PUBLIC CITIZEN HEALTH RESEARCH GROUP

# Health Letter

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February 2006 ◆ VOL. 22, NO.2

# High Blood Pressure

High blood pressure, or hypertension, is a major contributing factor to the development of strokes, heart attacks, kidney disease, and circulation disorders. Elevated cholesterol levels can also result in an increase in heart attacks and strokes. Heart disease and stroke remain the first and third leading causes of death in the United States. More than 33 million Americans are estimated to have high blood pressure; this includes more than 14 million persons between the ages of 45 and 64. Many people with increased blood pressure also have other risk factors such as elevated cholesterol, diabetes, and smoking. But many do not. Conversely, many people with higher cholesterol levels also have high blood pressure, smoke, or are diabetic, but many have only elevated cholesterol levels. In addition, the risk of cardiovascular disease — such as heart attacks and strokes — increases with age. Thus, it is extremely important to look at the global risk of cardiovascular disease rather than focusing on just the blood pressure or just the cholesterol level.

### High Blood Pressure in Pregnancy

Antihypertensive drugs may directly or indirectly harm the fetus. If the maternal placental circulation is reduced by lowering the mother's blood pressure too much, there is the danger of immediate harm to the fetus by depriving it of an adequate supply of blood and thus of essential nourishment.

*The Merck Manual* recommends that women with preexisting mild hypertension (140/90 to 150/100 millimeters of mercury) discontinue antihypertensive drugs as soon as pregnancy is confirmed and monitor their blood pressure regularly. For patients with preexisting moderate hypertension (150/100 to 180/110 millimeters of mercury), methyldopa (ALDOMET) is the drug of choice. Women with severe hypertension (greater than or equal to 180/110 millimeters of mercury) represent a much more complicated medical condition in which less desirable drugs may be appropriate.

### Leg Swelling (Edema) in Pregnancy

The routine use of diuretics in pregnancy is inappropriate and exposes the mother and fetus to unnecessary hazards. Edema occurs in a majority of pregnant women and is not harmful to either the mother or fetus. It can often be relieved by lying down or elevating the legs.

Diuretics, a group of drugs used to treat hypertension and edema, can cause harm by reducing the mother's circulating blood volume. This reduces the amount of oxygen and nutrition available to the fetus. Diuretics can also cause low levels of sodium and potassium as well as yellow skin (jaundice) and bleeding in the newborn and have, in addition, the potential for some of the adverse effects seen in the adult. Diuretics do not prevent the development of nor are they useful in the treatment of preeclampsia (toxemia of pregnancy). Thiazide diuretics can also cross the placenta and thus have the added

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potential for direct adverse effects.

Regardless of your age, reducing your blood pressure using diet and exercise, or diuretics or beta-blockers if drug treatment is necessary, reduces your risk of heart attack and stroke.

When your blood pressure is taken, you are given two numbers, which represent the systolic pressure and the diastolic pressure — 140/90 (mm Hg — millimeters of mercury, under pressure), for example. Systolic pressure, the upper number (140), reflects the pressure in the arteries as the heart contracts, pumps blood, and the blood vessels fill with blood. As the arteries harden with age (arteriosclerosis), the systolic pressure increases. Diastolic pressure, the lower number (90), reflects the pressure in the arteries as the heart relaxes and fills with blood. This is associated with a run-off of blood from the blood vessels.

A person's blood pressure can be higher when measured at the doctor's office than when measured at home; feeling nervous probably contributes to the higher reading. Ask your doctor about the various methods available for home monitoring of blood pressure, so you can see if yours is lower at home. If so, it is possible that you actually do not have high blood pressure and do not have to be treated.

Either your systolic or your diastolic pressure can be elevated. Elevations of either one or both of these pressures may significantly increase your chance of having a stroke or heart attack, much more so in the presence of other risk factors as discussed above.

## Nondrug Treatment of High Blood Pressure

A healthy lifestyle is critical for the prevention of high blood pressure and is an essential part of the management of those with hypertension. Major lifestyle modifications shown to lower high blood pressure include weight reduction in those who are overweight or obese. In addition, sodium reduction and a diet rich in vegetables, fruits, and low-fat dairy products lowers blood pressure in both those with and without hypertension. For example, a 1,600 milligram sodium restriction has effects similar to treatment with a single blood-pressure-lowering drug. Exercise and moderate alcohol intake are also beneficial in maintaining a healthy blood pressure.

A study of nutritional therapy showed that over one-third of people who previously needed drug treatment for high blood pressure were able to adequately control their blood pressure with nutritional therapy alone. In addition, these methods are safer than using medication, since they have no adverse effects. Trying them will often make other beneficial contributions to your health.

