



HEALTH LETTER LOOKS BACK

Losing Weight Safely and Effectively

The following is a partially updated version of a March/April 1986 Health Letter article.

Few aspects of self-image have so totally captured the American imagination as persistently as that of weight. In a complete turnabout from the “old-fashioned” view of plumpness as a sign of prosperity and health, Americans now rush to spend money on any book, service or product — however far-fetched, ineffective or even dangerous it may be — that promises to get rid of an extra pound or two. One recent report even stated that about 80 percent of fourth-grade girls are dieting!

With sales in excess of \$240 million in 1983, over-the-counter diet pills such as Acutrim, Control, Dexatrim and Dietac are among the leaders in over-the-counter drug sales. Combine this figure with sales of hundreds of other diet products and diet books that flood the market each year, and the American preoccupation with slimness jumps into sharp focus. (See the end of this article for a history of dangerous, now-banned diet drugs and a discussion about the future of such drugs.)

But while a constant barrage of movies, television programs and advertisements presents a slim body as the ideal, nutrition experts have become increasingly doubtful about the correlation between fashion-model, extra-thin looks and good health.

In a strict sense, the determination of whether someone is overweight or obese is based on the amount of total body weight that is fat. This can be measured in a variety of ways, including skinfold

Height (feet, inches)	Normal	Over-weight	Obese
4'6"	77-103	104-124	>124
4'7"	80-107	108-128	>128
4'8"	83-111	112-133	>133
4'9"	86-114	115-138	>138
4'10"	89-118	119-143	>143
4'11"	92-123	124-148	>148
5'0"	95-127	128-153	>153
5'1"	98-131	132-158	>158
5'2"	101-135	136-163	>163
5'3"	105-140	141-169	>169
5'4"	108-144	145-174	>174
5'5"	111-149	150-179	>179
5'6"	115-154	155-185	>185
5'7"	118-158	159-191	>191
5'8"	122-163	164-196	>196
5'9"	125-168	169-202	>202
5'10"	129-173	174-208	>208
5'11"	133-178	179-214	>214
6'0"	137-183	184-220	>220
6'1"	140-188	189-227	>227
6'2"	144-193	194-233	>233
6'3"	148-199	200-239	>239
6'4"	152-204	205-246	>246

**Updated from 1986 article*

thickness; height, weight and waist measurements; and body water-content calculation, but these techniques are usually used only in research.

Today, determining whether someone has a normal weight, is overweight or is obese is determined by calculating a person’s body mass index (BMI). BMI is calculated using a person’s weight and height. A normal BMI is 18.5-24.9, an overweight BMI

is 25-29.9, and an obese BMI is 30 or more. Table 1 provides the approximate weight ranges (measured in pounds) for normal weight, overweight and obese weight for a particular height.

What is wrong with being obese?

People who are obese have a significantly increased chance of getting the diseases discussed below:

- **Hypertension** (high blood pressure). There seems to be an overlap between obesity (especially obesity that develops late in life and that involves the upper half of the body) and high blood pressure.
- **Diabetes** (non-insulin dependent). As with hypertension, there is an overlap between diabetes and obesity. Ninety percent of non-insulin dependent diabetics, the type who become diabetic as adults, are obese. In many cases, losing weight, or even starting a weight-loss program (before the pounds come off), can improve the diabetic’s blood sugar levels. Diet is a better approach than diabetes medication in most non-insulin dependent diabetics.

see **WEIGHT**, page 2

In This Issue

Fourteen Years of Deceptive Television Drug Advertising.....	7
RECALLS.....	8
OUTRAGE!.....	12

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WEIGHT from page 1

- **Coronary artery disease** (blockage of blood vessels that supply the heart; the blockage causes heart attacks).
- **Heart disease.** Recent research has shown that being overweight alone makes the heart work harder and leads to a thickening of the heart muscle, which can increase the risk of dangerous heart rhythms or sudden death. This change is separate from the heart effects of high blood pressure and coronary heart disease and can be reversed by weight loss. Together, obesity, high blood pressure and coronary artery disease are a very hazardous combination.
- **Hypercholesterolemia** (high levels of a fatlike substance called cholesterol in the blood) and hyperlipidemia (high levels of fat in the blood).
- **Stroke** (the blockage of blood vessels that supply the brain).
- **Osteoarthritis** (the most common arthritis, considered "wear and tear" arthritis). Strain on joints bearing body weight, such as the hips and knees, causes and worsens this joint destruction. Excessive body weight increases this strain.
- **Pulmonary disease** (breathing difficulties). Obesity is associated with various respiratory problems, including sleep apnea.
- **Other diseases**, including hormone imbalances, gall bladder disease, and kidney disease. Obesity also causes increased risks to pregnant women and male or female surgical patients, since it results in a higher probability of medical complications. In addition, physical examination of very obese patients by doctors can be made very difficult.

Some of the conditions mentioned above may result not from obesity itself, but from the kind of diet or sedentary lifestyle that leads to obesity. A sensible diet and activity plan that will help you

lose weight will also help you reduce factors that may lead to other diseases.

What influences body weight?

