Today's Health Allergy. 2,674,608 bottles and boxes. Temperature Abuse: Kirk Pharmaceuticals is recalling Diphenhydramine Hydrochloride 25mg capsules, for sub-potent assay results due to improper storage conditions of the product during transit. Lot #: BK549; Kirk Pharmaceuticals, LLC.

Amlodipine Besylate and Benazepril HCl Capsules, 5mg/10mg (equivalent to amlodipine 5 mg and benazepril 10 mg), Rx only, 1000 counts, Sandoz, NDC 0781-2272-10. 1,910 units. During sample preparation of Amlodipine Besylate & Benazepril HCl 5 mg/10 mg combination product at the 6 month stability interval, one capsule of lot F1031 did not contain the Benazepril 10 mg tablet. Lot #: F1031, exp. date 03/2012; Novartis Pharmaceuticals Corp.

Compro prochlorperazine suppositories, USP 25 mg, NDC 0574-7226-12, for rectal use Only, 12 adult suppositories, RX only. 30,708 Expanded Recall: 12,720 units. Paddock Laboratories, Inc. is conducting a voluntary recall of Compro Prochlorperazine Suppositories, USP, 25 mg, due to the failing dissolution at the 6-month stability time point. EXPANDED RECALL: Paddock has expanded the recall to include lot 8172830 due to failing dissolution results. Use of this product is unlikely to present a health risk. Lot #: 9116177 EXPANDED RECALL: Lot #: 8172830. Paddock Laboratories, Inc.

Dipyridamole Tablets, USP 25 mg, a) 100 count bottles - NDC 0527-1461-01, and b) 1000 count bottles, NDC 0527-1461-10; Rx Only; 5,137 bottles. Failed USP dissolution test requirements. Lot #s: 2008261067, exp. date 06/2010 and 2008522883, exp. date 12/2010; b) Lot numbers: 2008261068, exp. date 06/2010 and 2008522884, exp. date 12/2010; Lannett Co., Inc.

Glyburide and Metformin HCl, USP, tablets, 2.5 mg/500 mg, 1000 count bottles, Rx only, NDC 55111-696-10. 685 bottles. Adulterated Presence of Foreign Tablets: One batch of Glyburide and Metformin Hydrochloride Tablets 2.5 mg/500 mg may have Glyburide Metformin Hydrochloride 5 mg/500 mg tablets co-mingled in it. Lot #: 18007859, exp. date 04/2011; Dr Reddy's Laboratories Inc.

Pilocarpine Hydrochloride Tablets 5 mg, Rx only, 100 Tablets Sandoz; NDC 0781-5100-01. 9851 bottles of 100 tablets. One lot of Pilocarpine Hydrochloride Tablets, 5 mg may contain out of specification tablets for weight and thickness. Lot #: 100535, exp. date 03/2011; Corepharma LLC.

CONSUMER PRODUCTS

Contact the Consumer Product Safety Commission (CPSC) for specific instructions or return the item to the place of purchase for a refund. For additional information from the Consumer Product Safety Commission, call its hotline at (800) 638-2772. The CPSC Web site is www.cpsc.gov. Visit www.recalls.gov for information about FDA recalls and recalls issued by other government agencies.

Name of Product; Problem; Recall Information

Allreds Design Baby Bracelets and Pacifier Clips. The recalled bracelets and pacifier clip clasps contain high levels of lead. Lead is toxic if ingested by young children and can cause adverse health effects. Allreds Design (doing business as Hidden Hollow Beads), (866) 695-3551 or www.hiddenhollowbeads.com.

Arctic Cat Snowmobiles. Fuel can leak from the fuel pump at the fuel tank mounting screws, posing a fire hazard to consumers. Arctic Cat Inc., (800) 279-6851 or www.arctic-cat.com.

BigBox Hockey Sets. The surface coating on the boards, which are assembled together to form the floor hockey playing-field, contain excessive levels of lead violating the federal lead paint standard. Sportime, (888) 388-3224 or www.schoolspecialty.com.

Boys' Hooded Jackets. The children's jackets have drawstrings through the hood which can pose a strangulation hazard to children. In February 1996, CPSC issued guidelines (which were incorporated into an industry voluntary standard in 1997) to help prevent children from strangling or getting entangled on the neck and waist drawstrings in upper garments, such as jackets or sweatshirts. Ten West Apparel, (212) 564-1007 or www.burlingtoncoatfactory.com.

Children's Bangles. The surface coating on the bracelets contains high levels of lead, violating the federal lead paint standard. Chandigarh Fashion Inc., Consumers should immediately take the recalled bracelets from children and return the bracelets to the store where purchased for a full refund.

Children's Hooded Jackets. The jackets have drawstrings through the hood which can pose a strangulation hazard to young children. In February 1996 CPSC, issued guidelines to help prevent children from strangling or getting entangled in the neck and waist drawstrings in upper garments, such as jackets or sweatshirts. Franshaw Inc., (800) 477-3274.

