

Health Letter

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Drugs Used to Treat High Blood Pressure

Last month, we discussed high blood pressure in detail, exploring its potential impact on health and different ways of treating it without using drug therapy. This month, we've taken another excerpt from the 2005 edition of Worst Pills, Best Pills that describes the different families of drugs that can be used to treat this condition. We'll continue our focus on treating conditions of the heart with articles on treating elevated cholesterol levels and potassium supplementation for patients taking certain types of drugs in this issue.

Diuretics

Eighteen different diuretics are available in the U.S., falling into three general categories: (1) the thiazide type, the best-known member of which is hydrochlorothiazide (ESIDRIX, HYDRODIURIL, MICROZIDE); (2) loop diuretics, which include furosemide (LASIX) (the "loop" pertains to the part of the kidney in which the drug works) and are more potent than the thiazide type for removing sodium and fluid, but are not first-choice drugs for the treatment of high blood pressure; and (3) potassium-sparing diuretics, which, as the name implies, cut down on the loss of potassium in the minority of patients whose blood levels of potassium decrease when taking thiazides or loop diuretics.

The latest revision of the National Institutes of Health's guidelines on

DIURETICS	
Generic Drug Name (Brand Name)	
Thiazide Type	
bendroflumethiazide (NATURETIN); chlorothiazide (DIURIL); hydrochlorothiazide (ESIDREX, MICROZIDE); hydroflumethiazide (SALURON, DIUCARDIN); chlorthalidone (HYGROTON); indapamide (LOZOL); methyclothiazide (ENDURON); metolazone (ZAROXOLYN, MYKROX); polythiazide (RENESE); trichlormethiazide (NAQUA)	
Loop Type	
bumetanide (BUMEX); ethacrynic acid (EDECRIN); furosemide (LASIX); torsemide (DEMADEX)	
Potassium-Sparing	
amiloride (MIDAMOR); eplerenone (INSPIRA); spironolactone (ALDACTONE); triamterene (DYRENIUM)	

high blood pressure, the Seventh Report of the Joint National Committee, or JNC VII, again recommends that thiazide diuretics should be used in the drug treatment for most patients with uncomplicated high blood pressure, either alone or in combination with other drugs.

The thiazide-type diuretics

improve survival in patients with high blood pressure. They also have been shown to reduce incidence of stroke and cardiovascular events in elderly people with a type of high blood pressure known as isolated systolic hypertension. The most widely used thiazide diuretics are hydrochloroth-

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iazide and chlorthalidone (HYGROTON).

We have long recommended, as does JNC VII, that the starting dose of hydrochlorothiazide should be 12.5 milligrams per day. For years the lowest strength available was a 25 milligram tablet that had to be broken in half to achieve the 12.5 milligram dose. There is now a 12.5 milligram capsule of hydrochlorothiazide available with the brand name Microzide.

There is growing evidence that thiazide diuretics, such as hydrochlorothiazide, significantly decrease the rate of bone mineral loss in both men and women because they reduce the amount of calcium lost in the urine. Research now suggests that thiazide diuretics may protect against hip fracture.

The loop diuretics can be used to treat high blood pressure in patients with kidney insufficiency. In those without kidney insufficiency, they may be less effective than the thiazides for the treatment of high blood pressure.

The potassium-sparing diuretics can cause dangerously elevated blood levels of potassium, particularly in patients with kidney impairment and in those taking ACE inhibitors, angiotensin receptor blockers (ARBs), or using potassium supplements.

Beta-blockers

Currently, there are 13 beta-blockers on the U.S. market. In addition to high blood pressure, some of the beta-blockers are also used to treat chest pain (angina), heart attacks, irregular heart rhythms, glaucoma, and migraine headaches.

Beta-blockers should not be taken if you have asthma, emphysema, chronic bronchitis, bronchospasm, allergies, or heart block. If you have heart failure, beta-blockers can cause dramatic improvement but must be taken under careful supervision. A baseline electrocardiogram (ECG, EKG) should be taken before a beta-blocker is first prescribed to be sure that you do not have heart block. Do

not smoke while taking a beta-blocker (you shouldn't be smoking anyway). If you smoke, you might as well stop taking the beta-blocker. Not only will smoking aggravate some of

BETA-BLOCKERS Generic Drug Name (Brand Name)

acebutolol (SECTRAL); atenolol (TENORMIN); betaxolol (KERLONE); bisoprolol (ZEBETA); carteolol (CARTROL); carvedilol (COREG); labetalol (NORMODYNE, TRANDATE); metoprolol (LOPRESSOR, TOPROL XL); nadolol (CORGARD); penbutolol (LEVATOL); pindolol (VISKEN); propranolol (INDERAL); timolol (BLOCADREN)

the respiratory adverse effects, but it greatly reduces the level of drug in your body.

Beta-blockers can cause a spasm in the air passages of the lungs (bronchospasm) and bring on asthmatic wheezing even when beta-blocker eye drops are used to treat glaucoma. Therefore, beta-blockers should not be used if you have asthma, bronchospasm, chronic bronchitis, or emphysema. If you are experiencing breathing difficulty while taking a beta-blocker, call your doctor immediately.