Several factors influence your weight:

- **Food intake.** The more you eat, the more fuel you have for your body. Extra fuel that is not used in daily activities is stored for use another day in the form of fat. If that day never comes, the fat remains.
- **Food's energy content** is measured in units of heat called calories. Despite the claims of many popular fad diets, the body does not really distinguish between different *kinds* of calories as far as weight accumulation is concerned.
- **Activity.** The more active you are, the more fuel you burn. That fuel may consist of recently eaten food or previously stored fat.
- **Size and body type.** The heavier you are, the more food you need just to maintain your weight. In addition, more fuel is required to maintain muscle mass and bone than to maintain fatty tissue. As a result, large-boned, muscular people need to eat more just to maintain their weight than do small-boned plump people.
- **Metabolism.** This is the process by which food and stored fat are converted into energy. People with higher metabolic rates burn food and fat at a higher rate than do those with low metabolic rates.

Genetics

A new study shows that the tendency to become fat can be transmitted genetically as well. Regardless of environment, children of obese parents were more likely to become obese adults; this happened even when the children were adopted into separate homes. But even if your parents are overweight, you should not be overly discouraged by this information. Instead, efforts

see **WEIGHT**, page 3

to achieve a sound weight control program, including lifestyle changes as discussed later in this article, need to start earlier and require more work in “obesity prone” individuals.

A much less common cause of changes in metabolic rate is hormonal disturbance, such as increased or decreased rates of thyroid activity.

Obviously, of all the factors influencing weight that were listed above, food intake and physical activity are the two over which you have the most direct control. A sensible weight reduction program should therefore begin with those two elements.

Principles of weight loss

The guiding principle of weight loss is simple: *If more calories are eaten than burned, weight is gained; if fewer calories are eaten than burned, weight is lost.*

Unfortunately, as most who have tried to diet can tell you, losing weight is not an easy task. Dieting must be a long-term process involving permanent changes in eating habits and physical activity.

Any program that results in, or promises to result in, short-term weight loss without any dietary or lifestyle changes will typically fail after the quick success: Pounds rapidly lost are rapidly gained back!

The fact that millions of people hop from the Last Chance Diet to the Scarsdale Diet to the Beverly Hills Diet to the Cambridge Diet reveals that sustained weight loss rarely occurs with any such diets.

Diet pills are similarly ineffective. They may help short-term weight loss, but they play no role in long-term weight loss. In addition, they are dangerous.

A reasonable plan: how to safely lose a pound a week

Setting a calorie adjustment that will result in permanent weight loss and allow you to integrate these changes into your life is a considerable challenge. The goal is to develop new, healthier

One recent report even stated that about 80 percent of fourth-grade girls are dieting!

diet and exercise habits, not just to lose weight fast (only to gain it back). Aiming for minor or gradual alterations in diet is a more realistic approach to long-term weight loss than switching to a radically different diet.

A pound of fat represents an estimated 3,500 calories. In other words, in order to lose one pound, you must use (through physical activity) 3,500 more calories than you eat.

A reasonable, fairly ambitious program is to make a calorie adjustment of 3,500 calories per week. This program will average about one pound lost each week, assuming that your weight is now constant with your current diet and activity.

In a long-term program like this one, weight loss may be more pronounced in the early weeks of this reducing program, as it is in any weight reduction program. During this initial period there is significant water loss as well as other body adjustments. After the initial drop in weight, your weight may level off (sometimes for a few weeks) before dropping again. This pattern of plateaus followed by drops in weight continues through a weight-loss program.

A caloric adjustment of 3,500 calories per week requires a net change of 500 calories each day. We recommend that you reduce 400 calories of this through a decrease in dietary intake and 100 calories in increased activity each day.

Diet: how to eat 400 fewer calories per day

Any effective weight control program involves changes in diet. We suggest that you design a reduction in calories that you can live with for good, not just for the short term.

To reduce your daily diet by 400 calories, review the foods you eat to see what you can eliminate. You may find a “calorie counter” book helpful; they are inexpensive and available in many

supermarkets and bookstores. Here are a few suggestions that may help:

- **Make some sensible substitutions, using more low-calorie foods in your daily diet.** For example, if you eat a lot of meat, substitute chicken, fish or seafood for beef, lamb or pork. The former have less fat and, generally, fewer calories. Eat more vegetables and less meat. Tofu (bean curd), one of a variety of vegetable protein sources becoming more widely available, has even fewer calories and is a good source of protein. Other simple substitutions can include low-fat cottage cheese rather than other cheeses; nonfat skim milk rather than whole milk; fresh fruit (more filling) rather than fruit juice; fresh vegetables rather than sweet, salty or fried snacks; and fresh fruit rather than sweet desserts.
- **Eliminate invisible calories** (calories that do not add to the taste, quality or appearance of food) by trying new methods of food preparation. Several excellent cookbooks now on the market will help you prepare flavorful meals with far less fat and sugar. Trimming visible fat from meat, removing skin (a major source of fat) from poultry prior to cooking (or eating), cooking food in bouillon or broth instead of butter or oil, and using lemon juice or bouillon instead of butter or oil for basting or seasoning fish and vegetables will eliminate calories that you will scarcely miss.
- **Learn to be calorie-wise when dining out.** Ask the waiter or waitress to remove the tray of rolls or bread from the table and, if possible, to bring some fresh celery or carrots. Enjoy a glass of club soda with a wedge of lime instead

[see WEIGHT, page 4](#)

of a drink before dinner — alcohol is a major source of non-nutritional calories. Substitute a squeeze of lemon wedge for that heavy salad dressing and avoid fried foods.