1. Lose weight: Nearly two-thirds of adults in the United States are overweight, and 30.5 percent are obese, according to data from a 1999-2000 National Institutes of Health survey. Many people in this category who lose weight can reduce their blood pressure by 15 percent.
2. Reduce your salt intake: Changing your diet by not using your salt shaker and reducing your intake of processed and salty foods is a good first step.
3. Restrict alcohol: Cutting alcohol intake to, at most, one drink a day also can reduce blood pressure.
4. Exercise: Mild aerobic exercise such as walking 15 or 20 minutes a day at a comfortable pace will have a beneficial effect on heart and blood pressure.
5. Decrease your fat intake: Decreasing the amount of animal fat in your diet has a beneficial effect on blood pressure. Furthermore, a high-fat diet is a risk factor for heart disease independent of high blood pressure. Decreasing the amount of fat in your diet will therefore help reduce your overall risk of developing heart disease.
6. Increase the fiber in your diet: Diets with a high fiber content can lower blood pressure. One study showed a drop of 10 mm Hg in systolic pressure and 5 mm Hg of diastolic pressure in people who took fiber supplements for two months, without any other dietary changes. Fiber can be increased by eating more fruits, vegetables, and whole grains.

In a clinical trial performed on people 60 to 80 years old with well-controlled blood pressures, who had been taking a high-blood-pressure-lowering drug for years, found that keeping salt intake to 1,800 milligrams per day or less and losing a moderate amount of weight (on the order of 10 pounds) were responsible for further significant decreases in blood pressure while continuing drug treatment. At the end of the study more than 30 percent of the patients had lowered their blood pressure enough through salt reduction and weight loss to no longer require blood-pressure-lowering drugs. Salt reduction was equally effective in overweight and nonoverweight participants and was as effective as weight reduction in preventing recurrence of high blood pressure, need for a blood-pressure-lowering drug, or a cardiovascular event such as a stroke, heart attack, or chest pain (angina). Salt reduction combined with weight loss was more effective than either alone for control of high blood pressure, with or without the use of a blood-pressure-lowering drug.

Decades of extensive research now make it possible to speak in terms of preventing high blood pressure rather than treating it with drugs, which is defensive, mainly reactive, time-consuming, associated with adverse drug effects, costly, only partially successful, endless, and not a cure. In the editorial that accompanied the study the author said: "Hence, there is now evidence for a 'fare for all seasons,' to be consumed from post weaning through older age, to prevent adverse BP [blood pressure] levels, other major risk factors, and cardiovascular and other chronic diseases. This fare is delectably high in fruits and vegetables; high in legumes and whole grains; high in fat-free and low-fat dairy products, poultry, fish, shellfish, and meats; high

in all essential nutrients; reduced in salt; reduced in total fat, saturated fat, and cholesterol; with no more than 2 drinks per day for those who choose to ingest alcohol; and controlled in calories to prevent or correct obesity."

### When Is Drug Treatment Necessary?

Several factors should be taken into account when considering whether your high blood pressure should be treated. One is the benefits of the treatment for your blood pressure, which vary significantly depending on how high it is, your age, and whether you have other risk factors such as high cholesterol or are a smoker or a diabetic, 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.

Several studies have shown that the treatment of an elevated diastolic pressure does decrease your chance of having a stroke or heart attack. However, if only your systolic pressure is elevated, which often occurs in older adults, it is controversial as to what benefits are gained by treatment. Doctors generally agree that systolic blood pressure readings above a certain level — such as 160 — are dangerous enough so that they require treatment. Treatment of systolic blood pressure below these levels is more controversial.

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

**Example A:** John is a 50-year-old man with a blood pressure of 160/90. With the upper limit of normal being 140/90, he has what is referred to as isolated systolic hypertension because of his systolic pressure of 160. However, John has a normal total cholesterol of 193 and a normal HDL (the "good" cholesterol) of 50. HDL is referred to as "good" cholesterol because it protects against coronary artery disease. He does not have diabetes, is not a smoker, has never had angina, a heart attack or heart failure, and does not have kidney damage. John turns out to have a 5-year risk of having a cardiovascular event (heart attack, stroke, etc.) of 6.2 percent, well under the 5-year risk of over 10 percent that might merit drug treatment. It would be a good idea for John — or most people, for that matter — to adopt the nondrug approaches to lowering his blood pressure discussed above, but since his global risk is as low as it is, drug treatment is not indicated even if his blood pressure stays the same.

**Example B:** Mary is a 60-year-old woman, also with a blood pressure of 160/90. Like John, Mary has a normal total cholesterol of 193 and a normal HDL (the "good" cholesterol) of 50. She also does not have diabetes, is not a smoker, and has never had angina, a heart attack, heart failure, or kidney damage. Using the same risk calculator, Mary's 5-year risk of having a cardiovascular event is 6.8 percent, about the same as John's even though she is 10 years older. Again, there is no reason for her to have drug treatment for her isolated systolic hypertension because her global risk is low.

There is little doubt that many Marys and Johns are being treated with drugs for high blood pressure even though their risk of strokes and heart attacks is as low as it is. This is because most doctors focus on just one risk factor — in this case blood pressure — instead of examining the total picture.

