

Health Letter

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New "Diseases": Often Invented by Drug Industry Marketing Departments To Sell You Drugs

In an effort to boost sales, drug companies are shaping definitions for new diseases and exerting massive influence on the organizations that devise guidelines for the treatment of existing diseases, according to a series of articles in the *Seattle Times* which ran from June 26th through June 30th. (<http://seattletimes.nwsources.com/news/health/suddenlysick/hypertension.html>.)

In the past few years, pharmaceutical companies have helped form the nationally recognized guidelines for the treatment of disorders that affect millions of people, from high blood pressure to high cholesterol to osteoporosis to obesity.

But the guidelines, which physicians across the country use to make their diagnosis and treatment decisions, should be objective and unburdened by the influence of parties that have a major stake in the decisions, such as drug companies, according to critics quoted in the *Seattle Times* pieces.

People treated for illnesses they do not really have, or whose diagnoses are not sufficiently severe to require medication, run the risk of suffering the negative adverse effects associated with the medicine involved — which can be severe in many cases.

The cases described in the *Seattle Times* series illuminate the success of the long arm of the drug industry in

determining how national standards are set and how physicians treat patients.

Among these stories is the situation of osteoporosis. Drug companies have continually pushed for expanding the definitions of osteoporosis and for the treatment of a new condition, "osteopenia," which is essentially pre-osteoporosis defined by criteria that would apply to almost every middle-aged woman.

In 1992, the World Health Organization (WHO), the medical agency of the United Nations, sponsored a conference in Rome along with the International Osteoporosis Foundation, a nonprofit organization

that currently has 31 drug and medical-equipment companies on its advisory board, according to the *Seattle Times*.

The conference, also sponsored by two drug companies and a drug-company foundation, set out to determine the definition of osteoporosis. The conference decided that women's bone densities should be compared to the bone density of an average 30-year-old woman, and any deviation of a certain amount or larger from that average 30-year-old-woman's score would constitute osteoporosis.

However, bone-density may be a poor proxy for bone strength: the strength of bones depends both on

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bone density and on the quality of the bone itself. In addition, the new definition essentially converted women who had never had a fracture but who had low bone density to women suffering from osteoporosis; in the past, osteoporosis was diagnosed if a woman had a problem, such as a fracture.

The idea of low bone-density measurement also applied to osteopenia: women whose bone densities were moderately lower than those of a 30-year-old woman were considered to have osteopenia and therefore became candidates for preventive treatment.

An emerging drug and medical-device industry strategy was therefore developing in the 1990s: peddle bone-density testing machines to the office of every doctor in America, encourage women to get tested as soon as they are menopausal, and push treatment for any woman whose bone-density score is "too low", a drug-industry convenient definition that would encompass a large proportion of women.

Merck, maker of the multi-billion-dollar osteoporosis drug Fosamax, was the most aggressive, according to the *Seattle Times* series, pushing for the bone measurement machines, creating the "Bone Measurement Institute" to increase usage of the machines, and lobbying for the Bone Mass Measurement Act, which authorized Medicare to reimburse doctors for performing the tests and paved the way for other insurers to pay for the tests. All of which eventually lands people on Fosamax or, more recently, its counterpart, Actonel.

However, Fosamax is associated with some serious adverse effects, including gastrointestinal irritation, ulcers of the esophagus, skin rash, low blood calcium, and in rare cases, a degenerative condition called necrosis of the jaw. Younger and younger women with no history of fractures or bones breaking are risking these adverse effects to take drugs that may — or may not — prevent osteoporosis in the future.

Time and time again over the past two decades, drug companies have helped set up official-sounding organizations that delineate liberal treatment guidelines and have sponsored doctors that populate special advisory committees to set disease definitions and treatment guidelines.

For instance, panels formed by WHO and the National Institutes of Health to devise blood-pressure recommendations were each stocked with doctors who had been paid by drug companies during their careers, the *Seattle Times* reported.

The newspaper noted that WHO now receives more private money — \$500 million per year, some of it from drugmakers, than it receives in dues from member nations. Meanwhile, nine of the 11 members of an NIH panel that in 2003 recommended broader use of hypertension drugs had ties to drug companies. Organizations funded by drug companies have consistently lowered the minimum level of systolic (the 'top' number) and diastolic (the 'bottom' number) that would dictate being treated with drugs.

The drug companies have also

been waging a campaign to discredit the largest study of hypertension ever, known as the ALLHAT trial, conducted solely with government funds. That study found that diuretics — older, cheaper medications that are commonly known as "water pills" — are just as effective as new drugs such as ACE inhibitors and calcium channel blockers, developed more recently by drug makers and sold at high prices with often severe adverse effects.

Another *Seattle Times* example of drug-company influence on doctor decision-making involved obesity. In 1995, the NIH asked 24 experts to write guidelines for diagnosing and treating obesity. The panel, which was later criticized for ties to the drug and weight-loss industries, defined obesity as a "body-mass index" (BMI) of 30 or higher. But the body-mass index simply compares height to weight and is a crude measure of fatness. In addition, it is unclear that obesity — independent of the diseases it might lead to, such as heart disease or diabetes — ought to be considered a separate disease or that it should be treated medically.

