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Health Letter

SIDNEY M. WOLFE, M.D., EDITOR

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A New Health Care Gimmick: Concierge Medicine

The doctor industry (let's forget that outdated, misleading term "medical profession") is beginning to consider a giant step backward in the national quest for universal health care. It's called "concierge-style" medicine — a term more reminiscent of innkeeping than of caregiving — and already seems to have the blessing of that sometimes sleepy watchdog of sound medical practice, the American Medical Association (AMA).

As described in a recent issue of the publication *Medical Economics*, a doctor-oriented magazine more concerned with economics than with medicine, the "concierge" idea came out of Louisville, Kentucky, about a year ago with the transformation of an old-fashioned doctor's office into an entity named OneMD. As described in the *Medical Economics* article, OneMD is "a retainer or concierge-style practice that caps the number of patients at 300 per doctor. In return for a $4,000 annual fee ($6,000 per couple), patients get 24/7 access, reduced in-office waiting time, house calls, an enhanced yearly health exam, and other gold-plated services not generally covered by insurers."

Exactly how these promises will be fulfilled remains an open question. "24/7 access" could be nothing more than the time-worn "take two aspirin and call me in the morning." But one thing is certain about the concierge plan: if widely adopted, it is going to exacerbate the No. 1 health care problem vexing the United States today: the multi-million load of Americans without medical resources of any kind except, perhaps, the dubious privilege of visiting an already overcrowded publicly operated emergency room.

Consider: Dr. X has 500 individuals on his patient roster at the time he decides to go the OneMD way. The first thing he must do is reduce that load by 40 percent (assuming that 300 is the maximum number allowed). This probably won't be hard if he (or his financial advisers) insist on $4,000 up front to become concierge clients. But then where do the other 200 people go? To already overloaded HMOs, obviously, or to doctors who are willing to accept patients without limit, or — a not unlikely possibility — who cook their books in the imaginative fashion so popular with the Enrons and Worldcoms of Wall Street in recent years.

A few old-fashioned family docs may hesitate, asking the obvious question: Is all this manipulative high-jinks ethical? Enter the ever-vigilant AMA's Council on Ethical and Judicial Affairs, which prescribes such "guidelines" as "Doctors must be honest in billing third-party payers" and (on the negative side) "Retainer-style practices shouldn't be marketed as providing better diagnostic and therapeutic services." Questions: (1) Isn't honesty in billing

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basic to decent business practice? And (2) If these high-ticket "concierge" or "boutique" practices *don't* "provide better ... services," how can they justify their existence, and if they *do* provide such services, why shouldn't they be able to "market" that fact — assuming also that the old-time rule that doctors don't advertise is dead-and-gone forever?

The *Medical Economics* piece is replete with advice, including (not surprisingly) how to "address legal issues." The key, acording to Step. No. 4 of nine in the article's cautionary list, is "to work with a good health-care attorney — someone familiar with the requirements for structuring retainer-style practices. (For more on these issues, see 'Avoid these legal pitfalls.')" These pitfalls mostly relate to billing problems, which can be considerable if the would-be concierge-doctor tries to ride two bicycles at once, maintaining his blue-chip relationship with a few hundred clients (patients doesn't seem to be the right word in this context) while continuing to handle cases shunted to him/her by HMOs and similar organizations.

The question of the elitist quality of concierge medicine recalls Claude Rains's reaction to allegations of funny business in the movie *Casablanca*: "I am shocked — shocked!" "And what about the criticism that concierge medicine is elitist?" the *Medical Economics* article asks. "Doctors we spoke to say that some of their patients are wealthy, but most aren't. They're either people with complex medical needs willing to reallocate resources slated for less urgent purposes, or healthy people for whom wellness and prevention are top priorities worth paying for."

The article goes on to quote a Massachusetts physician named Richard S. Goldman, who closed a conventional internal medicine practice in a far-out Boston suburb to open a boutique called AccessMD in a ritzier town closer in, on the question of elitism: "It would be nice to provide this level of care to everyone, but, until the system changes, I think this style of practice is a very viable option for both patients and doctors."

When a scheme with promising prospects for money-grabbing materializes, can corporate greed be far behind? You supply the answer. In the case of concierge/boutique medicine, the trend is already obvious in doctor-heavy Florida, where a company called MDVIP has emerged (Consider the elitist overtones of these initials: MD = doctor of medicine, and VIP = very important persons.) The company — whose stated role is "to [assist] doctors in transitioning from traditional to retainer-style practices" — has expanded its network in three years from a handful of local offices to 24 practices in seven states, with 40 more practices in the works, according to *Medical Economics*. MDVIP's president is quoted as saying, "We think there are as many as 2,000 primary care physicians out there who would qualify for this type of arrangement."