The following table lists the beta-blockers currently available on the U.S. market.

Alpha-blockers

This family of drugs includes doxazosin (CARDURA), prazosin (MINIPRESS), and terazosin (HYTRIN). The alpha-blockers are also used to treat benign prostatic hyperplasia, or an enlarged prostate gland.

The National Institutes of Health (NIH) no longer recommends the routine use of alpha-blockers for the treatment of high blood pressure.

In March 2000, the NIH announced that it had stopped one part of a large high blood pressure study because the alpha-blocker doxazosin proved to be less effective than the old thiazide diuretic chlorthalidone (HYGROTON) in reducing some forms of cardiovascular disease. The study, called the Antihypertensive and Lipid Lowering Treatment to Prevent Heart Attack Trial (ALLHAT), found users of doxazosin had 25% more cardiovascular events

and were twice as likely to be hospitalized for congestive heart failure as users of chlorthalidone.

Angiotensin Converting Enzyme (ACE) Inhibitors

There are now 10 angiotensin converting enzyme (ACE) inhibitors on the U.S. market. The ACE inhibitors work to lower blood pressure by preventing the production of angiotensin II, a potent, naturally occurring hormone that raises blood pressure.

The two most-studied ACE inhibitors, captopril (CAPOTEN) and enalapril (VASOTEC), are available at lower cost as generics.

All ACE inhibitors reduce blood pressure and various ACE inhibitors reduce mortality in patients with coronary artery disease. They prolong the survival of patients with heart failure after a heart attack, and preserve kidney function in those with diabetes. The ACE inhibitors may also preserve kidney function in nondiabetic patients with a kidney disorder. The table below lists the available ACE inhibitors and their FDA-approved uses.

When used in pregnancy during the second and third trimesters, ACE inhibitors can cause injury and even death to the developing fetus. You should always tell your doctor if you are pregnant or thinking of becoming pregnant before you use an ACE inhibitor.

A common adverse effect, after taking ACE inhibitors for a few weeks, is a dry, hacking cough, especially in women. Check with your doctor about a four-day withdrawal from your ACE inhibitor to determine if this is the cause of your cough. This trial withdrawal can prevent unnecessary and sometimes costly tests and treatments to determine other causes of cough.

Angiotensin Receptor Blockers (ARBs)

Seven ARBs are now on the market in the United States. These drugs work by blocking the effect of angiotensin II, a potent, naturally occurring hormone that raises blood

Generic Drug Name (BRANDNAME)	High Blood Pressure	Heart Failure	Left Ventricular Dysfunction after Heart Attack	Asymptomatic Left Ventricular Dysfunction	Acute Heart Attack	Risk Reduction of Heart Attack, Stroke, Cardiovascular Death
benazepril (LOTENSIN)	yes					
captopril (CAPOTEN)	yes	yes	yes			
enalapril (VASOTEC)	yes	yes		yes		
fosinopril (MONOPRIL)	yes	yes				
lisinopril (PRINIVIL, ZESTRIL)	yes	yes			yes	
moexipril (UNIVASC)	yes					
perindopril (ACEON)	yes					
quinapril (ACCUPRIL)	yes	yes				
ramipril (ALTACE)	yes	yes				yes
trandolapril (MAVIK)	yes	yes	yes			

pressure. In contrast, the previously mentioned ACE inhibitors prevent the production of angiotensin II in the body.

The best therapeutic role for the ARBs appears to be in patients in whom ACE inhibitors are indicated but who are unable to tolerate them.

The development of the dry, hacking cough often seen with the use of ACE inhibitors does not appear to be

as frequent with the angiotensin receptor antagonists. This family of drugs carries the same warning as ACE inhibitors about use in pregnancy.

The table below lists the available ARBs and their FDA-approved uses.

Calcium Channel Blockers

There are currently eight calcium channel blockers on the market in the United States. Despite recommenda-

tions of the National Institutes of Health's National Heart, Lung and Blood Institute dating back to 1993 that diuretics and beta-blockers should be used first in the treatment of mild to moderate high blood pressure, the calcium channel blockers remained the largest-selling family of high-blood-pressure-lowering drugs in the United States during the 1990s. In 2002, the calcium channel blocker amlodipine (NORVASC) was the fourth most frequently dispensed drug in the United States, with over 30 million prescriptions being dispensed.

The calcium channel blocker mibefradil (POSICOR) was withdrawn from the market because of harmful drug interactions.

In 1995, Public Citizen's Health Research Group filed a petition with the Food and Drug Administration to add warnings to the labeling of all calcium channel blockers about the increased risk of heart attack and death. Our petition was based on three well-conducted observational research studies.

Observational studies are frequently criticized by doctors who do not understand this type of research.