The drug industry again pushed for pills as the solution. It funded a new organization, the American Obesity Association, which was strongly in support of treatment. Almost all weight-loss drugs or supplements have carried harmful and sometimes deadly side effects.

The *Seattle Times* article described the approval process for, dexfenflu-

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Ten Additional Causes of Medical Malpractice Lawsuits

Doctors who communicate poorly with their patients, don't follow up with test results or referrals, and spend insufficient time talking with patients often wind up on the receiving end of malpractice lawsuits, according to a recent article in the journal *Medical Economics*.

With myriad reports in the media about grisly malpractice cases, high malpractice insurance and the overall problems with quality of care in American medicine, the record-keeping details and the important personal aspects of a doctor's visit are often overlooked as major contributors to some patients' thinking that they were treated poorly.

The *Medical Economics* article reflects interviews with malpractice attorneys who have represented both plaintiffs and doctors. They delineated 10 pitfalls — in addition to actual medical mistakes themselves — that doctors ought to avoid if they intend to be well regarded by patients and reduce the chance of potential lawsuits.

Patients should keep these tips in mind, too: they are ways to make your doctor accountable to you and treat you as you expect to be treated. It is worth noting that this list is not a substitute for good medical care, for the right diagnosis and the right treatment. Rather, it serves as a supple-

ment that can facilitate the right care. If any of the following 10 appear to be problems with your physician, you should discuss them with him or her.

The following pitfalls from *Medical Economics* relate to important clerical aspects of doctors' offices, communication skills, follow-ups, and time spent with each patient:

- Poor or incomplete medical records on patients. Doctors often do not write every step they have taken on their charts, do not explain everything they are writing to their patients, and do not write them clearly enough so colleagues — or lawyers — are able to discern their thinking.
- No documentation of discussions of informed consent. Even though signing an informed consent document is important, a discussion of consent and what it means in the context of the patient is paramount. Doctors should be sure to document the discussion and what the patient did, or did not, agree to.
- Adjustment of patient records to reflect an injury or damage because of the medical care. Any correction to medical records should be accomplished with a

straight line over the original wording, not with erasure, white-out, or scratching out the original entry. Everyone should be able to see the initial entry and then any additions or changes to the original assessment.

- Failure to follow through on referrals. Although it is up to the patient whether he or she makes an appointment with a specialist and actually attends that appointment, the referring doctor can get in legal trouble if the doctor does not follow up to make sure the patient took these steps. The *Medical Economics* article suggests the offices of doctors whose patients declined to follow through on a referral ought to make telephone calls to the patients and send certified letters.
- Failure to track test results. Laboratories may lose or delay test results, but doctors who ordered the tests should set up a method for following up to make sure the results have been sent. In addition, if a doctor's office mails test results to patients, it should include information about what the results mean, so patients are not left to interpret them on their own. "Patients should be informed of all test results,

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ramine (Redux), one of the two drugs in the combination known as fen-phen, which was approved in 1996 and later recalled in 1997 because it caused major heart valve damage and pulmonary hypertension in thousands of patients and killed others. During an FDA advisory committee meeting to discuss potential approval of dexfenfluramine, evidence of strokes and a sometimes-fatal lung condition (pulmonary hypertension) among people taking the drug in clinical trials was overshadowed by the pro-industry cacophony of

suggestions that losing just 10 or 15 pounds could make a dramatic medical difference. The potential for heart problems were not even explored at the time. The eventual withdrawal of dexfenfluramine and a similar, older drug, fenfluramine, now represents the one of the most disastrous withdrawals in prescription drug history.

The *Seattle Times* articles also cite the emerging definition of "female sexual dysfunction" and the overhyped danger of deep vein thrombosis among airline passengers as instances in which the drug industry

has exerted undue influence on guidelines and national goals.

Overall, the series of articles documents a pattern of unethical and biased drug-company influence over panels, organizations, and conferences that set guidelines and make recommendations for treatment. Although your doctor technically writes the prescription for you medicines, his or her hand may be dangerously guided by the marketing "needs" of drug companies. ■

Product Recalls

July 26 — Aug 19, 2005

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. A Class I recall is a situation in which there is a probability that the use of or exposure to the product will cause serious adverse health consequences or death. Class II recalls may cause temporary or medically reversible adverse health consequences. A Class III situation is not likely to cause adverse health effects. 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.