**Example C:** Larry is a 50-year-old man who also has a blood pressure of 160/90, but he is a diabetic and although his total cholesterol is also 193, his HDL is only 40 (less of the "good cholesterol"). Though his blood pressure is the same as that of John and Mary, his 5-year cardiovascular risk is 17.6 percent, more than twice as high as theirs. He should start a program of exercise and diet to see if his blood pressure can be lowered that way, and then, if it still remains elevated, a drug to treat the hypertension such as a thiazide diuretic should be tried.

Are many people being given antihypertensive drugs unnecessarily? One study found that 41 percent of patients 50 and older who were carefully taken off their high blood pressure medications did not need them, having normal blood pressure 11 months after the drug was stopped.

### Which Drug to Use?

Regardless of your age, much of the time high blood pressure can be controlled with just one drug. The National Institutes of Health's National Heart, Lung and Blood Institute recommends beginning treatment with a mild water pill (diuretic) at a low dose. The safest and best studied of the diuretics is hydrochlorothiazide (ESIDRIX, HYDRODIURIL, MICROZIDE). The starting dose should be low: 12.5 to 25 milligrams per day or even every other day. Confirming the advice we have been giving since 1988 is a large definitive study (named ALLHAT) involving more than 33,000 patients aged 55 or older that found "compelling evidence that thiazide diuretics (such as hydrochlorothiazide or chlorthalidone) should be the initial drug of choice for patients with hypertension." Thus, the widespread prescribing practice — spurred on by massive advertising — of starting people with newly diagnosed hypertension with calcium channel blockers (such as Norvasc, Cardizem, or Procardia), ACE inhibitors (such as Zestril, Accupril, or Vasotec), or other drugs that are not thiazides lacks any scientific rationale.

For older adults, in general, the rule for treating high blood pressure, as with so many other drug treatments, is "start low and go slow." According to experts in prescribing for older adults, for mild hypertension (or heart failure) start with half the standard starting dose and increase gradually.

If a second drug is needed the

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# The Unaffordably High Cost of Cancer Drugs

One problem of health care that has quietly arisen and not been publicly addressed is the multiplicity of costs associated with the use of new cancer drugs. These new drugs are being approved that add only a few months of life, are mostly marginally effective as add-ons to other drugs, cost many thousands of dollars, and produce a multitude of adverse effects which can lead to further hospitalizations, death, and/or more drug treatments. Few people are raising critical questions: What is the cost to the individual, both financially and in reduced quality of life? What is the cost to the health care system? And if there are limited health care dollars along with millions of citizens without health care, doesn't this issue merit discussion?

We use as an example the treat-

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National Heart, Lung, and Blood Institute recommends beta blockers, although they are not as effective in older adults as they are in younger adults. Because of this, beta-blockers should never be used as the first drug in treating high blood pressure in older adults. ACE inhibitors are also effective drugs to use as a second agent. It is rarely necessary to take more than two drugs to treat high blood pressure. If you are taking more than two, a reassessment is indicated.

### Common Adverse Effects of High Blood Pressure Drugs

The decision to use drugs to treat high blood pressure should be based on a consideration of both the benefits and the risks of the treatment. Therefore it is very important that you report any adverse effects of the drugs to your doctor, so that your situation can be reassessed. These are some of the possible adverse effects of the various antihypertensive drugs (see www.worstpills.org or Chapter 3 of the newest edition of *Worst Pills, Best Pills* for complete lists of drugs that cause many of these adverse effects):

- **Depression** — especially with beta-blockers, reserpine, methyldopa, and clonidine.
- **Sedation and fatigue** — especially with beta-blockers, reserpine, methyldopa, and clonidine.
- **Impotence and sexual dysfunction** — especially with beta-blockers, methyldopa, and many other heart drugs.
- **Dizziness** (from a drop in blood pressure after standing up, which can result in accidental falls and broken bones) — seen with all high blood pressure drugs to some degree, and especially with guanethidine, prazosin, and methyldopa. Older adults are more prone to this adverse effect because the internal blood pressure regulation system works more slowly as we age.
- **Loss of appetite and nausea** — especially with hydrochlorothiazide, digoxin, and potassium supplements.

These and other adverse effects can occur with any medication for high blood pressure. Those listed occur most often. If you experience any effects, or just feel worse in general, tell your doctor. It is often better to tolerate a slightly higher blood pressure with no adverse effects from medication than to have a lower blood pressure along with serious effects from medication that will adversely affect your life.

For example, let's consider the steps in devising a treatment for a 75-year-old woman whose baseline blood pressure is 200/90 mm Hg:

1. She is first treated with 12.5 milligrams of hydrochlorothiazide. This results in a blood pressure of 170/90, and she feels quite well.
2. Her doctor attempts to lower her blood pressure further by adding another drug, propranolol, to her treatment. This results in a blood pressure of 160/90, but she "feels awful" and complains of fatigue and confusion.
3. Her doctor might consider discontinuing the propranolol and using another drug. A better idea might be to accept a blood pressure of 170/90 using hydrochlorothiazide alone or to lower it further with nondrug therapy.