- **Arrange for low-calorie meals.** If your meals are prepared in a school dormitory, company cafeteria or similar kind of institutional setting where you are not in control of food preparation, consult the director of food services. Sometimes he or she will be able to help you work out a low-calorie meal plan using the available food or, depending on the size and resources of the kitchen or food source, help you to obtain specially prepared meals. Most major airlines will serve low-calorie meals if you request them a day before your trip.
- **Keep a record of what you eat and when you eat, even checking out portion sizes with a small scale.** This will help you to learn what you should avoid in order to acquire and maintain your desirable weight.
- **Learn to recognize and handle stress without responding by overeating.** Frequently, people with weight problems use food as a way of coping with stress. Anxiety, anger, sadness and even boredom are feelings that at times can be attributed to stressful situations. People sometimes handle these uncomfortable emotions by seeking comfort in food, and consequently, they overeat. Then, after eating too much food, or the wrong kind of food, people frequently feel guilty or disappointment with themselves, which results in still more stress.

Proper nutrition and dieting

During a weight control program, it is especially important to provide the body with proper nutrition. A program that involves only a slight change from past habits, as described in this article, should not result in nutritional deficiencies, as long as those past habits

In order to succeed, dieting must be a long-term process involving permanent changes in eating habits and physical activity.

were nutritionally adequate.

Basically, it is best to maintain a balanced diet, which provides adequate protein, vitamins and minerals. A diet for weight loss should also include high fiber foods. Many high fiber foods, whole grain vegetables and beans are also higher in complex carbohydrates, a better source of energy than simple sugars such as sugar, honey or molasses).

Many of the problems associated with the most recent fad diets — including liquid protein diets, the Doctor's Quick Weight Loss Diet, Dr. Atkins' Diet Revolution and the Beverly Hills Diet, — stem from inadequate allowance of vitamins or protein. In a moderate, more sensible, weight-loss program, you will benefit most from avoiding items containing large quantities of fats, oils and sugar.

There are a number of books of varying quality published on nutrition. *Jane Brody's Nutrition Book* is an up-to-date, sensible guide that we can recommend as a source for further information.

Exercise: 100 calories more per day

As anyone who has tried it knows, losing weight and keeping it off by dieting alone is very difficult.

As an example, a woman of 120 pounds with a sedentary job (burning about 1,800 calories per day) would have to cut calories by 28 percent to lose one pound per week through dieting alone. To lose weight, she would have to cut her meals back to Spartan portions (which maintain minimally adequate nutrition), with little or no leeway for fattening "treats." If, however, she walked at a brisk pace for 20 minutes (such as to and from her job) each morning and evening, she would only have to cut back calories by 17 percent to lose the same amount.

Starting a serious exercise program after years of relative inactivity can be a strain on your body, especially your heart. If vigorous exercise has not been a part of your regular activities for some time, we recommend that you start slowly with walking rather than another more strenuous form of exercise.

You should seek medical advice before starting an exercise program if any of the following are true: You 1) are over 45 and have not had a check-up by a physician in the last year, especially if you have been fairly inactive; 2) have heart disease or high blood pressure, or are under the care of a physician for any other chronic disease; 3) have a family history of heart attacks; or 4) experience any chest pain, dizziness or shortness of breath with or without physical exertion.

We recommend that you use (burn) at least an additional 100 calories every day. One hundred calories is roughly equivalent to one of the following: 20 minutes of brisk walking (about one mile), 12 minutes of bicycle riding, nine minutes of swimming, or five minutes of fast running. You should exercise hard enough to make yourself breathe faster. Any kind of new exercise should be preceded and followed by several minutes of stretching exercises, especially at the ankles and hips.

Depending on your physical condition, you may find that you are able to increase this amount of exercise, and hence improve upon your weight control program. Keep in mind that this increased activity should become permanent daily activity.

Keep a log of your exercise. This can serve not only to keep you faithful to your new program, but also to encourage progress. With exercise, many people feel an increased sense of energy and a decreased desire for food.

see WEIGHT, page 5

Weight control in children and adolescents

Moderately overweight young people, otherwise in good health, are usually able to safely increase the calories expended by exercising more. This can be very effective when combined with a program of restrained dieting that is very careful not to sacrifice any nutritional needs. Drastic weight-control programs in children and adolescents may cause a variety of health problems (including slowing growth and development) and are not recommended. Very obese children and adolescents should seek professional assistance.

Some adolescents, overly concerned about weight and appearance, may be tempted to use over-the-counter diet aids. As with adults, these products should not be used, as they can be dangerous.

History of unsafe diet drugs

The road to safe and effective diet drugs is littered with a rapidly increasing number of banned products, both over-the-counter and prescription, which were approved based on relatively short-term weight loss but without any evidence of long-term safety.

In the past 14 years alone, four such drugs have been removed from the market in the United States when it became unequivocally clear that serious injuries and deaths caused by these drugs vastly outweighed the meager, transitory benefits of weight loss.