Name of Drug or Supplement; Class of Recall; Problem	Lot #: Quantity and Distribution; Manufacturer
CVS pharmacy brand Wart Remover , Maximum Strength, Salicylic Acid, 17% w/w, Net Wt. 1/2 oz (14mL); Over the Counter, Class III, Misabeled: cartons of CVS pharmacy brand Wart Remover (Liquid) were printed with the Drug Facts Panel referencing Corn Remover (Liquid).	Lot Nos. 5A012A, exp. date 01/2007 and 5E001 exp. date 02/07; 45,642 units distributed nationwide; Clay Park Labs, Inc., Bronx, NY.
Glucotrol XL (Glipizide) Extended Release Tablets , 10mg, Rx only, Class III, Incorrect tablet imprint.	Lot 4XP036A; 1,920 units distributed nationwide; Pfizer, Inc., Cruze Davila, NY.

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whether normal or abnormal," *Medical Economics* recommends.

- Ignore a patient's potential adverse reactions to certain medications. Doctors should always look at a patient's chart before prescribing or ordering new medications to make sure the patient will not have an allergy to or adverse reaction from the treatment being considered.
- Diagnosis over the phone before even seeing the patient. Diagnosing over the phone without seeing the patient is imprecise and risky, and can lead to medical error. Doctors and patients should be wary of this method. Patients often can be inaccurate in their verbal descriptions and need further examination; body language and symptom severity are best assessed in person.
- Ignore the 'likeability' aspect.

Doctors who get sued are often the ones who do not appear as personable to patients. The patient and the doctor should have a good personal relationship, with the doctor treating the patient with respect, not dismissing the patient's feelings, and listening to the patient's concerns. Doctors should take more than a passing interest in the care of their patients and should appear concerned with and involved in patients' conditions.

- Do not take enough time with patients. Because of insurance companies, there is pressure to see more patients each day, making five-minute visits the norm and causing patients to feel neglected. *Medical Economics* suggests doctors offices should schedule patients for time slots based on the nature of their problems and their upcoming visit, not for cookie-cutter five- or ten-minute standard slots.

- Poor communication when injuries or adverse events occur. The *Medical Economics* article recommends that doctors, not staff members, explain the reason that particular diagnosis and treatment decisions were made and how the new problem will be handled. If the doctor makes a mistake, it is best to admit it, rather than cover it up, which makes patients and families even angrier. Sometimes patients will forgive honest mistakes, the article suggests, but not if they believe doctors are not being forthcoming with them.

As mentioned above, if any of these 10 "pitfalls" seem to be getting in the way of good care from your physician, have a discussion with him or her. If they do not want to have such a discussion, you might consider another doctor. ■

DRUGS AND DIETARY SUPPLEMENTS *cont.*

Name of Drug or Supplement; Class of Recall; Problem

Hyoscyamine Sulfate Oral Solution, USP, Hyoscyamine Sulfate, USP 0.125mg, Alcohol 5%, 15mL bottle, Rx only, Class II, Impurity.

K Effervescent Tablets Potassium (978mg), Orange Flavored, Potassium Bicarbonate Effervescent Tablets for Oral Solution, Rx only, Class III, Mispacked; outer carton incorrectly labeled as K Effervescent Tablets actually contains correct labeled product Effervescent Potassium/Chloride Tablets Fruit Punch Flavor.

Nicotine Polacrilex Gum, USP, 2mg (nicotine), over the counter, Rx Only, Class III, Degradation failure.

Renaphro Softgels, Each softgel contains: Vitamin C 100mg, Folic Acid 1mg, Niacinamide 20mg, Thiamine Mononitrate 1.5mg, Riboflavin 1.7mg, Vitamin B6 10mg, Vitamin B12 6mcg, Calcium Pantothenate 5mg and Biotin 150 mcg, Stress/Dialysis Vitamin, Rx only, Class III, Subpotent (calcium pantothenate).

Lot #: Quantity and Distribution; Manufacturer

Lot L030L04A, exp date 11/2006; 11,611 units nationwide and in Puerto Rico; Vintage Pharmaceuticals LLC, Huntsville, AL.

Lots KL40834-1, exp. date 8/2007, and KL50126-1, exp. date 1/2008; 7,680/30-tablet boxes distributed nationwide; Bajamar Chemical Co, Inc., Olivette, MO.

Lot 2NB04043, exp. date 02/2006, Lot 2NB04048 exp. date 02/006; 26,160 cartons of 110 chewing pieces and 5,704 cartons of 220 chewing pieces distributed nationwide; Watson Laboratories, Inc., Copiague, NY.

All lots whose first 3-digits start with 664; 208,692 units distributed nationwide and in Puerto Rico; Rising Pharmaceuticals, Inc., Allendale, NJ.

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.

Name of Product; Problem

ATVs. A significant impact to the front wheel of the ATV while the steering is fully turned to either side can result in suspension damage, wear, and an eventual loss of steering control that could result in injury or death.

Baby sandals. A plastic flower attached to the sandals can pull or snap off, posing a choking hazard to young children.

Baby's jackets. The metal buttons can come loose and detach from these garments, posing a choking hazard to young children.

Bicycle aero bars. The centerpiece of these bicycle aero bars can crack or break, causing the bicycle rider to lose control and crash.

Bicycle tires. The tire can separate from the wheel, resulting in a flat tire. This can cause the rider to lose control and fall.