### Stopping Drug Treatment

Historically, patients have been taught that hypertension means treatment for life, although countless thousands of patients have abandoned their treatment without their doctors' knowledge or consent. For some patients, this may be a dangerous idea, but for many others the treatment may no longer be needed. Two large studies in Australia and Britain have shown that one-third to one-half of patients with mild hypertension for whom treatment was stopped had normal blood pressures a year or more later.

An editorial in the *British Medical Journal* stated, "Treatment of hypertension is part of preventive medicine and like all preventive strategies, its progress should be regularly reviewed by whoever initiates it. Many problems could be avoided by not starting antihypertensive treatment until after prolonged observation....Patients should no longer be told that treatment is necessarily for life: the possibility of reducing or stopping treatment should be mentioned at the outset."

This view is shared by American experts in hypertension who have stated that "once blood pressure has been normal for a year or more, a cautious decrease in antihypertensive dosage and renewed attention to nonpharmacologic treatment may be worth trying." ■

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ment of metastatic colorectal cancer. The main drugs used for its treatment are the older drug fluorouracil, and the newer drugs irinotecan, oxaliplatin, cetuximab, and bevacizumab (see Table).

Fluorouracil (with leucovorin) has been the standard treatment since the early 1960s. Fluorouracil works by blocking the formation of some of the required building blocks of DNA and RNA, which are necessary for cell division and growth. Fluorouracil is toxic but does not stay in the body long so that if there are adverse effects, they are more easily dealt with (half of the fluorouracil is gone in about 15 minutes and most is gone after 1.5 hours).

In 1996, irinotecan (Camptosar) was approved. It binds to and blocks an enzyme that is needed for DNA synthesis, causing double-strand breaks in the DNA that mammalian cells cannot efficiently repair. Irinotecan is converted in the body into a form that is about 1000 times more potent as the parent drug. In contrast to fluorouracil, this drug stays in the body a relatively long time (half is gone in about a day so it takes about a week for all of it to disappear).

In 2002, oxaliplatin (Eloxatin) was approved. Eloxatin forms chemical links with DNA preventing it from replicating and forming RNA. The drug stays in the body a very long time; it takes about 2 weeks for half the drug to be removed from the body and about 2 months for all to disappear.

In 2004, cetuximab (Erbitux) was approved. It is a monoclonal antibody that binds to the epidermal growth factor receptor, a protein that is present in cell membranes. Erbitux prevents not only the epidermal growth factor from binding to cells but inhibits other growth factors as well. Cells stop growing and begin to die. The drug stays in the body a long time; it takes about 5 days for half the drug to be removed from the body and about 1 month for all to disappear.

Also in 2004, bevacizumab (Avastin) was approved. It is a monoclonal antibody that binds to the vascular endothelial growth factor and prevents it from binding with its receptors on endothelial cells (such as the cells lining blood vessels). Avastin causes the reduction in blood vessel growth in a mouse model. This drug stays in the body a very long time; it takes about 20 days for half the drug to be removed from the body and about 4 months for all to disappear making treatment of adverse events more difficult.

An article in the *New England Journal of Medicine* in 2004 compared the financial costs of 8 weeks of treatment for metastatic colorectal cancer. Monthly fluoruracil was compared with more recently approved drugs.

The two most expensive treatments employed cetuximab, yet the FDA-approved drug label for cetuximab states that, *"Currently, no data are available that demonstrate an improvement in disease-related symptoms or increased survival with Cetuximab"*. In addition, although this drug supposedly works through blocking the epidermal growth factor receptor, the label states that there was no correlation of tumor response with either the number of receptors per cell or the percent of cells that had receptors.

And last but not least, adverse reactions increase when adding additional drugs. When cetuximab was added to irinotecan, there were increases (vs. cetuximab alone) in weakness and malaise (73 percent vs. 48 percent), abdominal pain (45 percent vs. 26 percent), diarrhea (72 percent vs. 25 percent), inflammation of the membranes of the mouth (26 percent vs. 10 percent), and decreases in white blood cells (that fight infection; 25 percent vs. <1 percent). An acneform rash of pustular-appearing

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**Treatments for Metastatic Colorectal Cancer**

| Drugs | Median duration of survival | Approval date | Cost ($) for 8 weeks[2] |
|---|---|---|---|
| **Fluororuracil** +leucovorin (=FU/LV) | Approximately 12 months | 1960s | 63 |
| **Irinotecan** alone (weekly) | Increased 2.3 months (vs. FU/LV alone[1]) | 1996 | 9,500 |
| Fluororuracil +leucovorin **+ irinotecan** | Increased 2 or 3 months (vs. FU/LV alone[1]) | 1996 | 9,400 |
| Fluororuracil + leucovorin **+ oxaliplatin** (biweekly) | No significant increase (vs. FU/LV alone[1]) | 2002 | 12,000 |
| Fluororuracil + leucovorin + oxaliplatin **+ bevacizumab** | No data (trials in progress) | 2004 | 21,000 |
| Fluororuracil +leucovorin + irinotecan **+ bevacizumab** | Increased 1.6 months [(10 mg dose) or 4.1 months (5 mg)[1]] | 2004 | 21,400 |
| Irinotecan + **cetuximab** | No significant increase (vs. irinotecan alone[3]) | 2004 | 30,800 |
| Fluororuracil + leucovorin + irinotecan + **cetuximab** | No data | 2004 | 30,700 |