Scary? Well, there may be a ray of hope for the future (however dim, considering its source). Last April, five congressmen wrote a letter to President Bush questioning the legality of MDVIP's program, stating — according to the publication *American Medical News* — that it seems to violate Medicare balance-billing rules, and asking the administration to review the matter. That is the good news; the bad news is that all five congressmen are Democrats.

Another legislative attack on concierge-ism was launched last year in the Senate — again, predictably, by a Democrat, Bill Nelson of Florida. Referring to actual experiences of former MDVIP clients who did not meet the company's financial standards and were dropped, Nelson said (according to American Medical News), "If this practice continues to spread, it could mean the end of Medicare."

The Bush White House's much-touted compassionate conservatism, together with its attitude toward Democrat-initiated legislative proposals, does not bode well for those who think that concierge-ism must go. In fact, the boutique movement — more than a year after it got started — seems to be on a roll.

It's nice to know that someone is watching, but don't get your hopes up too high. That light you see at the end of the tunnel may actually be a train approaching.

THE PUBLIC CITIZEN HEALTH RESEARCH GROUP
Health Letter

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

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Our Web site address is **www.citizen.org/hrg**.

DO NOT USE!

Rosuvastatin (CRESTOR) — A New But More Dangerous Cholesterol-Lowering "Statin" Drug

Rosuvastatin (CRESTOR) became the sixth cholesterol-lowering "statin" drug on the U.S. market when it was approved by the Food and Drug Administration (FDA) on August 13, 2003. The other members of the statin family are atorvastatin (LIPITOR), fluvastatin (LESCOL), lovastatin (MEVACOR), pravastatin (PRAVACHOL), and simvastatin (ZOCOR). These drugs are approved only for use along with a low-cholesterol diet and an exercise program to lower cholesterol.

Another drug of this family, cerivastatin (BAYCOL), was removed from the market because of at least 31 reports of fatal rhabdomyolysis, an adverse reaction involving destruction of muscle tissue that can lead to kidney failure (see *Worst Pills, Best Pills News* October 2001). We had warned patients not to use this drug more than three years before it was removed from the market.

Rosuvastatin will be sold by AstraZeneca of Wilmington, DE under license from Shionogi & Co., Ltd., of Osaka, Japan.

AstraZeneca originally filed its application with the FDA in June 2001 to market rosuvastatin. The application was delayed when the company halted clinical trials worldwide after reports of kidney damage and muscle weakness (an early signal for rhabdomyolysis) in trials involving patients taking 80 milligrams of the drug per day. The FDA thereupon asked AstraZeneca for more data. The company stopped development of the 80-milligram dose because of the safety problems, and rosuvastatin will only be sold in 5, 10, 20, and 40 milligram strengths. Because of safety concerns there will be special restrictions on the distribution of the 40-milligram strength that will be discussed further below.

On July 9, 2003 the Health Research Group made a formal presentation before the FDA's Endocrinologic and Metabolic Drugs Advisory Committee strongly opposing the approval of rosuvastatin because of its unique kidney toxicity. We were also seriously concerned because of seven cases of rhabdomyolysis that were common enough to have shown up in the pre-approval clinical trials of rosuvastatin in which the 80-milligram dose was used. Not one case of rhabdomyolysis appeared in any of the pre-approval studies of the previously approved statins, including cerivastatin, which was removed from the market because of rhabdomyolysis.

The text of our advisory committee presentation is available on our web site at http://www.citizen.org/publications/release.cfm?ID=7262. Readers not connected to the Internet can write us for a copy.

As we said in our testimony before the advisory committee, a major factor that distinguishes rosuvastatin from the other five statins still on the market is the drug's potential to cause kidney damage. In the FDA review documents posted on the agency's web site before the Endocrinologic and Metabolic Drugs Advisory Committee it was noted "In contrast to currently approved statins, rosuvastatin was also associated with renal [kidney] findings not previously reported with other statins."

A number of patients taking primarily the 80 and 40 milligram doses of rosuvastatin had an increased frequency of persistent protein in the urine (proteinuria) and blood in the urine (hematuria), that in some subjects was also associated with another abnormal test result that is an early signal for kidney toxicity known as the serum creatinine level. The FDA documents pointed out that there were two cases of kidney failure and one case of kidney insufficiency with 80 milligrams of rosuvastatin in which these patients also had experienced both protein and blood in the urine.