Lot #: Quantity and Distribution; Manufacturer

Suzuki 2004-2005 TwinPeaks™ All-Terrain Vehicles (ATVs); about 3,400 vehicles sold at Suzuki dealerships nationwide, Dec 2003-Jul 2005; American Suzuki Motor Corp., of Brea, Calif; (800) 444-5077 or www.suzukicycles.com.

Caroline Flower Baby Sandals; about 5,600 sold at Gymboree stores and Web site nationwide, May-Jul 2005; The Gymboree Corp., of San Francisco, Calif.; (877) 449-6932 or www.gymboree.com.

Baby Denim and Knit Jackets; about 750 sold at H&M retail stores nationwide, Jan-May 2005; H&M, of New York, N.Y.; (877) 439-6261 or www.hm.com.

VisionTech USA SuperMax, TriMax, TriMax Plus and Pro model Integrated Bicycle Aero Bars; about 280 units sold at bicycle specialty stores nationwide, Mar 2002-Mar 2003; VisionTech USA, Inc., of Auburn, Wash.; (866) 204-5798, pin number 0118.

Bicycle Tires; about 1,100 sold at bicycle specialty stores nationwide, Feb-July 2005; Torelli Imports, of Camarillo, Calif.; (800) 523-6604 or www.torelli.com.

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Type of Product; Problem

Bicycle wheels. The hub in the bicycle's rear wheel can fail to engage properly, causing no resistance when pedaling. The bicycle rider can lose balance, fall and suffer injuries.

Bicycles. The rear axle on the bicycle is harder than required by the manufacturer's specification and could crack.

Children's folding chairs — multiple recalls. Children's fingers can become caught or entrapped in the hinge and slot areas of the chair. In Fourstar and Idea Nuova models, the chair's safety lock can fail, allowing the chair to collapse or fold unexpectedly. This can cause severe lacerations and finger tip amputations to children's fingers.

Children's wagons. The tips of the clickers, which make a clicking sound when the Walker Wagon wheels move, can break off. The broken clickers pose a choking or aspiration hazard to young children.

Children's watches. The band on the watch contains liquid petroleum distillates. If punctured the watch band could leak. Petroleum distillates could be harmful if ingested and cause irritation to the skin or eyes on contact.

Coffeemaker carafes. The carafe handle can unexpectedly loosen or break, resulting in the carafe falling. This can cause burn injuries from hot coffee or lacerations from broken glass.

Constructed deck materials. When the decking or railing material is exposed to hot temperatures and sunlight, it can prematurely degrade. The degraded material could break, posing a fall hazard to consumers.

Drills. The battery packs on these drill/drivers can overheat, expand and possibly rupture, creating an explosion or thermal burn hazard.

Electric bicycles. The front and/or rear wheel can collapse, causing the rider to fall and suffer injuries.

Gas fireplaces. The burner tube connection to the gas valve can leak gas when the main burner is on. This leaking gas can ignite, causing a minor flare-up, which could cause nearby combustibles to ignite.

Lot #: Quantity and Distribution; Manufacturer

Ritchey WCS — Protocol, Carbon, DS, DS Aero, Girder models; about 2,000 sold at bicycle specialty stores nationwide, Jan 2003-Jul 2005; Ritchey Design, of San Carlos, Calif.; (888) 776-8625 or www.ritcheylogic.com/wcsrecall.

2005 Cypress and Sedona bicycles; 76 units sold at authorized Giant Bicycle dealers nationwide after May 16, 2005; Giant Bicycle Inc., of Newbury Park, Calif.; (866) 458-2555 or www.giant-bicycle.com/us.

Children's folding chairs; about 1,797,000 sold nationwide by various manufacturers at furniture and wholesale club stores, discount department and toy stores, and grocery stores, Jul 2003-Jun 2005; Meco Corp., of Greeneville, Tenn, (800) 251-7558, csr@meco.net, or www.meco.net; Idea Nuova Inc., of New York, N.Y., 866-772-1666 or repair@ideanuova.com; Fourstar Group Inc., of Hopkinton, Mass., (866) 290-6191 or www.fsgrecall.com.

Classic Walker Wagon; about 38,000 sold at toy, department and discount stores, in catalogs, and by Web retailers, Aug 2003-May 2005; Radio Flyer Inc. of Chicago, Ill.; (800) 621-7613, www.radioflyer.com, or 12repair@radioflyer.com.

Water Watch; about 50,400 sold at Dollar General Stores nationwide, Mar-Jul 2005; Almar Sales Co. Inc., of New York, N.Y.; (800) 251-2522.

10-Cup Coffeemaker Carafes and Replacement Carafes; about 14,000 units sold at AAFES, Dillards, Bi-Mart and retail stores that sell housewares, Jul 2004-Jul 2005; West Bend Housewares LLC, of West Bend, Wis.; (800) 874-4084 or www.westbend.com.