[1] Label
[2] Numbers are for the May 2004 average wholesale price and are rounded off
[3] NEJM 2004;351:337

# Product Recalls

## *December 23, 2005 — January 23, 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.

### CLASS I Recalls

***Indicates a problem that may cause serious injury or death***

*Name of Drug or Supplement; Problem; Recall Information*

a) **Liqiang 1 Herbal Supplement Capsules,** (Codonopsis 67.5mg, Astragalus Root 67.5mg, Figwort Root 67.5mg, Mai Dong 45.00mg, Sciomon's Root 67.5mg, Anemarrena 37.35mg, Polygonatum 37.35mg and Tian Hua Fen 60.30mg); b) **Liqiang 4 Herbal Supplement Capsules,** (Codonopsis 67.5mg, Astragalus Root 67.5mg, Red Sage Root 13.5mg, Poria Rubra 38.25mg, White Atractylodes 67.5mg, Rehmannia 67.5mg, Chinese Wolberry Root Bark 90mg, and Wild Yam 38.25mg); c) **Liqiang 5 Capsules,** (Trichosanthes Root, Dried Rehmannia Root, Figwort Root, and Chinese Magnoliavine); Unapproved New Drug: found to contain undeclared prescription drug Glyburide. All lots and codes, Bugle International, Inc.

**Trypan Blue 0.06% Ophthalmic Solution,** packaged one cc syringes; Microbial contamination (Pseudomonas aeruginosa). Lot numbers: 08182005:43@17; 08012005:63@24; 06282005:91@27; 05252005:36@13 and 05042005:86@17; Custom-Rx Compounding Pharmacy.

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lesions occurred in about 90 percent of all patients taking cetuximab, lesions that became infected in some cases.

In 2004, reviewers at the Food and Drug Administration concluded after an analysis of the drug company studies that there were no data that "demonstrate a clinical benefit, such as improvement in disease-related symptoms or survival" by adding oxaliplatin to FU/LV therapy.

Progress in most studies is determined by the change in tumor size as determined by radiographs using X-rays. This can be misleading since tumors are composed of a number of tissue types with the non-tumor types being more susceptible to treatment. When these other tumor types die, it may look like progress, but it leaves the original tumor to regrow.

Furthermore, drugs that target DNA are not magic bullets; they are not tumor-specific and many normal cells are targeted. Certain cells grow and reproduce all the time such as blood-forming cells in the bone marrow, germinal layers of the skin, and the epithelium of the gut. One reason for gastrointestinal problems is that the cells lining the gastrointestinal tract need to be frequently replaced. By preventing these cells from dividing, a variety of new problems emerge such as those seen with bevacizumab: gastrointestinal perforations and complications of wound healing.

The Cochrane Collaboration, an independent group of specialists who analyze the medical literature, concluded in 2005 that studies of anti-cancer drugs had not provided information about these drugs' effects on quality of life. Since most clinical trials are done by drug companies that have a huge stake in getting drugs approved, this important aspect of treatment has often been left aside.

With drug sales for cancer treatments now the fastest growing drug sector and expected to double over the next five years, there is a clear need for discussion. When Avastin, for which there are no data that "demonstrate an improvement in disease-related symptoms or increased survival", is talked about on financial pages as being "on track to become a blockbuster this year at its current rate of growth", it is clear something is very wrong. In the end, several months are added to the end of life, but at what cost? ■

# 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*

**Children's Motrin Bubblegum Suspension** 4 oz bottle, Ibuprofen 100 mg/5ml; Presence of particulate matter: product intended for destruction due to white fiber material found on packaging transfer screen was possibly diverted to retail stores. Lot number HHM187, exp. date 8/2006, McNeil Consumer and Specialty Pharmaceuticals.

**Children's Tylenol Flu Suspension** 4 oz bottle. Acetaminophen 160 mg, chlorpheniramine maleate 1 mg, dextromethorphan HBr 7.5 mg, pseudoephedrine HCl 15 mg per 5 ml suspension; Presence of particulate matter: Product intended for destruction due to a small piece of black foreign material observed on the packaging screen was possibly diverted to retail stores. Lot number JAM149, exp.date 01/2006, McNeil Consumer & Specialty Pharmaceuticals.

a) **Children's Tylenol Oral Suspension,** (Acetaminophen), 160 mg/5mL (teaspoon), Bubblegum Yum Flavor; b) Children's Tylenol Oral Suspension, (Acetaminophen), 160 mg/5mL (teaspoon), Cherry Blast Flavor; Presence of foreign substance; pieces of wire tie found, product intended for destruction was possibly diverted to retail stores. a) Lot numbers: JLM121, exp. date 9/2006, and JLM122, exp. date 9/2006; b) Lot number: JLM123, exp. date 9/2006, McNeil Consumer and Specialty Pharmaceuticals.