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FDA-APPROVED USES FOR ANGIOTENSIN RECEPTOR BLOCKERS				
Generic Drug Name (Brand)	High Blood Pressure	Reduce the Risk of Stroke	Prevent Kidney Damage in Diabetics with High Blood Pressure	Heart Failure in Those That Can't Take ACE Inhibitors
candesartan (ATACAND)	yes			
eprosartan (TEVETEN)	yes			
irbesartan (AVAPRO)	yes			
losartan (COZAAR)	yes	yes	yes	
olmesartan (BENICAR)	yes			
telmisartan (MICARDIS)	yes			
valsartan (DIOVAN)	yes			yes

Elevated Cholesterol Levels

Elevated cholesterol levels are another clear risk factor for heart disease. But when is drug treatment necessary? This Worst Pills, Best Pills excerpt examines who is most likely to benefit from drug treatment to reduce cholesterol and who would do better to simply focus on nondrug measures to lower their risk.

Nondrug Lowering of Cholesterol

In addition to exercise to lower cholesterol, another safe and less costly measure is to eat a low-fat diet, using mostly polyunsaturated fats (such as canola, corn, safflower, and sunflower oils) or monounsaturated fats (such as olive oil). A change from

animal to vegetable proteins often corrects high cholesterol. However, it is inadvisable to go on a very low-fat diet. The main focus on cholesterol-lowering diets has been on saturated fat and cholesterol content, not soluble fiber. (When added to the diet, psyllium or oat bran is a safe, effective way of lowering cholesterol.) Exercise and weight reduction are also recommended. Conditions that aggravate high cholesterol, such as dependence on alcohol or tobacco, diabetes, high blood pressure, low magnesium or potassium, and thyroid disease, should be corrected before adding a cholesterol-reducing drug. If cholesterol remains high despite diet, add 10 grams of psyllium (METAMUCIL,

PERDIEM) a day. Numerous studies have shown that psyllium, for example five grams twice a day, can significantly lower total cholesterol and LDL cholesterol. Psyllium, a naturally occurring vegetable fiber, is clearly safer than any of the cholesterol-lowering drugs.

Cholesterol-Lowering Drugs for People 70 and Older

It is clear that the relationship between moderately elevated cholesterol levels and increased risk of heart disease is not as clear as people get older. As geriatricians Fran Kaiser and John Morely have written: "Given the uncertainty of the effects of cholesterol manipulation in older individuals, what should be the approach of the prudent geriatrician to hypercholesterolemia (elevated blood cholesterol levels)? In persons over 70 years of age, life-long dietary habits are often difficult to change and overzealous dietary manipulation may lead to failure to eat and subsequent malnutrition. Thus in this group minor dietary manipulations such as the addition of some oatmeal (or other sources of oat bran or soluble fiber) and beans and modest increases in the amount of fish eaten, may represent a rational approach. Recommending a modest increase in exercise would also seem appropriate. Beyond this, it would seem best to remember that the geriatrician's dictum is to use no drug for which

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Most of what we know about adverse drug reactions and what we are likely to learn in the future about them comes from observational research. This type of research was used to show the link between cigarette smoking and lung cancer.

Our petition helped to bring about important labeling changes in February 1996 on one of the calcium channel blockers, the short-acting form of nifedipine. The labeling for this form of nifedipine now warns doctors that this product should not be used for the treatment of high

blood pressure because of sudden, life-threatening decreases in blood pressure that can occur.

The calcium channel blockers currently marketed in the United States are listed in the following table. ■

CALCIUM CHANNEL BLOCKERS

amlodipine (NORVASC)
diltiazem (CARDIZEM, CARDIZEM CD)
felodipine (PLENDIL)
isradipine (DYNACIRC)
nicardipine (CARDENE)
nifedipine (PROCARDIA XL)
nisoldipine (SULAR)
verapamil (COVERA HS)

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THE PUBLIC CITIZEN HEALTH RESEARCH GROUP

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there is not a clear indication.”

The use of cholesterol-lowering drugs in people 70 or older should be limited to patients with very high cholesterol levels (greater than 300 milligrams) and those who manifest cardiovascular disease (previous history of heart attack or angina).

The only large clinical trial looking exclusively at the effect of statins on people over the age of 70 provides clear evidence for avoiding these drugs for use in primary prevention of cardiovascular disease in older people who have not had a previous heart attack, stroke, angina, or other cardiovascular diseases or family history. Five thousand eight hundred and four people aged 70 through 82 were randomized to get a statin or a placebo and were followed for an average of 3.2 years. For the more than 3,200 people in this study without prior cardiovascular disease, the statin had no beneficial effect in preventing subsequent cardiovascular disease. There was, however, a significant 25% increased amount of cancer in those getting the statin, particularly gastrointestinal cancers, the cancer predicted in the animal studies of these drugs (see below). The increase was larger the greater the number of years the drug was being used. No other study analyzing cancer exclusively in large numbers of older patients getting statins has refuted this finding of increased gastrointestinal cancer.