GeoDeck(tm) Decking and Railing Materials; about 11,000 constructed decks sold at retail lumberyards nationwide, Apr 2002-Jul 2005; Kadant Composites Inc., of Bedford, Mass; (800) 545-1710 or www.KadantCompositesRecall.com.

3/8-Inch Drive Cordless Drill/Driver; about 2,000 sold at Mac Tools distributors, Nov 2003-Apr 2005; JS Products, of Las Vegas, Nev.; (877) 622-3494 or www.MacTools.com/vcs.

TidalForce S-750 High Performance Electric Bicycles; 110 units sold at authorized TidalForce High Performance Electric Bicycle dealers nationwide, May 2005-Jun 2005; WaveCrest Laboratories LLC, of Dulles, VA.; (888) 880-1988 or www.tidalforce.com.

"Vanguard" and "FMI" Compact Fireplaces; 534 sold at hearth shops, central heat and air conditioning retailers and gas suppliers nationwide, April 2004-June 2005; DESA Heating Products, of Bowling Green, Ky.; (866) 279-3225 or www.desatech.com.

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CONSUMER PRODUCTS *cont.*

Type of Product; Problem

Heater fans. The power cord on the units can fray or sever causing the fan to stop working and overheat. This could pose a fire hazard to consumers.

Pub stools. The amount of glue used to bond and hold the joints together on these stools could be insufficient. These stools could break and collapse during use, causing consumers to fall.

Slow cooker. The handles on the base of the slow cookers can break, posing a risk of burns from hot contents spilling onto consumers.

Snowmobiles. There are three separate issues involved in this safety recall: Front Suspension Spindle — The nut that fastens the upper control arm ball joint to the suspension spindle can loosen. If this occurs, continued operation could allow the spindle to break and release the upper control arm, posing a risk of loss of control of the vehicle. Fuel Tank Chaffing — The fuel tanks can contact the chassis along the bulkheads leading to wear on the tank walls. This could pose a fuel leakage and possible fire hazard to consumers. Gasket — The gasket sealing the fuel pump assembly to the tank can develop cracks. This poses a risk of fuel leakage and fire hazard to consumers.

Strollers. Stroller handle can disconnect from stroller frame during use.

Toy boxes. The toy box's lid support can fail, allowing the lid to collapse suddenly. This poses a strangulation hazard to young children, and possible impact injuries to a child's head, neck, fingers or hands.

Treadmills. If assembly instructions are not properly followed the gas spring/shock can be damaged during assembly if the walking platform is folded up and goes beyond the vertical position. This action can cause the shock to contact the treadmill roller and be damaged and could propel shock parts out. The parts of the shock could hit a bystander causing injury.

Treadmills. The treadmill can unexpectedly accelerate and cause users to fall and sustain injuries.

Lot #: Quantity and Distribution; Manufacturer

Holmes® and Bonaire® Tower Heater Fans; about 180,000 sold at Wal-Mart, Target, Linens N Things, Bed Bath & Beyond and additional department and specialty stores nationwide, Jul 2004-Jun 2005; The Holmes Group Inc., of Milford, Mass.; (800) 593-4269 or www.holmesheaterrecall.com.

Chelsea Pub Stool; about 2,200 sold at Home Centers, Garden Centers, Outdoor Furniture Specialty Retailers, and Unfinished Furniture stores nationwide, Dec 2004-Jun 2005; (800) 653-3336, Ext. 164 or Ext. 251.

Rival(r) Slow Cooker; about 2.6 million sold at Wal-Mart, Kmart, Target and additional discount department stores nationwide, Jan 1999-May 2005; www.rivalrecall.com or (800) 299-1284.

Polaris "900 Fusion" "900 RMK" and "900 Switchback" Snowmobiles; about 7,800 sold at Polaris dealers nationwide, Aug 2004-Jun 2005; Polaris Industries Inc., of Medina, Minn.; (800) 765-2747 or www.polarisindustries.com.

Kelty Speedster Deluxe and Speedster Deuce Jogging Strollers; 349 units sold at juvenile baby product stores, sporting good stores and Web retailers, May-June 2005; Kelty Division of American Recreation Products Inc., of Boulder Colo.; (800) 535-3589 Ext. 3335.

Stork Craft Toy Boxes; about 3,300 sold at Wal-Mart and J.C. Penney Web sites, and at furniture, baby and juvenile stores nationwide, Dec 2002-Apr 2005; Stork Craft Manufacturing Inc., of Richmond, British Columbia, Canada; (877) 274-0277 or www.Storkcraft.com.

Epic T60 treadmill; about 16,700 sold at Costco Wholesale stores nationwide, Sept 2004-Feb 2005; model number EPTL81804; ICON Health & Fitness, Inc., of Logan, Utah; (800) 999-3756 or www.iconfitness.com.

Tredex 6.0, TX 440 and TX 550 Treadmills; about 12,000 sold at discount department and other retail stores nationwide, Dec 2002-Apr 2005; Sportcraft Ltd., of Mt. Olive, N.J.; (800) 526-0244 or www.sportcraft.com.