**Children's Tylenol Plus Flu Suspension** Bubblegum Flavor 4 oz. Acetaminophen 160 mg per 5 ml, chlorpheniramine maleate 1 mg per 5 ml, dextromethorphan HBr 7.5 mg per 5 ml, and pseudophedrine HCl 15 mg per 5 ml; Presence of particulate matter: product intended for destruction due to wood found on mesh screen was possibly diverted to retail stores. Lot number JAM217, exp. date 2/2006, McNeil Consumer & Specialty Pharmaceuticals.

**Dollar General Delight brand Dishwashing Liquid Antibacterial Hand Soap,** Orange Blossom, 50 fl. oz; Microbial contamination: Contaminated with the bacteria Pseudomonas aeruginosa. Lots 10105T, 10115T and 10125T, Korex, Wixom, MI.

**Infant's Tylenol Concentrated Drops** Cherry Flavor 1/2 oz. Acetaminophen 80 mg/0.8 ml; Presence of particulate matter: Product intended for destruction due lint free cloth found in mixer was possibly diverted to retail stores. Lot number JMM075 exp. date 10/2006, McNeil Consumer and Specialty Pharmaceuticals.

**Prednisolone Oral Solution,** USP 15 mg/5mL (formerly Prednisolone Syrup, USP 15 mg/5 mL); Degradant/Impurity level exceeded specification requirements of not more than 0.50%. Lot numbers 26503A and 27163A (8 oz bottles) and 26504A, 26505A and 26625A (16 oz bottles), Morton Grove Pharmaceuticals, Inc.

**Simply Sleep Mini-Caplets,** (Diphenhydramine HCl) 25mg, Presence of particulate matter: product intended for destruction due to white fiber material found on packaging transfer screen was possibly diverted to retail stores. Lot number JFM058, exp. date 5/2006, McNeil Consumer and Specialty Pharmaceuticals.

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THE PUBLIC CITIZEN HEALTH RESEARCH GROUP
**Health Letter**



The Health Research Group was co-founded in 1971 by Ralph Nader and Sidney Wolfe in Washington, D.C. to fight for the public's health, and to give consumers more control over decisions that affect their health.

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Annual subscription price is $18.00 (12 issues). Mail subscriptions and address changes to Health Letter, Circulation Department, 1600 20th St., NW, Washington, D.C., 20009.
Our Web site address is **www.citizen.org/hrg.**

## DRUGS AND DIETARY SUPPLEMENTS

### CLASS II Recalls *cont'd.*

*Name of Drug or Supplement; Problem; Recall Information*

**Tylenol Arthritis Extended Relief Caplets** 100 count bottles. Each caplet contains acetaminophen 650 mg; Presence of particulate matter: product intended for destruction due to the possibility of broken metal pieces from the compression punches being compressed in the caplets was possibly diverted to retail stores. Lot number HAM149, exp date 1/2006, McNeil Consumer & Specialty Pharmaceuticals.

**Tylenol Sinus Nighttime Caplets,** Each caplet contains Acetaminophen 500 mg, Doxylamine succinate 6.25 mg, Pseudoephedrine HCl 30 mg; Mispacked: product intended for destruction due to foreign object (ball bearing) found in blister card was possibly diverted to retail stores. Lot number JMM087, exp. date 7/2006, McNeil Consumer and Specialty Pharmaceuticals.

## 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*

**Baseball gloves.** These Mizuno "Gamer" baseball gloves could contain aspergillus mold. Such mold usually does not affect healthy individuals, but could cause respiratory or other infections in individuals with chronic health problems or in individuals who have impaired immune systems. Mizuno USA, Inc., (800) 966-1211.

**Bicycle handlebar stems.** The recalled F99 (Force 99) Bicycle Handlebar Stems can crack or break under normal conditions, causing the rider to fall and suffer serious injury. Syntace USA, (800) 448-3876, extension 233, www.syntaceusa.com, syntaceusa@syntace.com, or Syntace USA, 1902 Miller Drive, Olney, Ill. 62450.

**Chain saws.** Stihl-brand MS 192 T chain saws can leak fuel, posing a fire hazard. A connection in the ignition grounding system could loosen and create a spark, posing a fire hazard. Also the springs in the clutch assembly could come out of position allowing a spring of the clutch to be projected from the saw housing resulting in injury to the user. Stihl Inc., (800) 610-6677 or www.stihlusa.com.

**Electric lawnmower.** When the handlebar is released on the recalled 2005 Model NEUTON® Cordless Electric Lawnmowers, the motor could continue to run, which causes the blade to continue to spin. In addition, there is excessive heat build up in the wire coil inside the housing and also in the safety key. Country Home Products, Inc, (888) 294-5029 or www.CEM-TechAlert.com.

**Fuel hoses.** 12" Braided Flex Fuel Hose sold with certain Guardian® Home Standby Air-Cooled Generators can leak if bent in an unreasonable fashion during installation or upon completion of installation. If an ignition source is present, a fire or explosion can occur. Generac Power Systems Inc., (800) 949-7440 or www.generac.com.