In summary, people over 70 using statins for primary prevention of cardiovascular disease have no benefit, compared to a placebo, but an increased risk of muscle damage (rhabdomyolysis), liver damage, and, as found in the study described above, an increased risk of cancer. It needs to be emphasized, however, that for those over 70 who have had previous cardiovascular disease, the use of statins may be beneficial.

There are even questions as to whether elderly people who are hypertensive should have their cholesterol lowered by drugs. One review concluded, “Further trials are required before routinely suggesting that it is advantageous to lower

cholesterol in an elderly hypertensive who does not have pre-existing evidence of coronary heart disease.”

Cholesterol-Lowering Drugs and Cancer

Researchers from the University of California have raised questions about the correlation between an

*“Further trials are
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who does not have
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coronary heart
disease.”*

increased risk of cancer and lifelong use of cholesterol-lowering drugs by millions of people who have no signs of illness other than an elevated blood cholesterol level. This research is based on animal studies and is sure to be controversial.

Animal studies consistently show a cancer-causing effect for the two most popular classes of cholesterol-lowering drugs, the fibrates or fibric acid derivatives, which include clofibrate (ATROMID-S) and gemfibrozil (LOPID), and the widely used statin drugs, fluvastatin (LESCOL), lovastatin (MEVACOR), pravastatin (PRAVACHOL), and simvastatin (ZOCOR). Evidence of a cancer-causing effect from these drugs based on clinical trials in humans is inconclusive because of inconsistent results and a follow-up period that, to date, is too short to detect some cancers that can

take years to develop. The ultimate effect of cholesterol-lowering drugs in humans may not be known for decades.

As part of the Food and Drug Administration’s requirements for getting a new drug approved, companies are required to report the result of cancer experiments on rodents (rats and mice). The most common technique is to give three groups of rodents different doses of a new drug for two years and then compare the incidence of cancer among these groups as well as with a fourth group that received a dummy drug called a placebo. Rats and mice are used because almost all known agents that cause cancer in humans have been found to cause it in these animals. The results of rodent studies are generally not published in scientific journals, but are summarized in a product information sheet, or “package insert,” distributed to the pharmacist with each prescription drug. You can get a package insert for any drug you are taking by asking your pharmacist for one.

Researchers have taken the rodent cancer data from the 1992 and 1994 editions of the *Physicians’ Desk Reference* (PDR, a compilation of package inserts available in many public libraries). The package inserts for cholesterol-lowering drugs show that all the fibrates and statins cause cancer in rats and mice. In most instances, cancer-causing dose levels corresponded to maximums recommended for humans.

How should consumers weigh the worrisome but uncertain risk of cancer based on animal studies against the demonstrated benefits of lowering cholesterol? With some caution.

On the one hand, the study’s authors clearly state that they do not know whether treatment with these cholesterol-lowering drugs will lead to an increased rate of cancer in coming decades. They believe that, for patients with known heart disease, the recent studies suggest that benefits of cholesterol-lowering drugs exceed their risks, at least in men and in the short term (five years). Given the strength of this

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CHOLESTEROL LEVELS, from page 5 evidence, it is reasonable to treat high blood cholesterol with drugs in patients with heart or other atherosclerotic disease. On the other hand, for patients not at high short-term risk of heart disease (especially patients with life expectancies of more than 10 to 20 years), drug treatment should probably be avoided. For this group, the benefits of treatment are smaller and the potential risk of increased cancer in the decades after treatment is of greater concern. The authors suggest that cholesterol-lowering drug treatment should be avoided except in patients at high short-term risk of coronary heart disease.

This question of whether the risks of cancer may outweigh the benefits has been answered, at least for older people, in a study published six years after the above-mentioned review of animal evidence of carcinogenicity was published. For those over 70 without previous cardiovascular disease, there was no benefit but there was an increased risk of cancer, especially gastrointestinal cancer as discussed in the section on cholesterol-lowering drugs for people 70 or older.

When Is Drug Treatment Necessary?

Several factors should be taken into account when considering whether people with elevated cholesterol levels should be treated. One is the benefits of the treatment, which vary significantly depending on how abnormal the levels are. Other factors include your age and whether you have other risk factors such as high blood pressure, smoking, or diabetes, and whether you have had a heart attack, heart failure, a stroke, or have kidney damage. The other consideration is the risks or the adverse effects of the treatment, which will vary depending on what is being considered.

Although there is clear evidence that certain of the statin drugs not only lower total cholesterol and LDL cholesterol (the “bad” cholesterol) but also decrease the risk of heart attacks and strokes, this evidence is strongest for people who are at much higher risk of these diseases because

they have already had a heart attack, angina, bypass surgery or angioplasty, or a stroke. The treatment of such people to reduce the chance of further cardiovascular disease is known as secondary prevention.

The evidence for treatment, especially with cholesterol-lowering drugs, is much weaker for people who have not yet had the cardiovascular disease described above, known as primary prevention. This is especially so for those people who do not have more than one of the following risk factors: hypertension, diabetes, smoking, obesity, or a close family history of premature heart attacks or strokes. Other predisposing risk factors include a sedentary lifestyle and a high-fat diet. It is likely that millions of people being given cholesterol-lowering drugs such as statins for primary prevention do not have more than one of these risk factors and are only being treated because of their total cholesterol or LDL cholesterol levels.