Preventing the Epidemic of Skin Cancer: A Guide for Protecting Yourself and Your Family

Young People are Increasingly the Victims, Although Most Cases are in Older Adults

A study just published in the Journal of the American Medical Association has shown that between 1976 and 2003 there has been a three-fold increase in the incidence of skin cancer (not including melanoma, the deadliest form of skin cancer) in people under the age of 40, affecting females and males but especially prominent in women. Not surprisingly, the main areas where the cancers occurred were the head, neck, shoulders and upper torso. Although the study was based on people living in Olmstead County (near Minneapolis), the authors stated that its findings could be generalized to much if not all of the United States.

The study emphasizes that there is a virtual epidemic of skin cancer, with more than one million new cases a year occurring in the United States. Among the reasons is the increasing popularity of tanning salons, especially among younger people. In addition, surveys done by other researchers find that only about half of people with significant sun exposure use sun screen and about 40% of people do not understand that even moderate doses of the ultraviolet (UV) light in sun exposure can cause skin cancer.

The authors stated that, "This increase may lead to an exponential increase in the overall occurrence of nonmelanoma skin cancer over time as the population ages. This may mean even greater demands for health care related to nonmelanoma skin cancer. Our results also emphasize the need to focus on the prevention of skin cancer in the very young so that the increasing incidence of a potentially preventable cancer can be halted."

A story that ran on the Reuters news wire on August 15th gave some interesting historical background to this alarming trend:

"Tanning was dismissed as gauche until the 1920s, when couture guru Coco Chanel returned from a vacation

in the south of France with golden skin, instantly turning a tan into a fashion statement. Fashion magazines and celebrities like Jessica Simpson and Lindsay Lohan help keep the trend alive. Tanning beds and tanning creams make it possible to get bronzed year-round....Even after research has tied tanning to skin cancers like melanoma and basal cell carcinoma, young people still see a tan as a fashion accessory and can be lax about protection." For example, Reuters cited a study by dermatologists that found that 61 percent of women 18 and older

*About 40% of people
do not understand
that even moderate
doses of the ultraviolet
(UV) light in sun
exposure can cause
skin cancer.*

think they look better with a tan, and more than half think it makes them appear healthier.

What You Can Do to Reduce Your Risk of Skin Cancer

Stay out of the sun when it is hottest, if possible: Between the hours of 10 AM and 2 PM the ultraviolet radiation from the sun is greatest and is more likely to cause sunburn and the accompanying increased risk of skin cancer, so use common sense. Even if it is cloudy, you will still get a significant amount of exposure. Ultraviolet rays bounce off sand and

other reflective surfaces and will affect someone under an umbrella. About 80% of the sun's rays will pass through clouds, so a cloudy, but hot day offers little protection.

Avoid Indoor Tanning Beds/Booths: Although this advice may sound silly to many older adults, an astounding proportion of younger people have used these skin cancer-generating devices. A study in Minnesota found that 34% of adolescents had used a tanning facility — 51% of women and 15% of men.

Wear Protective Clothing: Wear a wide-brimmed hat and clothes that cover as much of your body as possible and avoid loose-knit clothes that allow the sun to hit your skin. A child wearing a cotton tee-shirt will be protected as long as the shirt does not become wet; when wet it will allow up to 50% of UV radiation through.

Use Sunscreen Products: Sunscreen products contain UV filters, i.e. chemicals which reflect and scatter UV radiation (physical UV filter) or absorb UV radiation (chemical UV filter). The inorganic compounds titanium oxide and zinc oxide are commonly used as physical UV filters in sunscreen products. However, a wider range of organic compounds is used as chemical UV filters including benzophenone, benzylidene camphor, butyl methoxydibenzoylmethane, camphor benzalkonium methosulfate, drometrisole trisiloxane, homosalate, isoamyl p-methoxycinnamate, 4-methylbenzylidene camphor, octocrylene, octyl dimethyl PABA, octyl methoxycinnamate, octyl salicylate, octyl triazone and PEG-25 PABA.

Cover all parts of your body that will be exposed to the sun with sunscreen that has an SPF (sun protective factor) of at least 30. ■

Asthma Medicines That Can Cause Asthma Attacks: Do Not Use SEREVENT,ADVAIR, or FORADIL

A Food and Drug Administration advisory committee has voted in favor of putting stronger warnings on three widely used asthma inhalers — salmeterol (SEREVENT), salmeterol with the steroid fluticasone (ADVAIR) and formoterol (FORADIL). These medicines are long-acting asthma inhalers, used to keep asthma under control over time, rather than helping to stop an acute asthma attack.

DO NOT STOP ANY ASTHMA MEDICATION WITHOUT FIRST CONSULTING YOUR PHYSICIAN. ABRUPTLY STOPPING A MEDICATION MAY RESULT IN ACUTELY DETERIORATING ASTHMA CONTROL.