Children's hooded sweatshirt sets with drawstrings. The sweatshirts have a drawstring through the hood, which can pose a strangulation hazard to young children. In Feb. 1996, CPSC issued guidelines (which were incorporated into an industry voluntary standard in 1997) to help prevent children from getting entangled at the neck and waist by drawstrings in upper garments, such as jackets and sweatshirts. LELE & Company Inc., (213) 745-8979 or www.leleforkids.com.

Children's Metal Charm Bracelets. The bracelets contain high levels of cadmium. Laboratory analysis determined that following a 24-hour incubation in simulated stomach acid, over 20,000 micrograms of cadmium were released from the snowman alone. Cadmium can be toxic if ingested by young children and can cause adverse health effects. Buy-Rite Designs, Consumers should immediately take these charm bracelets away from children and dispose of the jewelry.

Coil Nailers. The nailers could have a faulty feeder that can allow nails to be ejected sideways, posing a serious injury hazard to the user or bystanders. Hitachi Koki Co. Ltd., (800) 706-7337 or www.hitachipowertools.com.

Copco and Wild Leaf Tea Co. Bristol model and Martha Stewart Collection® Enameled Steel Tea Kettles. The handle on the tea kettle can come loose, posing a burn hazard to the consumer. Copco, (866) 255-9237 or www.copco.com.

Easy-Fold and Easy-Store Step Stools. The step stools can crack or break, posing a fall hazard to consumers. Kikkerland Design Inc., (800) 367-9444 or www.qvc.com.

Fellowes Climate Control Footrests. The footrest's fan can become blocked and overheat when used in the upright position, posing a fire hazard. Fellowes, Inc., 800-955-3344 or www.fellowes.com.

Fluke VoltAlert® Voltage Detector. The testers can fail to give an indication of live voltage, resulting in the operator falsely believing the electrical power is off, posing a risk of serious injury or death from electrical shock or thermal burns. Fluke Corporation, (888) 983-5853 or www.fluke.com/1AC-A1recall.

Gerber® Gator® Machete and Gator® Machete Jr. The saw side of the machete can stick in wood during use, and if the user's hand slips off the handle and slides forward across the machete blade, this poses a laceration hazard. Gerber Legendary Blades, of Portland, Ore., (877) 314-9130 or www.gerbergear.com.

GE Telaire Airestat and Carrier Single Beam Carbon Dioxide (CO2) and Temperature Sensors. The CO2 and temperature sensors can overheat, posing a fire hazard. GE Infrastructure Sensing Inc., (877) 243-5086 or www.gesensing.com.

CONSUMER PRODUCTS

Girls' Cargo Pocket Jackets. The drawstrings on the neck and waist of the jacket can pose a strangulation or entrapment hazard to children. In February 1996, CPSC issued guidelines (which were incorporated into an industry voluntary standard in 1997) to help prevent children from strangling or getting entangled on the neck and waist drawstrings in upper garments such as sweatshirts and jackets. Byer California DBA Amy Byer, (800) 998-2937 or www.burlingtoncoatfactory.com.

Hooded Jackets with Drawstrings. The jackets have a drawstring through the hood, which can pose a strangulation hazard to young children. In February 1996, CPSC issued guidelines (which were incorporated into an industry voluntary standard in 1997) to help prevent children from strangling or getting entangled on the neck and waist drawstrings in upper garments such as sweatshirts and jackets. Regaliti Inc., (212) 840-0202, Bobens Trading Co. Inc., (516) 433-8490 or www.burlingtoncoatfactory.com, Baycreek Inc., (212) 279-2777, Weeplay Kids LLC, (800) 505-0490 or www.weeplaykids.com.

Innovations and "At Home with Meijer" Roman Shades and Roll-Up Blinds. Roll-up Blinds-Strangulations can occur if the lifting loops slide off the side of the blind and a child's neck becomes entangled on the free-standing loop or if a child places his/her neck between the lifting loop and the roll-up blind material. Roman Shades-Strangulations can occur when a child places his/her neck between the exposed inner cord and the fabric on the backside of the blind or when a child pulls the cord out and wraps it around his/her neck. Meijer, (800) 927-8699 or www.meijer.com.

Locks All Over Boys' Hoody, All Over Skaters Boy's Hoody and Rock Mask Boy's Hoody. The hoodies have drawstrings through the hoods that pose a strangulation hazard to children. In February 1996, CPSC issued guidelines to help prevent children from strangling or getting entangled on the neck and waist drawstrings in upper garments such as sweatshirts and jackets. Brand Evolution, (877) 330-3911 or www.burlingtoncoatfactory.com.