The following examples are applicable to people who do not have cardiovascular diseases such as heart attack, angina, heart failure, or stroke and who are between the ages of 30 and 74. The results are from an on-line cardiovascular risk calculator that can be found at www.widebaydgp.org.au/Resources/5yrRiskCalc.xls.

Example A: Ben is a 55-year-old man with a total cholesterol of 240 and an HDL of 50. However, his blood pressure is a normal 120/90 and he is neither a diabetic nor does he smoke. Ben turns out to have a 5-year risk of having a cardiovascular event (heart attack, stroke, etc.) of only 5.1%, about one-half of the 5-year risk of over 10% that might merit drug treatment. It would be a good idea for Ben — or most people, for that matter — to adopt the nondrug approaches to lowering his cholesterol discussed above, but since his global risk is as low as it is, drug treatment is not indicated even if his total cholesterol and HDL cholesterol stay the same.

Example B: Sally is a 65-year-old woman who, like Ben above, has a total cholesterol of 240, an HDL of 50, a normal blood pressure of 120/90 and is neither a diabetic nor smokes. She turns out to have a 5-year risk of having a cardiovascular event (heart attack, stroke, etc.) of only 5.0%, similar to Ben's even though she is 10 years older, and she also has one-half of the 5-year risk of over 10% that might merit drug treatment.

There is little doubt that many Sallys and Bens are being treated with drugs to lower their cholesterol even though their global risk of having a heart attack or stroke over the next five years is as low as it is. This is because most doctors focus on just one risk factor—in this case cholesterol — instead of examining the total picture including blood pressure and other factors.

Example C: David is a 55-year-old man who, like Ben above, has a total cholesterol of 240, but a lower HDL of 30, a slightly higher blood pressure of 130/90, and does not smoke but is a diabetic. David turns out to have a 5-year risk of having a cardiovascular event (heart attack, stroke, etc.) of 16.1%, more than three times higher than that of either Ben or Sally and well above the 5-year risk of over 10% that might merit drug treatment. If this has not already been done in the context of treating his diabetes, David should start a program of exercise and diet to see if his total cholesterol can be lowered (and HDL — the “good cholesterol” — increased), and then, if total cholesterol still remains elevated, a drug to lower cholesterol, such as niacin-containing drugs or statins should be tried. It is likely that an exercise and diet program would also lower his mildly elevated blood pressure. ■

Who Needs Nondietary Potassium Supplementation?

Very few people actually need to take a potassium supplement or a potassium-sparing diuretic. If, however, you take digoxin, have severe liver disease, or take large doses of diuretics (water pills) for heart disease, eating a potassium-rich diet may not be sufficient to replace the potassium that you are losing. If you fall into one of these categories, it is very important for your doctor to precisely monitor and regulate the amount of potassium in your bloodstream. A potassium supplement or a potassium-sparing diuretic may be necessary. Read about the methods of increasing the potassium in your body discussed below and consult with your doctor about which will be best for you.

Who Does Not Need It?

Most people taking a thiazide diuretic (hydrochlorothiazide or metolazone, for example) for high blood pressure (hypertension) do not need potassium-sparing diuretics or potassium supplements. This is especially true if treatment is started at a low dose (12.5 milligrams of hydrochlorothiazide for treatment of mild hypertension). Supplementing the diet with potassium-rich foods or beverages (see tables below) is sufficient to prevent low levels of potassium.

Mild potassium deficiency (between 3.0 and 3.5 millimoles of potassium per liter of blood) can occur during diuretic therapy, but it usually has no symptoms and requires no treatment other than eating foods that are rich in potassium. Most people do not get severe potassium deficiency (less than 3.0 millimoles per liter) from treatment with diuretics. Comparisons of people eating a potassium-rich diet, people taking potassium supplements, and people taking potassium-sparing drugs have shown that (1) diet is the safest method of replacing potassium and (2) potassium supplements and potassium-sparing drugs return potassium levels to normal in only 50% of the users. Therefore, if you have mild potassium deficiency, eat a few bananas before risking the adverse

POTASSIUM LEVELS IN MILLIEQUIVALENTS (mEq) OF SELECTED FOODS AND POTASSIUM SUPPLEMENTS		
Potassium Source	Amount	(mEq)
Peaches, dried, uncooked	1 cup	39
Raisins, dried, uncooked	1 cup	31
Dates, dried, cut	1 cup, pitted	29
Apricots, dried, uncooked	17 large halves	25
Figs, dried	7 medium	23
Prune juice, canned	1 cup	15
Watermelon	1 slice (1 1/2 inches)	15
Banana	1 medium	14
Beef round	4 ounces	14
Cantaloupe	1/2 (5 inches in diameter)	13
Orange juice, fresh	1 cup	13
Turkey, roasted	3 1/2 ounces	13
Klotrix Tabs	1 tablet	10
Kaon Cl-10	1 tablet	10
Milk, whole, 3.5% fat	1 cup	9
Slow-K	1 tablet	8
Kaon-Cl	1 tablet	6.7

effects of potassium supplements or potassium-sparing drugs. Ask your doctor what your potassium levels were before and after you started diuretic treatment. You probably do not need a nondietary potassium supplement or potassium-sparing drug.