In chronological order, they begin with Fen-Phen and, as of now, end with Meridia (sibutramine).

- **Fen-Phen.** This combination of two separate drugs, fenfluramine and phentermine, a relatively old amphetamine-like drug, became quite popular in the early 1990s and even more popular following the approval of dexfenfluramine (a version of fenfluramine, brand name Redux) in 1996. Several hundred cases of primary

The basic, primitive human drive to eat is so fundamental to our survival and is so enmeshed in our overall body function that any of the drugs that “work” to lose weight are certain to affect other parts of the body.

pulmonary hypertension (high blood pressure in the lungs, much more difficult to treat than the common systemic hypertension and more likely to result in death) were reported in people using dexfenfluramine or fenfluramine. Then a researcher at the Mayo Clinic discovered that the drug also causes serious damage to heart valves, and the drug was banned in 1997.

- **PPA (phenylpropanolamine).** This over-the-counter diet drug, most popularly sold as Dexatrim, had been on the market since 1960 when, in the late 1990s, because of a suspicion that it caused strokes in younger women, its manufacturer sponsored an epidemiological study to look into the claim. The study clearly confirmed the increased risk of hemorrhagic (bleeding) strokes in people — mainly women — using the drug, and it was removed from the market in 2000.
- **Ephedra.** This “natural,” also available over-the-counter dietary supplement was widely promoted for weight reduction. Since it is also in the same family as amphetamines, it increased heart rate and blood pressure. As it became more and more popular in the late 1990s and early 2000s, many cases of sudden death — including in healthy soldiers — began being reported to the Food and Drug Administration (FDA). Public Citizen petitioned the FDA to ban ephedra in the fall of 2001, and after congressional hearings and many additional cases of heart attacks and strokes, the FDA banned ephedra in 2004.
- **Meridia (sibutramine).** This drug

also possessed some amphetamine-like properties. Meridia was approved in 1997 despite the conclusion by the FDA reviewer and an FDA advisory committee that the risks outweighed the benefits. Both risks, high blood pressure and increased heart rate, threaten increased heart attacks and strokes. Public Citizen originally asked the FDA to ban the drug in 2002, but the petition was denied in 2005.

Late in 2009, a large European study involving 10,000 overweight people — 5,000 randomized to sibutramine, 5,000 given a placebo — was finished. This was the only long-term study ever done to test the safety of a diet drug. Although people using sibutramine lost more weight than those getting a placebo, there was a statistically significant increase in both heart attacks and strokes in the sibutramine group. Public Citizen again asked the FDA to ban the drug. Europe immediately banned the drug when the results of the study were made public, but in the United States, the FDA delayed for almost a year, taking no such action until October 2010.

Before fenfluramine and after Meridia?

Fenfluramine was not the first, nor will Meridia be the last, diet drug to be banned after injuring or killing large numbers of people. In the 1940s and 1950s, both amphetamine and thyroid medications were used for weight loss. They both had risks — psychosis

[see WEIGHT, page 6](#)

WEIGHT from page 5

and addiction for amphetamine and dangerous hyperthyroidism for thyroid medications — that greatly outweighed their benefits, and their use for weight loss was eventually stopped.

Public Citizen recently — in April 2011 — asked the FDA, for the second time (first in 2006), to ban the diet drug orlistat. Its prescription version is called Xenical; over-the-counter, it is sold as Alli. The most recent evidence, which we obtained from FDA adverse reaction files, concerned 47 cases of acute pancreatitis and 73 cases of kidney stones. This is in addition to FDA's admission in 2010 that the drug causes hepatitis. As in the examples above, the loss of weight was not very impressive and was clearly overshadowed by the increasing number of serious adverse reactions in patients.

The future of diet drugs

In February 2010, immediately after Europe banned the use of Meridia, a very wise editorial by Professor Gareth

Learn to recognize and handle stress without responding by overeating.

Williams, of the University of Bristol, appeared in the *British Medical Journal* on the larger topic of losing weight by using drugs. The key point made is quoted below:

“The fate of sibutramine reminds us how little antiobesity drugs have had to offer—at best, a reduction of a few per cent in the total burden of excess weight carried until death. With energy homeostasis so deeply enmeshed in physiology, it has always seemed unlikely that a magic bullet could ever switch off food intake without hitting something vital.”

In other words, Professor Williams is saying that the basic, primitive human drive to eat is so fundamental to our survival and is so enmeshed in our overall body function that any of the

drugs that “work” to lose weight are certain to affect other parts of the body. As soon as this magic-bullet notion is more thoroughly discredited, the rush for magic ways to lose weight (with the risks inevitably outweighing the benefits) will be seen as the dangerous folly that it is.

The same can be said for the seemingly infinite number of magic, but usually unsustainable or unhealthy, diets in diet books that keep surfacing and, in most cases, keep being forgotten before too long.

As discussed earlier in the article, there is a relatively slow, but effective, route to *safely* lose a pound a week. It involves eating 400 fewer calories a day and exercising enough to burn 100 more calories a day. Some may prefer a different combination — say, eating 300 fewer calories and burning 200 more. We hope that those of you who want to lose weight will try this instead of the seemingly limitless parade of diet drugs that do more harm than good. ♦

Are your medicines SAFE?