**Holiday lights.** These Mini Light and Chasing Light sets have undersized and exposed wires, which pose a risk of electric shock and fire hazards. Target, (800) 440-0680 or www.Target.com.

**Pilates balls.** The plastic black clips at the end of the rubber tubing of these pilates balls can come apart when in use. In addition, the grommet used to hold the black rubber tubing could separate from the nylon webbing. Consumers using the pilates balls could fall and be hit by pieces that separate. LTD Commodities and The Lakeside Collection, (866) 736-3654, (866) 847-4327, www.ltdcommodities.com or www.lakeside.com.

**Power strips.** The metal enclosure on Direct Connect 8 Power Strips is not properly grounded, which could result in an electrical shock. Neptune Systems, recall@neptunesys.com, or www.neptunesys.com/recall.

**Snowmobiles.** Cracks could appear in the starter ring gears of certain Model Year 2006 Ski-Doo REV500 SS, REV 600 HO, and REV 600 HO SDI snowmobiles, allowing gear fragmentation at high speeds. The debris could act like projectiles and cause serious injury or death to riders or bystanders. Bombardier Recreational Products Inc., (888) 864-2002 or www.ski-doo.com.

**Snowmobiles.** The steering columns of certain Model Year 2006 Ski-Doo REV, RT, and RF snowmobiles could have a missing weld, which could allow a steering component to become loose. This could lead to a loss of control or possible collision causing serious injury or even death. Bombardier Recreational Products Inc., (888) 864-2002 or www.ski-doo.com.

# Exercise in People Age 65 Years and Older Is Associated with Lower Risk for Dementia

Summaries for Patients *are a service provided by* Annals of Internal Medicine *to help patients better understand the complicated and often mystifying language of modern medicine. The full report is titled "Exercise Associated with Reduced Risk for Incident Dementia among Persons 65 Years of Age and Older." It is in the 17 January 2006 issue of* Annals of Internal Medicine *(volume 144, pages 73-81). The authors are E.B. Larson, L. Wang, J.D. Bowen, W.C. McCormick, L. Teri, P. Crane, and W. Kukull.*

### What is the problem and what is known about it so far?

Dementia is a condition that affects memory and thinking enough to interfere with normal daily activities. About 1 of every 10 Americans older than 65 years of age has some degree of dementia. Poor memory alone is not dementia, and some declines in short-term memory are normal as people age. Several diseases can cause dementia, but the 2 most common are Alzheimer disease and vascular dementia. In Alzheimer disease, the buildup of abnormal proteins damages brain cells. In vascular dementia, low blood flow to the brain damages brain cells. There is no cure for dementia, so strategies for preventing it are of great interest.

Previous studies suggest that older people who exercise regularly have better mental function and a lower chance of developing dementia than do older people who do not exercise. However, it is difficult to determine whether this relationship is because exercise actually prevents dementia or because people with early dementia become less active.

*People who exercised at least 3 times per week were less likely to develop dementia than those who were less active.*

### Why did the researchers do this particular study?

To see whether people 65 years of age and older who had normal mental function and reported exercising regularly were less likely to develop dementia over coming years than those who reported being physically inactive.

### Who was studied?

1740 people 65 years of age and older who were members of Group Health Cooperative in Seattle, Washington. To be in the study, a person had to have normal mental function on a screening examination.

### How was the study done?

The researchers collected information about study participants' mental function, health, exercise, and lifestyle at the beginning of the study. The researchers asked participants to report the number of days per week during the past year that they did each of the following activities for at least 15 minutes: walking, hiking, aerobics or calisthenics, swimming, water aerobics, weight training, stretching, or other exercise. The researchers defined "regular exercisers" as those who reported exercising at least 3 days per week. They then evaluated participants every 2 years to determine if they had developed dementia by using a standard set of examinations done by physicians,

*continued on page 10*

## CONSUMER PRODUCTS *cont.*

*Name of Product; Problem; Manufacturer and Contact Information*

**Toy chair.** A child can become lodged between the seatback and side table of the Fisher-Price® Laugh & Learn™ Musical Learning Chair™, possibly leading to an entrapment of the neck. This can pose a strangulation hazard to young children. Fisher-Price, (866) 552-3914 or www.service.fisher-price.com.

**Utility vehicles.** The steering knuckle of Kawasaki 2005-2006 model year Mule 600 Utility Vehicles can twist or break from wheel forces transmitted to the steering system during operation. This can cause a loss of steering control and possible collapse of the front suspension, posing a risk of incident or injury to the operator or passenger. Kawasaki Motors Corp., U.S.A, (866) 802-9381 or www.kawasaki.com.

**Windbreaker jackets.** These boy's windbreaker jackets with drawstring have a drawstring through the hood, posing a strangulation hazard to children. In February 1996, the CPSC issued guidelines to help prevent children from strangling or getting entangled on the neck and waist drawstrings of upper garments such as jackets and sweatshirts. Hurley International, (800) 747-9994, help@hurley.com, or www.hurley.com.