Three Ways to Increase Your Potassium Levels

The safest and least expensive way is to increase the amount of potassium-rich food in your daily diet. This will provide sufficient potassium replacement for the overwhelming majority of people taking diuretics (people who also take digoxin or who have liver disease may be exceptions).

Restricting sodium (salt) intake also helps to maintain potassium levels while lowering sodium levels. In fact, salt substitutes containing potassium chloride may be an additional source of potassium intake. If you are already taking potassium supplements or potassium-sparing diuretics, consult your doctor before using salt substitutes. A dosage adjustment may be necessary to prevent too much potassium in the body, a potentially fatal condition.

Potassium supplements are a second method for replacing potassi-

FOODS HIGH IN POTASSIUM	
All-bran cereals	Lentils
Almonds	Liver, beef
Apricots (dried)	Milk
Avocado	Molasses
Bananas	Peaches
Beans	Peanut butter
Beef	Peas
Broccoli	Pork
Brussels sprouts	Potatoes
Cantaloupe	Prunes (dried)
Carrots (raw)	Raisins
Chicken	Shellfish
Citrus fruits	Spinach
Coconut	Tomato juice
Crackers (rye)	Turkey
Dates and figs (dried)	Veal
Fish, fresh	Watermelon
Ham	Yams

um, but these can cause serious adverse reactions. Potassium is an irritant to the mucous membranes that line the mouth, throat, stomach, and intestines. If not properly dissolved and dispersed in the digestive tract, potassium can come in contact with these membranes and cause bleeding, ulcers, and perforations. Use of potassium supplements, because of serious potential adverse effects, should be restricted to people who are eating plenty of potassium-rich foods, yet still have a low level of potassium in their blood

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Product Recalls

January 24, 2006 — February 15, 2006

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.

DRUGS AND DIETARY SUPPLEMENTS

CLASS II Recalls

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

Name of Drug or Supplement; Problem; Recall Information

Adrenalin Chloride Solution, Epinephrine Nasal Solution, USP, 1 mg per mL, 30mL, Vasoconstrictor, For Topical Application; Split cap thread defects which may lead to a lack of sterility assurance. Lot numbers: 01184M, exp 01/06; 009N4M, exp 03/06; 02325M, exp 08/06, Parkedale Pharmaceuticals, Inc., Rochester, MI

Children's Tylenol Strawberry Suspension 4 oz. Acetaminophen (APAP) 160 mg per 5 ml suspension; Presence of particulate matter: product intended for destruction due to a piece of latex glove found on a mesh screen was possibly diverted to retail stores. Lot number JFM184 exp 6/06, McNeil Consumer & Specialty Pharmaceuticals, Fort Washington, PA

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(less than 3.0 millimoles per liter).

There are several kinds of potassium supplements:

- **Liquids:** Liquid supplements are safer than tablets because, when taken in a diluted form over a five- to ten-minute period, potassium is effectively dispersed in the digestive tract, and thus causes less stomach and intestinal irritation and ulceration. Packaged as a liquid, powder, or dissolvable tablet, all forms must be completely dissolved in at least one-half cup of cold water or juice before drinking, and then sipped slowly over five to ten minutes

- **Extended-release tablets or capsules:** Although liquid supplements are safest, tablets and capsules are widely used to avoid the unpleasant taste of the liquids. Rarely, but often unpredictably, these tablets and capsules can cause stomach and intestinal ulcers, bleeding, blockage, and perforation when the potassium in the

tablets and capsules does not dissolve and comes in contact with the lining of the digestive tract. Abdominal pain, diarrhea, nausea, vomiting, and heartburn have also been reported. Because the amount of time required for food to be digested and travel through the digestive tract increases with age, older people are more likely to experience adverse effects with these tablets or capsules. Increased transit time leaves more opportunity for an undissolved or partially dissolved tablet or capsule to damage mucous lining.

- **Enteric-coated tablets:** Avoid these. "Enteric-coated" potassium tablets are not reliably absorbed and have frequently been blamed for intestinal ulceration.

The last method for increasing potassium levels is with a of drugs called potassium-sparing diuretics. Examples of these drugs are spironolactone (ALDACTONE), triamterene (DYRENIUM), and amiloride (MIDAMOR). Potassium-sparing diuretics are also

found in combination products such as Moduretic and Aldactazide. These should not be used for older adults. These drugs can cause potentially fatal adverse effects such as kidney failure and the retention of too much potassium, which causes irregular heartbeats and heart rhythm. Studies have shown that the potassium supplements discussed above are equally effective and less dangerous than potassium-sparing diuretics, if nondietary potassium replacement is required.