Find out which drugs are safe — and which you should avoid — with Public Citizen's WorstPills.org and *Worst Pills, Best Pills News*. To subscribe to WorstPills.org, our online database, for only \$15 a year, visit www.WorstPills.org and type in promotional code **PNMAY11** when prompted.

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Fourteen Years of Deceptive Television Drug Advertising

The following article, by Martha Rosenberg, originally appeared on OpEdNews.com. It has been reprinted with permission.

Can anyone remember life before Ask Your Doctor ads on TV?

All you knew about prescription drugs were creepy ads, with a lot of fine print, in a *Journal of the American Medical Association* at the doctor's office. Even if you knew the name of a drug, you'd never ask your doctor for it because that would be self-diagnosing and cheeky for a patient.

Flash forward to the late 1990s when direct-to-consumer (DTC) drug advertising, drug Web sites and online drug sales came on board, and self-diagnosing and demanding pills became medicine-as-usual for many doctors and patients.

The DTC/Web perfect storm didn't just sell drugs like Claritin, Prozac and the Purple Pill. It sold the diseases to go with them, like seasonal allergies, gastroesophageal reflux disease and depression. It sold *risk* of diseases — like heart events, for which you'd take a statin like Lipitor; osteoporosis, for which you'd take a bone drug like Boniva; and asthma attacks, for which you'd use a second asthma drug like Advair. Of course, by the very definition of prevention, you didn't know if the drugs were working but you weren't paying out of pocket anyway so what the hay.

Thanks to DTC advertising, people started taking seizure drugs like Topamax and Lyrica for everyday pain or headaches and *antipsychotics* — hello? — for everyday blues or mood problems. They started taking monoclonal antibodies — made from *genetically engineered hamster cells*, like Humira, which *invite cancer, superinfections and TB* — when they didn't have to. And FDA-mandated



I thought I was fine. (Illustration by Martha Rosenberg)

risk disclosures — brain bleeds, sudden death, difficulty breathing, stomach bleeding, liver failure, kidney failure, muscle breakdown, fainting, hallucinations — *perversely sold the drugs more*, either because ad frequency itself sells or because people like the identity in having a disease, like chemically experimenting on themselves or like taking a dare.

Soon anxiety graduated to depression, which graduated to bipolar disorder. Children got schizophrenia and depression like adults and adults got ADHD like kids. And it didn't stop there. If the depression you or your kid had didn't go away — maybe because it wasn't depression in the first place but a thing called “life” — you needed to add a drug like Abilify or Seroquel on to the original drug(s) because your depression was “treatment resistant.”

Of course if people were paying

for the drugs out of their pockets and you told them to add a drug that costs almost \$500 a month because the first one isn't working, they would say the only thing “treatment resistant” is your *sales pitch* — go find another sucker. But if third-party payers get stuck with the bill, no one seems to mind pharma's “Double (and Triple) Its Money” plan — or even notices it.

In fact psychiatric drug cocktails of eight, 10 and 12 drugs are now common medical practice for “treatment resistant” depression and post-traumatic stress disorder (often paid by government entitlement health plans), even though the drugs have never been tested when taken together — unless you count the patients taking them now!

Pharma also adds an urgency pitch to the sell in case you think you can wait

[see ADVERTISING, page 11](#)

Product Recalls

April 15, 2011 – May 11, 2011

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

Recalls and Field Corrections: Drugs – Class I

Indicates a problem that may cause serious injury or death

Clomed Capsules Dietary Supplement, 50 mg proprietary blend, 60 capsules/bottle. Volume of product in commerce: 20,000 bottles. Marketed without an approved NDA/ANDA. Lot#: All lot codes. Watson Industries Inc.

Nifedipine Extended-Release Tablets, USP, 60 mg, 100-count unit dose box (10 blister cards of 10-unit dose tablets), Rx only. Volume of product in commerce: 1,153 cartons (each containing 100 tablets in blister packs). Does not meet sustained-release specifications: Above specification dissolution results at four hours were found during nine-month stability testing. Lot#: 0809T01A, expiration date 06/2010. Biovail International Corp.

Recalls and Field Corrections: Drugs – Class II

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

Carvedilol Tablets, USP, 12.5 mg, 500-count bottle, Rx only. Volume of product in commerce: 5,568 bottles. CGMP Deviations: Firm's laboratory investigations were not performed in accordance with strict adherence to the "FDA Guidance for Industry." Lot #: 04C118, expiration date 7/12. Teva Pharmaceutical Industries.

Gemfibrozil Tablets, USP, 600 mg, 60-count bottle, Rx only. Volume of product in commerce: 17,667 units. CGMP Deviations: Firm's laboratory investigations were not performed in accordance with strict adherence to the "FDA Guidance for Industry – Investigating Out-of-Specification Test Results for Pharmaceutical Production." Lot #: 01G495. Teva Pharmaceutical Industries.

Chlorzoxazone Tablets, USP, 500 mg, 100 tablets, Rx only. Volume of product in commerce: 9,435 bottles. Adulterated: presence of foreign tablets: Isoniazid residue found in bottle of Chlorzoxazone tablets. Lot #: 314134, expiration date 12/2012. Barr Laboratories Inc.