OUTRAGE, *from page 12*
with this model, calling it "difficult to imagine the proposed dichotomization of the target population into mildly-to-moderate overweight adults with and without weight-related comorbidities [illnesses]...succeeding in the real world ."

Results from clinical trials support the FDA's assesment. Of 247 subjects with certain conditions that would make the over-the-counter use of orlistat inappropriate, such as diabetes or hypertension, only 32 percent made the correct decision regarding use, electing to consult with a physician or not to use the drug. Moreover, becaue of the mechanism that orlistat utilizes to assist in weight loss (preventing the absorption of fat from food as it is digested), users may suffer from a deficiency in certain fat-soluble vitamins. Clinical trials, however, showed that only 54 percent of users took the recommended vitamin supplementation according to the directions on the label.

On average, orlistat users lost about four to five pounds more than trial participants who were randomized to receive a placebo over a six month period. Data showed that as time progressed and participants returned to a diet with a normal intake of calories, subjects regained at least some of the weight that they had lost and the gap between the drug and the placebo narrowed. This means that as users of the drug will experience fewer of the benefits of the drug as time progresses while continuing to expose themselves to its adverse effects.

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Adverse effects are not an uncommon problem with drugs designed to assist in weight loss. Two striking examples are the infamous "fen-phen" combination, which caused a serious heart condition, and sibutramine (Meridia), which causes serious elevations in heart rate and blood pressure. Over-the-counter diet drug phenylpropanolamine (PPA) caused hemorrhagic strokes, and the dietary supplement ephedra, used for weight loss, caused serious hypertension, heart attacks, and strokes. Of these, only sibutramine remains on the market, despite over 40 deaths attributable to the use of the drug.

Orlistat, too, causes substantial undesirable adverse effects that occur with disturbing regularity — about half of users (??source of this :Reuters story) experience some form. The most disturbing adverse effect are gastrointestinal — users report problems with abdominal discomfort, gas, and oily stools and loss of bowel control. But orlistat may also interact with other prescription drugs, most significantly the blood thinning drug warfarin. When taken under a doctor's supervision, this interaction is less problematic, as it is easy for the prescribing physician to monitor a patient's blood coagulation levels and prevent unnecessary bleeding episodes. But in an OTC setting, patients may not even tell their physicians that they are taking the drug, thus opening up the possibility that their blood will become too thin and put them at risk for severe bleeding episodes.

What, then, is the benefit of taking this drug? With the cost of a 30-day supply of OTC orlistat coming in at about $55, users will certainly pay dearly for every pound they shed. Is minimal, short-lived weight loss it worth the price of potentially serious health problems? Is taking a pill without evidence that it can prevent the medical problems obesity brings with it worth the risk? ■

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DEMENTIA, *from page 9*
nurses, and a neuropsychologist.

### What did the researchers find?

The researchers followed participants for an average of 6 years. During this time, 158 of the 1740 participants developed dementia. People who exercised at least 3 times per week were less likely to develop dementia than those who were less active.

### What were the limitations of the study?

Exercise was self-reported and was only reported at the beginning of the study. The study sample was mostly white and well educated, and all had health insurance. The association between exercise and dementia might be different in less advantaged populations. In addition, the study suggests but cannot prove that exercising delays the onset of dementia.

### What are the implications of the study?

Preventing dementia may be another benefit of exercise in people older than age 65 years. ■

# Why Over-the-Counter? Diet Drug Poses Risks, Questionable Benefits

Pushing questionably effective cures for hazily defined, chronic conditions has long been a signature sales strategy for the pharmaceutical industry. But the approval given by an FDA advisory committee on January 23rd to allow the prescription weight loss drug orlistat (Xenical) to be marketed over-the-counter brings the potential for the utilization of that tactic to a new level. As a prescription drug, orlistat combines minimal efficacy with not-insubstantial safety concerns. As an over-the-counter medication, the potential exists for these safety concerns to multiply and cause serious harm.

Obesity in and of itself is a serious health problem. Obese persons put themselves at increased risk for type-2 diabetes, cardiovascular problems, and other health difficulties. However, obesity interacts with other risk factors, such as high blood pressure, family history, activity level, and smoking history, in a global assessment of general health. Thus, simply medicating obesity is unlikely to prevent the health problems associated with being overweight. Indeed, the professional product labeling for Xenical, the prescription version of orlistat, states that "the long-term effects of orlistat on morbidity or mortality [illness and death] associated with obesity have not been established."

Yet drug-induced weight loss (often insignificant and/or unenduring though it may be) without accompanying lifestyle changes will be exactly the "impact" that the over-the-counter sale of orlistat will have. Glaxo Smith Kline, the company that will sell orlistat over the counter with the brand name Alli (pending FDA approval), argued that patients with obesity-related illnesses were not the intended consumers of the drug in its over-the-counter version, arguing that these conditions required the supervision of a physician. This meant, essentially, that anyone likely to suffer from the adverse health effects associated with obesity should not take this drug to lose weight unless they are under the supervision of a physician. The FDA disagreed

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