The FDA convened a meeting of its Pulmonary-Allergy Drugs Advisory Committee on July 13, 2005 to discuss the safety of these drugs. The advisory committee voted to keep these drugs on the market but recommend stronger safety warnings on the professional product labels for all three drugs.

These inhalers are in the family of asthma drugs known as long-acting beta-agonist bronchodilators. Note that this is a different family of medicines than the asthma drugs albuterol (PROVENTIL, VENTOLIN), metaproterenol (ALUPENT) and pirbuterol (MAXAIR). Those are short-acting beta-agonist bronchodilators, and are used to improve breathing during an asthma attack.

GlaxoSmithKline of Research Triangle Park, N.C., sells both of the salmeterol-containing products. Salmeterol by itself was dispensed over 2.1 million times in U.S. pharmacies in 2004, with sales exceeding \$200 million. The combination product, Advair, is what Wall Street terms a "blockbuster." More than 16.1 million Advair prescriptions were sold in the U.S. in 2004; sales topped \$2.1 billion for the year.

Formoterol is produced by the Schering Corp. of Kenilworth, N.J.

Formoterol is not a top seller and sales figures for 2004 are not available.

We listed salmeterol as a DO NOT USE drug in the March 2003 issue of *Worst Pills, Best Pills News* after the FDA announced on January 23, 2003 that a large safety study involving salmeterol had been halted prematurely. The study was halted because an interim analysis of outcomes suggested that the drug may be associated with an increased risk of life-threatening asthma episodes or asthma-related deaths.

The prematurely terminated study went by the name of the Salmeterol Multi-center Asthma Research Trial, or SMART for short. GlaxoSmithKline initiated the study in 1996. It was designed to assess the safety of salmeterol because of concerns regarding the safety of regular use of short- and long-acting beta agonists in the management of asthma. There were 25,858 patients recruited before the study was stopped.

At that time, Public Citizen's attempts to obtain detailed information about the SMART study from the FDA were fruitless. Because the SMART study was conducted after salmeterol was approved and did not fulfill any regulatory requirement on the part of GlaxoSmithKline, details of the study could not be released under the FDA's interpretation of the Freedom of Information Act. The agency considered this important safety information to be protected confidential commercial information that could not be released to the public.

On August 14, 2003, the FDA announced that a black box warning had been added to the professional product labeling for drug products containing salmeterol. This warning applied to both salmeterol by itself and Advair. The FDA can ask for black box warnings for drugs that have been associated with the deaths of patients and may also require them if there is strong evidence from animal experiments. A black box

warning is the strongest type of safety warning that the FDA can seek for a drug's professional product labeling (see *Worst Pills, Best Pills News* November 2003).

In the first serious congressional hearings examining drug safety held in almost 14 years, Dr. David Graham, an FDA medical epidemiologist, testified before Senator Charles Grassley's Senate Finance Committee in October 2004 that the safety of salmeterol was of concern to the FDA.

It was not until the day before the July 13, 2005 Pulmonary-Allergy Drugs Advisory Committee meeting, when the FDA posted its review on the Internet, that the public was able for the first time to view the details of the SMART study. This was an unacceptable 31 months after the SMART study was stopped prematurely. The FDA's review of the SMART study is available at http://www.fda.gov/ohrms/dockets/ac/05/briefing/2005-4148B1_03_00-FDA-TOC.htm.

The main purpose of the SMART study was to measure the combined number of respiratory-related deaths or respiratory-related life-threatening experiences such as the need for intubation and mechanical ventilation in patients taking salmeterol. This is called the primary endpoint. The study consisted of a single clinic visit for each participant during which the person's eligibility status was evaluated. To be eligible to participate, patients had to have a clinical diagnosis of asthma and currently take prescription asthma medications. During the single clinic visit, patients were randomly assigned to receive either two puffs daily of salmeterol or a placebo.

At the end of the 28-week study, 50 patients out of 13,176 given salmeterol either died or suffered a life-threatening event compared to 36 receiving the placebo. The difference in life-threatening respiratory events

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reviewed the drug wrote that "sibutramine has an unsatisfactory risk-benefit ratio and therefore this Reviewer recommends non-approval of the original submission." The concern of both the advisory committee and the FDA medical officer was based on the fact that sibutramine significantly increases blood pressure and heart rate in many people. In the clinical trials, compared to patients receiving a placebo, an excess of 10 percent of Meridia users had a sustained increase in diastolic blood pressure of 10 mm Hg (millimeters of mercury) or more and 4 percent had a sustained increase in systolic pressure of 15 mm Hg or more at the commonly used 15 milligram dosage.

When announcing its seriously mistaken approval of sibutramine in November 1997, the FDA stated that the average weight loss in obese people taking the drug for one year — beyond the weight loss in those getting a placebo — was only 6 1/2 pounds in the group taking 10 mg of the drug.