Lansoprazole Delayed-Release Capsules, USP, 30 mg, 30-count bottle, Rx only. Volume of product in commerce: 74,521 bottles. CGMP deviations. Firm's laboratory investigations were not performed in accordance with strict adherence to the "FDA Guidance for Industry – Investigating Out-of-Specification Test Results for Pharmaceutical Production." Lot #: 44L007. Teva Pharmaceutical Industries.

Diovan (valsartan), 160 mg, 7,000 tablets, NOVARTIS label, Rx only. Volume of product in commerce: 278 bottles of 7,000 tablets. Adulterated: presence of foreign tablets; a bottle of Diovan 160 mg tablets was found to contain some tablets identified as Diovan HCT 320/12.5 mg. Lot #: F0976, expiration date 12/2013. Novartis Pharmaceuticals Corp.

Levothyroxine Sodium Tablets, USP, 150 mcg (0.15 mg), 100 tablets (10 x 10), NDC 51079-445-20 (packaged in blister packs, 10 tablets/card, 10 cards/package). Volume of product in commerce: 2,004 packages. Subpotent (single ingredient) drug: Pharmaceutical did not meet assay specification. Lot #: OA432, expiration date 04/2011. Mylan Pharmaceuticals Inc.

Fexofenadine Hydrochloride Tablets, USP, 180 mg, 100-count bottle, Rx only. Volume of product in commerce: 14,072 units. CGMP deviations. Firm's laboratory investigations were not performed in accordance with strict adherence to the "FDA Guidance for Industry – Investigating Out-of-Specification Test Results for Pharmaceutical Production." Lot #: 26F109. Teva Pharmaceutical Industries.

Metformin Hydrochloride Tablets, USP, 500 mg, 1,000-count bottle, Rx only. Volume of product in commerce: 6,494 bottles. Failed tablet hardness: Some tablets may not meet friability specification. Lot #: 35201115A, expiration date 10/2011. Novopharm Ltd.

DRUGS AND DIETARY SUPPLEMENTS (continued)

Nabumetone Tablets, USP, 750 mg, 100-count bottle, Rx only. Volume of product in commerce: 8,085 bottles. CGMP deviations. Firm's laboratory investigations were not performed in accordance with strict adherence to the "FDA Guidance for Industry – Investigating Out-of-Specification Test Results for Pharmaceutical Production." Lot #: 05N243. Teva Pharmaceutical Industries.

Pravastatin Sodium Tablets, USP, 1) 20 mg, a) 1,000-count bottle and b) 90-count bottle; 2) 40 mg, 1,000-count bottle, NDC 0093-7202-10, Rx only. Volume of product in commerce: 12,552 units. CGMP Deviations: Firm's laboratory investigations were not performed in accordance with strict adherence to the "FDA Guidance for Industry – Investigating Out-of-Specification Test Results for Pharmaceutical Production." Lot #s: 1) a) 04Y223, b) 04Y233; 2) 05Y219. Teva Pharmaceutical Industries.

Simvastatin Tablets, USP, 20 mg, 30-count bottle, Rx only. Volume of product in commerce: unknown. CGMP deviations. Firm's laboratory investigations were not performed in accordance with strict adherence to the "FDA Guidance for Industry – Investigating Out-of-Specification Test Results for Pharmaceutical Production." Lot #: 23S031, expiration date 11/2012. Teva Pharmaceutical Industries.

Simvastatin Tablets, USP, 20 mg, 1,000-count bottle, RX only. Volume of product in commerce: unknown. CGMP deviations. Firm's laboratory investigations were not performed in accordance with strict adherence to the "FDA Guidance for Industry – Investigating Out-of-Specification Test Results for Pharmaceutical Production." Lot #: 14S228, expiration date 06/2011. Teva Pharmaceutical Industries.

Simvastatin Tablets, USP, 80 mg, 1,000-count bottle, Rx only. Volume of product in commerce: unknown. CGMP deviations. Firm's laboratory investigations were not performed in accordance with strict adherence to the "FDA Guidance for Industry – Investigating Out-of-Specification Test Results for Pharmaceutical Production." Lot #: 04S406, expiration date 05/2011. Teva Pharmaceutical Industries.

Zolpidem Tartrate Tablets, 10 mg, 100-count bottle, Rx only. Volume of product in commerce: 62,803 units. CGMP Deviations: Firm's laboratory investigations were not performed in accordance with strict adherence to the "FDA Guidance for Industry – Investigating Out-of-Specification Test Results for Pharmaceutical Production." Lot #: 10Z005. Teva Pharmaceutical Industries.

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 CPSC, call its hotline at (800) 638-2772. The CPSC website is www.cpsc.gov. Visit www.recalls.gov for information about FDA recalls and recalls issued by other government agencies.

Name of Product; Problem; Recall Information

Beaded Curtains. The beaded curtains are prone to entanglement. When an adult or child plays with or runs through the beaded curtains, the risks of entanglement and strangulation are posed. Tween Brands Inc., d/b/a Justice, at (800) 934-4497 or www.shopjustice.com.

Bumble Bee and Lady Bug Infant Slipper Socks. The balls at the end of the bug's antennae can detach, posing a choking hazard to young children. Meijer Inc., at (800) 927-8699 or www.meijer.com.