Lutron Shading Solutions Roman Shades. Strangulations can occur when a child places his/her neck between the exposed inner cord and the fabric on the backside of the blind or when a child pulls the cord out and wraps it around his/her neck. Also, in manual Roman shades, strangulations can also occur if the shade's looped bead chain is not attached to the wall or to the floor and a child's neck becomes entangled on the free-standing loop. Lutron Electronics Co. Inc., (866) 793-4270 or www.lutron.com/CERUSromans.

Outdoor Lighting Fixtures. Improper wiring in the light fixtures poses a shock hazard to consumers. American Electric Lighting, (800) 754-0463 or www.americanelectriclighting.com.

Pumptec Electric Motor Controllers for Submersible Pump Systems. The product label can lose adhesion, exposing the circuitry. This could pose a shock hazard to consumers. Franklin Electric Co., (866) 841-6039 or www.franklin-electric.com.

Roman Shades. Strangulation can occur when a child places his/her neck between the exposed inner cord and the fabric on the backside of the shade or when a child pulls the cord out and wraps it around his/her neck. Also, strangulation can occur when a child's neck become entangled on the free-standing loop. Ethan Allen Global Inc., (888) 339-9398 or www.ethanallen.com.

Scooby Doo, Tweety and Batman Fork and Spoon Sets. The middle two prongs of the plastic fork can detach, posing a choking hazard to children. Peachtree Playthings, (800) 290-4831 or www.peachtreeplaythings.com.

Scotsman® Commercial Modular Cube Ice Machines (Modular Cubers). The solenoid, an electrical component in the product, can fail and result in an electrical arc that can pose a fire hazard. Scotsman Group LLC, (800) 541-0520 or www.scotsman-ice.com.

Therma Scarf scarves. The heat packs can overheat when heated in a microwave oven, posing a fire and burn hazard to consumers. Telebrands Corp., (800) 777-4034 or www.telebrands.com.

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certainty of harm already having been established and other countries acting accordingly for two of them, the FDA seems incapable of protecting the public.

The top leaders in the FDA, Commissioner Margaret Hamburg and Principal Deputy Commissioner Joshua Sharfstein, stated last year that the "overriding purpose [of the FDA is] protecting the public health," and that "some benefits are not worth the risk." Unless this statement is empty rhetoric with regard to drugs, Hamburg and Sharfstein must insist on the ban of these three drugs, as we have previously petitioned the agency to do. Until this is done, they will be complicit, as leaders of the FDA, in the needless, preventable deaths of hundreds or more people a year from drugs with no unique benefits, only unique, life-threatening risks. ✦

PUBLICCITIZEN
Health Letter, Public Citizen Health Research Group
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PUBLICCITIZEN Health Letter

Outrage! FDA Cautious on Food Safety, Reckless on Drug Safety

The Food and Drug Administration (FDA) has brought welcome, increased focus and action to protect people from unsafe or possibly unsafe foods. The most recent example is the massive recall of products containing hydrolyzed vegetable protein, in which the FDA stated that although "no illnesses are known to be associated with this problem of [salmonella bacterial] contamination," the agency was "taking steps to protect the public."

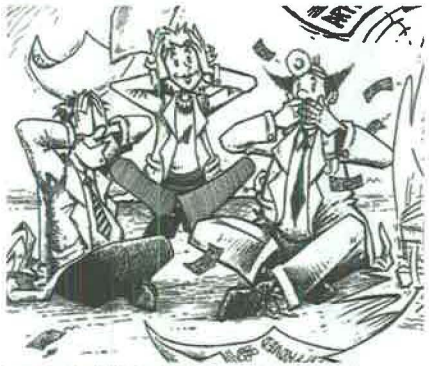

Image courtesy www.NaturalNews.com and Mike Adams

In contrast to becoming more active and cautious in enhancing food safety by removing potentially dangerous products before they have caused harm, several FDA decisions in the past year regarding prescription drugs can only be described as reckless. By deciding not to ban three drugs in particular, the FDA has endangered the lives and health of hundreds of thousands of people. For each of these drugs there is unequivocal evidence that their dangers, resulting collectively in hundreds of deaths each year, clearly outweigh their health benefits.

This evidence is so clear that two of the drugs — the pain killer propoxyphene (included in Darvocet) and the diet drug sibutramine (Meridia) — have already been removed (propoxyphene) or removal has been recommended (sibutramine) from the market in the U.K. and in Europe. The American and European diabetes associations recommended a year ago that the third drug, the diabetes drug Avandia, should not be used. In 2009, there were approximately 23 million prescriptions filled for these three drugs in the U.S.

Why is the FDA cautious on food safety but reckless on prescription drug safety? The agency has clearly made a decision to take the lead and insist on a more public health protective effort in the food area. But it has deferred to the existing, dangerously flawed leadership in FDA's Center for Drug Evaluation and Research (CDER). For foods with possible harm but no evidence yet, there have been recalls, but for these three drugs with the

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