It is especially ironic that Abbott, caught hiding information about Meridia deaths by the FDA, claims that our efforts to ban Meridia are "not based on valid scientific analyses." A 3/21/02-4/03/02 FDA inspection report of the Abbott Laboratories plant in Abbott Park, Ill., found that "[one] death associated with Meridia was not reported and several records [involving seven other deaths]

reviewed showed that the adverse drug information reported to FDA was either not accurate, not supported by source data, or was missing additional information found in the source data."

Once again, the FDA is siding with a large drug company, much as the agency did several years ago with Merck concerning Vioxx, when it failed to demand a black box warning on that drug. How many more dangerously flawed decisions will the FDA make before the Congress repeals the Prescription Drug User Fee Act, which brings the agency ever closer to — and makes the agency less vigilant over — the companies that give it almost \$200 million a year in funding? ■

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and asthma-related deaths between the groups was significant in the FDA analysis.

The following is the proposed revised black box warning for salmeterol.

FDA RECOMMENDED BLACK BOX WARNING

WARNING: Data from a large placebo-controlled US study that compared the safety of salmeterol (SEREVENT Inhalation Aerosol) or placebo added to usual asthma therapy showed a small but significant increase in asthma-related deaths in patients receiving salmeterol (13 deaths out of 13,176 patients treated for 28 weeks) versus those on placebo (3 of 13,179).

The black box warning added to salmeterol's labeling on August 14, 2003 suggested that the risk may be greater in African-American patients compared to Caucasians. The FDA has proposed deleting this information from the black box warning because the risk for asthma-related deaths in Caucasians and African Americans treated with salmeterol relative to being treated with placebo were quite similar.

Warnings for Formoterol

The advisory committee also voted that formoterol should carry stronger warnings. At this time, formoterol does not have a black box warning in its professional product labeling as do salmeterol and Advair. The evidence for problems with formoterol is not as strong as it is with salmeterol.

In the three studies submitted by formoterol's manufacturer to the FDA before the drug was approved, two dosages were evaluated: 12 micrograms and 24 micrograms, each given twice daily. The drug's approval was restricted to the lower dosage because serious worsening of asthma occurred with more frequency in both adult and pediatric patients who received the higher dose. This result was serious enough to warrant a commitment from the manufacturer to conduct a post-marketing safety study, known as a phase IV study, to further examine the relative safety of the different doses of formoterol. No deaths occurred in this study.

The FDA concluded that the formoterol phase IV study was too small to provide a strong answer similar to the SMART study for salmeterol, but the results were generally compatible with the decision not to approve the higher 24-microgram-twice-daily dose of the drug.

The long-acting beta agonist asthma drugs should not be used as a replacement for inhaled steroids. These drugs should not be started in patients whose asthma is significantly worsening or acutely deteriorating. This may be life threatening. The long-acting beta agonists should not be used to treat acute asthma symptoms.

The weight of the available scientific evidence points to the long-acting beta agonists as being less safe than their short-acting counterparts. There is no evidence that patient outcomes are better with the long-acting agents compared to the older short-acting drugs.

What You Can Do

Do not stop any asthma medication without first consulting your physician. Abruptly stopping a medication may result in acutely deteriorating asthma control.

You should not use salmeterol (SEREVENT), the combination of salmeterol with the steroid fluticasone (ADVAIR), or formoterol (FORADIL) for the treatment of your asthma.

You should report to your physician any increased need for a short-acting beta agonist. This is a sign of deteriorating asthma. ■

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Outrage: FDA Denial of Public Citizen's Petition to Ban Meridia Is Misguided

On March 19, 2002, Public Citizen's Health Research Group petitioned the FDA to remove the diet drug Meridia (sibutramine) from the market because of its association with cardiovascular adverse events, including death. We supplemented our petition with updated data on September 3, 2003. On August 9th, 2005, the FDA rejected the petition. Below is the statement of Dr. Sidney Wolfe in response to the denial.

For a drug such as Meridia to be approved or for it to stay on the market, there must be evidence that its benefits outweigh its risks. Evidence prior to its approval and more than 50 cardiovascular deaths, many in young people, since its

approval confirm that its benefits do not outweigh its risks and that it should be removed from the market despite efforts by the FDA/Abbott duo to keep the drug alive.

Although there was a 60 percent decrease in prescriptions filled for this drug in the United States between 2001 (1.7 million prescriptions filled) and 2004 (670,000 prescriptions filled), many people are still getting this dangerous but not very effective drug that we have warned people not to use since 2001 and petitioned the FDA to ban in 2002.

One of the only independent reviews of this drug was published a year ago in the *Annals of Internal Medicine* by researchers from the

University of Washington. Predictably, this study was not mentioned by either the FDA or by Abbott in their responses to our petition. The authors concluded that:

"Weight loss with sibutramine was associated with modest increases in heart rate and blood pressure....There was no direct evidence that sibutramine reduces obesity-associated morbidity or mortality....Thus, we conclude that there is insufficient evidence to accurately determine the risk-benefit profile for sibutramine."

Prior to sibutramine's approval in 1997, an FDA advisory committee voted 5-4 that the benefits of sibutramine did not outweigh the risks. The FDA medical officer who

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