Danbar Knight Hawk Toy Helicopters. The battery housing under the helicopter canopy can overheat while charging, posing a fire hazard. UJ Trading, at (800) 536-2691 or www.UJToys.com.

Disney Princess Plastic Racing Trikes. The plastic castle display and the princess figures protruding from the top of the handlebar pose a laceration hazard if a child falls on it. Kiddieland Toys Limited, at (800) 430-5307 or www.kiddieland.com.hk.

Edge and HOG (Highly Optimized Gear) Buoyancy Control Devices (BCD). The spring in the over pressure valve can corrode and break, preventing the buoyancy control device from retaining air, posing a drowning hazard to consumers. WRK Enterprises d/b/a Edge Dive Gear, at (888) 370-3483 or www.edge-gear.com.

Fixed-Side Cribs. The bottom rails on the crib sides can separate from the sides when the mattress is in the lowest position, causing the spindles to separate and the mattress to drop. This poses fall and entrapment hazards for young children. Ducduc LLC, at (212) 226-1868 or www.ducducnyc.com.

Girl's Hooded Sweater with Drawstring. The hooded sweaters have drawstrings through the hood that can pose a strangulation or entrapment hazard to children. In February 1996, CPSC issued guidelines, which were incorporated into an industry voluntary standard in 1997, to help prevent children from strangling or getting entangled on the neck and waist drawstrings in upper garments, such as jackets and sweatshirts. El Gringo Imports, at (877) 278-1434 or www.elgringoimports.com.

CONSUMER PRODUCTS (continued)

Kohler Courage Engines. A wire connector on the engine can become disconnected, causing the operator's seat switch to fail. When this happens, the blades will not shut down, posing a laceration hazard to consumers. Kohler Co., at (800) 451-2294 or www.kohlerengines.com.

Light Bulbs. The light bulbs can overheat, posing a fire hazard to consumers. Telstar Products, d/b/a Sprint International Inc., at (888) 828-1680 or www.telstarpro.com.

Lights and Sounds Children's Scooters. A child's finger can get caught in the hinge mechanism between the steering column and the platform, posing a laceration hazard. Kiddieland Toys Limited, at (800) 430-5307 or www.kiddieland.com.hk.

Lithium-Ion Batteries Used with Magicshine Bicycle Lights. The lithium-ion batteries can overheat, posing a fire hazard to consumers. Shenzhen Minjun Electronic Co. Ltd., at www.MagicshineBatteryRecall.com or recall@geomangear.com.

Marineland Stealth and Stealth Pro Aquarium Heaters. A wiring problem can cause the aquarium heaters to overheat or break during normal use, damaging the aquarium and posing fire and laceration hazards to consumers. Overheating can cause the heater to shatter or the aquarium glass to break. United Pet Group, at (800) 338-4896 or www.marineland.com.

Pacifier Clip. The clip can break apart, posing a choking hazard to young children. Sandbox Medical, LLC, at (800) 396-1550 or www.gumdroppacifier.com.

Photon Carabiners, Photon and Mach Express Quickdraws. The carabiner gate may open under a heavy load, posing a risk of serious injury or death if the climber falls. CAMP USA Inc., at (877) 421-2267 or www.camp-usa.com.

Ryobi 1/4 Sheet Sanders. Pieces of the fan can break off from the fan assembly and be ejected from the product, posing a laceration hazard to consumers. One World Technologies Inc., at (800) 597-9624 or www.ryobitools.com.

Sea Elite Systems Buoyancy Control Devices. The spring in the overpressure valve can corrode and break, preventing the buoyancy control device from retaining air and posing a drowning hazard to consumers. WRK Enterprises, at (888) 370-3483 or www.edge-gear.com.

Spot Satellite Communicator. The internal voltage regulator can stop working, resulting in the inability to transmit messages and tracking information in emergency situations. Spot LLC, at (866) 727-7733 or www.findmespot.com/replacement.

Tea Lights. The candles have a clear, plastic cup that can melt or ignite, posing a fire and burn hazard to consumers. Pacific Trade International Inc., at (800) 331-8339 or www.chesapeakebaycandle.com.

Toro Power Clear Snowblower and the Toro 20" Recycler Mower. The carburetors on both products develop fuel leaks and can ignite when exposed to an ignition source, posing a fire or burn hazard. The Toro Company, at (877) 738-4440 or www.toro.com.

Toy Story 3 Bowling Game. The red paint used on some bowling pins has been measured to be in excess of the maximum allowable level of 90 ppm, a violation of the federal lead paint standard. G.A. Gertmenian and Sons LLC, at (888) 224-4181 or Gertmenian@Gertmenian.com.

Wooden bunk beds. The wooden side rails that run from the headboard to the footboard and hold the bunk bed's mattress in place can split and cause the bunk bed to collapse, posing a fall hazard to consumers. Dorel Asia SRL, at (800) 638-2772 or (301) 595-7054 (teletypewriter) or www.cpsc.gov/cpsclist.aspx.

Wooden Stool. The legs and seat of the stool can crack and break, causing the consumer to fall. Heartland America, at (800) 398-8163 or www.heartlandamerica.com/stoolrecall.

ADVERTISING from page 7

to take your or your child's treatment resistant drug cocktail until symptoms worsen.