If you are taking a potassium-sparing diuretic, you should never also use a potassium supplement or salt substitute containing potassium. You also should not use an ACE inhibitor such as captopril (CAPOTEN) with potassium supplements because of the risk of high levels of potassium. Too-high levels of potassium, a potentially fatal condition that may not produce warning symptoms, may develop rapidly. ■

DRUGS AND DIETARY SUPPLEMENTS

CLASS II Recalls *cont'd.*

Name of Drug or Supplement; Problem; Recall Information

Children's Motrin Dye Free 4 oz bottles Berry Flavor; Product intended for destruction due to foreign organic material/black speck was possibly diverted to retail stores. Lot number FPM009 exp 11/05, McNeil Consumer & Specialty Pharmaceuticals, Division of McNeil, Fort Washington, PA

Citrucel FiberShake Chocolate .38 oz Packets which are distributed individually as well as in a 5 count starter kits. Methylcellulose (a non-allergenic fiber) 2g. Bulk-forming laxative; During stability testing of non-commercial/undistributed lots, packets were found to exceed "Total Coliforms" specification of NMT 10 cfu/g at the 12 month station. All lots: Case lots with have an A or N() after the lot number, GlaxoSmithKline, Parsippany, NJ

Histex I/E Capsules (Carbinoxamine Maleate) 2mg/8mg, 60 count bottles and bulk containers, Each capsule contains: Carbinoxamine Maleate 2mg designed for immediate-release to provide rapid action, Carbinoxamine Maleate 8mg in a specially prepared base to provide extended-release action, Rx Only; 60 count bottles; Product does not meet dissolution specifications. Numerous lot numbers, PharmaFab Lp, Grand Prairie, TX

Mylanta Gelcaps (Calcium Carbonate 550mg) 50 solid gelcaps, Microbial Contamination: product intended for destruction due to pseudomonas aeruginosa found in water port was possibly diverted to retail stores. Lot number JDM166 exp 3/06, McNeil Consumer & Specialty Pharmaceuticals, Division of McNeil, Fort Washington, PA

Simply Sleep (Diphenhydramine HCl-25 mg) Nighttime Sleep Aid, 130 mini-caplets, and 100 mini-caplets OTC; Presence of foreign tablets: product intended for destruction due to foreign tablets found in filler was possibly diverted to retail stores. Lot number JJM120 exp 7/06 and Lot number JJM121 exp 7/06, McNeil Consumer & Specialty Pharmaceuticals, Division of McNeil, Fort Washington, PA

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 their 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; Manufacturer and Contact Information

Baby Walkers. Walkers can fit through a standard doorway and are not designed to stop at the edge of a step. Babies using these walkers can be seriously injured or killed. Ace Han Corp. (800) 521-5115, Bike Pro, Inc., (800) 261-2559 and SunTome Trading Corp., (888) 786-8663

Boilers. Blower assembly is not properly sealed. GV Series. Gas can leak during operation and accumulate. If an ignition source is present, a fire or explosion could occur. Weil-McLain Company (219) 879-6561

Children's Outerwear. Garments have a drawstring through the hood, posing a strangulation hazard to children. Steve & Barry's University Sportswear, (877) 866-7776 or www.steveandbarrys.com

Electric Smokers. Models BTST02 (stainless steel) and BTIS1 (black). These units have an electric cord with prongs on both ends that connect the generator to the smoker. If the unit is plugged into the wall socket and one end of the connecting cord is unplugged, there is an electric shock hazard. Bradley Technologies (Canada) Inc., (800) 665-4188 or www.bradleysmoker.com

Espresso Makers. Models 889-45 and 890-41. Electrical connectors in the espresso machine can erode, posing a fire hazard. Krups 866-832-7690 or www.krupsrecall.com

Fans. Lasko, General Electric, Galaxy, and Air King Brand Box and Pivoting Floor Fans. An electrical failure in the motor can pose a fire hazard to consumers. Lasko Products Inc. (800) 984-3311 or www.laskoproducts.com

Fire Extinguishers. Dry Chemical extinguishers model numbers WBSF-ABC110AP, WBSF-ABC210AP, and WBSF-ABC340AP. Extinguishers can fail to discharge properly when trigger is activated, putting consumers at risk of fire-related injuries. Strike First Corporation of America, (800) 255-5515 or www.strikefirstusa.com

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OUTRAGE, from page 12

providers report that they work with people who show poor clinical judgment. However, the problems seem to be concentrated among about 10 percent of their colleagues,

- Fewer than 10 percent of doctors, nurses and other caregivers said

they directly confront colleagues about their concerns. One-fifth of the doctors said they've seen harm come to patients as a result of the behavior of those colleagues.

Kathy McCauley, president of the nurses' association, concluded that "Everything that's been learned about

reducing mistakes says that people must be able to share information freely. We must build environments that support and demand greater candor among staff if we are to make a demonstrable impact on patient safety." ■

CONSUMER PRODUCTS cont.

Name of Product; Problem; Manufacturer and Contact Information

Heaters. Model CH920Maxi-Heat™ Dream Tower Heaters. The Wires inside oscillating heater can short circuit and spark, posing a fire hazard to consumers. King of Fans Inc. (866) 443-1291 or www.kingoffans.com

Leaf Blowers. Homelite Vac Attack II Model number UT08542 or UT08542A. Blowers are missing the doors covering the vacuum inlet, exposing the blower's fan blade, posing a risk of finger laceration to the user. Homelite Consumer Products Inc. (800) 242-4672 or www.homelite.com

Paintball Markers. Blade Turbo™ and Paintball Breakout Players Kit. Carbon dioxide cartridges can be forcibly ejected out the back of the and break the plastic screw-on cap posing a serious risk of injury to the operator. Overtightening the screw-on cap after cartridges are pierced can result in a serious impact injury. Brass Eagle, (866) 363-8241 or <http://www.brasseagle.com>

Phone Batteries. Lithium Ion batteries in SoundStation2W wireless conference phones. Batteries can overheat, which could pose a fire or burn hazard. Polycom Inc., (800) 917-5738 or www.polycom.com/2WBattery

Pilates Balls. Plastic black clips at the end of the rubber tubing can come apart when in use. In addition, the grommet used to hold the black rubber tubing could separate from the nylon webbing. abc distributing LLC., (866) 736-3654 or www.abcdistributing.com

Propane Convection Heaters. 40-80,000 BTU Portable Models Reddy Heater (RCP80VC), All-Pro (SPC-80CC), MASTER (TC80VC), Universal (80-CC), and Dayton (6BY73) with serial numbers between 017390000 and 017632220. Burners can "flashback," when fire burns inside the burner tube rather than out the end — lower portion of burner tube can get hot enough to ignite combustible material under the heater. DESA Heating Products. (866) 279-3225 or www.desatech.com

Routers. Porter-Cable 890 Series models 891, 892, 893PK, 894PK, 895PK, 8902. The motor coil insulation can be worn away by vibration from the motor, which could pose a shock hazard. Porter-Cable. (800) 949-6348 or www.porter-cable.com

Safety Kits. Auto Safety Kits, Auto Aid in a Bottle Kits, Winter Safety Kits, and Outdoorsman in a Bottle Kits. Products have flashlight that relies on a powerful magnet and copper coil for manual recharging. Magnet adversely affects the polarity of the compass rendering it unreliable. The magnet could be powerful enough to disrupt a heart patient's Implantable Cardiac Defibrillator (ICD). Product's packaging lacks appropriate warning information. L.L. Bean (800) 555-9717 or www.llbean.com

Sewing Machines. Designer I Sewing and Embroidery Machines. Electrical arcing can occur in the machine's power supply, posing a risk of fire. VSM Sewing Inc. (Husqvarna Viking) (800) 446-2333 or www.husqvarnaviking.com

Sweatshirts. Garments have a drawstring through the hood, posing a strangulation hazard to children. The Black Dog Tavern Company Inc. (800) 626-1991 or www.theblackdog.com

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Health Care Quality?

This month's outrages are compiled from a very outspoken government web site, that of the Agency for Healthcare Research and Quality (AHRQ), found at <http://psnet.ahrq.gov>. The site is called the Patient Safety Network and is sponsored by AHRQ, which is part of the federal Department of Health and Human Services. Although the site does not talk about worst pills and best pills as we do in our book and newsletter and on our web site (www.worstpills.org), it frequently describes wholly inadequate delivery of health care. Examples include the following:

Quality of cardiopulmonary resuscitation (CPR) during in-hospital cardiac arrest. A study, published on January 19th of last year in the *Journal of the American*

Medical Association, found that CPR at a leading medical center, the University of Chicago, was seriously deficient in both components of the sometimes lifesaving procedure: the chest compression component (to pump blood out of the heart) and the assisted breathing (ventilation) component. For adults, a lay rescuer should give 30 chest compressions followed by two breaths at a rate of 100 compressions per minute.

For 28 percent of the patients, chest compression was too slow and, for 37 percent, it was too shallow. The breathing rate was too high in 61 percent of patients and 20 percent of patients experienced prolonged periods of interrupted CPR. The authors concluded that the "quality of multiple parameters of CPR was inconsistent...even when performed by well-

trained hospital staff. The importance of high-quality CPR suggests the need for rescuer feedback and monitoring of CPR quality during resuscitation efforts."

Silence Kills. This 2004 survey of physicians, nurses and other healthcare providers for the American Association of Critical-Care Nurses is available at <http://www.post-gazette.com/pg/05039/454114.stm>. The findings included the following:

- Eighty-four percent of physicians and 62 percent of nurses and other care providers have seen co-workers repeatedly taking shortcuts that could endanger patients,
- Eighty-eight percent of physicians and 48 percent of nurses and other

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