And don't think kids will outgrow mood problems either, says pharma. That erratic behavior is no doubt early mental illness that will become worse if you don't treat it in the bud. Even mothers of one-year-olds with the sniffles are told serious asthma is just around the corner if they don't treat their toddler now.

Pharma is also having a field day with sleep, because everyone is in the demographic. In fact comedian Chris Rock riffs about hearing a DTC ad that asks, "Do you fall asleep at night and wake up in the morning?" and recognizing himself. "Yeah, I got *that*," he says.

Not falling asleep soon enough, of course, is the disease of insomnia, which can have strains like "middle of the night" and "terminal" insomnia. But it also sets you up for — what's the pharma euphemism — *wakefulness problems* the next day. And once you're using a wakefulness aid like Adderall or

Because of pharma-paid doctors, public relations firms, industry-subsidized medical journals and Web sites like *WebMD*, pharma is able to create new diseases, "humanize" others by giving them nicknames and elevate others to public health problems.

Nuvigil, what do you bet you'll have sleep problems?

Because of pharma-paid doctors, public relations firms, industry-subsidized medical journals and Web sites like *WebMD*, pharma is able to create new diseases (osteopenia, the "risk" of osteoporosis; perimenopause and Low T), "humanize" others by giving them nicknames (ED, RA, RLS, Hep C) and elevate others to public health problems like HPV/venereal warts. (It doesn't hurt that Julie Gerberding, M.D., and former Centers for Disease Control and Prevention head, resurfaced as head of Merck vaccines after she left the government.)

But more insidious sells are pharma-subsidized "patient groups," which lobby FDA and state agencies about expensive drugs, often psychiatric.

While these "patients" — often flown by pharma to testify at FDA hearings — pretend they can't get needed drugs like terminal cancer patients can, the issue is seldom availability but *money*: either pharma wants a new use covered by insurers or doesn't want an older, cheaper drug substituted.

The same patients appear on Web site testimonials and phony grassroots public service messages about the epidemic of depression or childhood mental illness. How can you tell they're not real patients but pharma plants? The Web sites and PSAs look exactly like direct-to-consumer ads. ♦

An earlier version of this report appeared on the online journal State of Nature.

OUTRAGE from page 12

for each individual physician reader — data that Avid Radiopharmaceuticals (Avid), a wholly owned subsidiary of Eli Lilly Inc. and the company that makes florbetapir, had submitted to the FDA on Sept. 17, 2010, four months before the JAMA article was published.

FDA analyses of the individual physician reader data showed the substantial variation among the three

independent, highly trained physician readers. This led FDA reviewers to seriously doubt the validity and usefulness of florbetapir-PET scan for detecting beta-amyloid plaques in the brain.

Given the poor performance of the test at the individual physician reader level in a rigorously controlled setting, the variability and unreliability will only get worse when the test is widely distributed across the country. As a

result, tens of thousands of patients will have either a false-positive test (told they have beta-amyloid deposits when they do not) or a false-negative test (told they don't have beta-amyloid deposits when they do). This will lead to unnecessary anxiety and treatment in some patients, false reassurance in others and a waste of millions of health-care dollars. ♦

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Outrage of the Month! Unreliable Alzheimer's Diagnoses

In a letter published in the May *Journal of the American Medical Association* (JAMA), Public Citizen criticized the authors of a study in a previous issue of the journal who tested the effectiveness of brain scans using an experimental dye to detect brain abnormalities found in Alzheimer's disease patients. The authors withheld critically important data from the journal when documenting the extent to which interpretation of these scans varies from one physician to another, Public Citizen said.

The public health implications of these unreliable tests would be twofold: First, substantial numbers of people could be incorrectly diagnosed as having such brain abnormalities when they really do not, and by the same token, others could be falsely reassured that they do not have such brain abnormalities when they actually do. By withholding important information, the authors misled the journal and its readers to believe that this test for identifying brain abnormalities was more reliable than it actually is.

Given what is known about Alzheimer's disease and the lack of effective treatments, any proposed test for diagnosing this disease must be proven to be highly accurate in large, rigorously conducted studies before it is approved by the Food and Drug

Administration for marketing.

In the JAMA study criticized by Public Citizen, researchers tested whether injection of an experimental radioactive dye, called florbetapir F 18, can be used to detect beta-amyloid plaques in the brains of living people using an imaging procedure called a positron emission tomography (PET) scan. The researchers proposed that the injected dye would bind to beta-amyloid plaques in the brain and be visible on a brain PET scan.

For the key part of the study, the researchers performed florbetapir-PET brain scans in 35 elderly, terminally ill subjects (only 17 of whom had been diagnosed with Alzheimer's disease). After their deaths, the researchers compared those scan results to measurements of beta-amyloid plaques in their brains during autopsy. Importantly, three nuclear medicine physicians, who had undergone extensive training, independently read and scored each florbetapir-PET scan for the amount of beta-amyloid seen in the subject's brain.

In their JAMA article, the researchers presented only the median score of the three physician readers for the amount of beta-amyloid seen on each florbetapir-PET scan. They withheld critical data on the scores

see [OUTRAGE, page 11](#)

Health Letter, Public Citizen Health Research Group
1600 20th Street, N.W., Washington, D.C. 20009

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