An FDA medical officer reviewing rosuvastatin had sobering comments on the cases of kidney problems with the drug:

> These three cases of renal insufficiency of unknown etiology are of concern because they present with a clinical pattern, which is similar to the renal disease seen with rosuvastatin in these clinical trials. There is mild proteinuria associated with hematuria and the suggestion of tubular inflammation or necrosis [death of cells]. All cases occurred at the 80 mg dose which was also associated with the greatest number of patients with abnormal renal findings in these clinical trials. Proteinuria and hematuria could be potentially managed with regular urinalysis screening. However, if they are the signals for the potential progression to renal failure in a small number of patients, this may represent an unacceptable risk since currently approved statins do not have similar renal effects.

AstraZeneca attempted to "spin" the drug's potential for causing elevated protein levels in the urine by claiming that it was due to a previously unobserved effect of the statin family of drugs. However, the

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research submitted by AstraZeneca to the FDA did not show a similar degree of urine protein elevation with any of the other statins.

The Endocrinologic and Metabolic Drugs Advisory Committee recommended that kidney monitoring be required for patients taking 40 milligrams of rosuvastatin per day. The FDA failed to take this advice; rather, the agency approved this puzzling statement in the Laboratory Tests section of the drug's professional product labeling or package insert:

> In the rosuvastatin clinical trial program, dipstick-positive proteinuria and microscopic hematuria were observed among rosuvastatin treated patients, predominantly in patients dosed above the recommended dose range (i.e., 80 mg). However, this finding was more frequent in patients taking rosuvastatin 40 mg, when compared to lower doses of rosuvastatin or comparator statins, though it was generally transient and was not associated with worsening renal function. Although the clinical significance of this finding is unknown, a dose reduction should be considered for patients on rosuvastatin 40 mg therapy with unexplained persistent proteinuria during routine urinalysis testing.

The problem with this statement is that it is very unlikely that the average patient would routinely receive urine testing for protein. National guidelines recommend periodic urine testing only for people without symptoms who have diabetes or are pregnant. At a minimum the FDA should have required routine urine testing for all dosages of rosuvastatin.

Any elevation of protein in the urine beyond a trace is abnormal and is a possible signal of more serious kidney problems, even more so if there is also blood in the urine.

A popular buzz word frequently used by the FDA these days is Risk Management — assessing public health risks, analyzing methods for reducing them, and taking appropriate action. The FDA's Risk Management strategy for the safety problems associated with rosuvastatin can hardly be called "appropriate." The 40-milligram tablet will not be stocked in retail pharmacies and the pharmacy would need to go through a wholesaler to obtain them. This would take an extra day before the tablets arrived at the pharmacy. Somehow the FDA believes that "[t]hese steps will help to ensure that the 40-mg dose is available only to patients who truly need this dose." To easily beat this restriction, there is nothing to prevent a physician from writing a prescription for 20 milligram tablets and instructing the patient to take two tablets of rosuvastatin daily.

Clearly, the only "appropriate" and safe Risk Management strategy for rosuvastatin would have been not to approve the drug in the first place.

Rosuvastatin's professional labeling also carries warnings about elevated liver enzymes, an early signal for possible liver toxicity, and muscle pain and weakness that may be precursors to rhabdomyolysis. These warnings appear in the labeling for all statin drugs:

It is recommended that liver function tests be performed before and at 12 weeks following both the initiation of therapy and any elevation of dose, and periodically (e.g., semiannually) thereafter.

Rare cases of rhabdomyolysis with acute renal failure secondary to myoglobinuria [a protein from muscle] have been reported with rosuvastatin and with other drugs in this class.

The professional product labeling goes on to instruct physicians to tell patients "... to promptly report unexplained muscle pain, tenderness, or weakness, particularly if accompanied by malaise or fever."

The risk of muscle damage leading to rhabdomyolysis during treatment with rosuvastatin may be increased when it is used together with other cholesterol-lowering drugs and cyclosporine (NEORAL, SANDIMMUNE), a drug used after transplantation to prevent organ rejection.

A single rosuvastatin dose given to healthy volunteers on the cholesterol lowering drug gemfibrozil (LOPID) resulted in a significant increase in the amount of rosuvastatin in the body. There is a bolded statement in the Warnings section of rosuvastatin's labeling stating that **"[c]ombination therapy with rosuvastatin and gemfibrozil should generally be avoided."** The risk of muscle problems possibly leading to rhabdomyolysis is also increased when niacin is used in combination with rosuvastatin to lower cholesterol.

When rosuvastatin was given together with cyclosporine in heart transplant patients, the amount of rosuvastatin increased significantly in the blood compared with healthy volunteers. This increase is considered to be clinically significant.

When rosuvastatin was given to patients on stable warfarin (COUMADIN) treatment to prevent blood clots, there was a clinically significant rise in the International Normalized Ratio (INR), a laboratory test used to monitor warfarin therapy that can increase the risk of bleeding.

A number of factors went into our decision to list rosuvastatin as a DO NOT USE drug:

1. Rosuvastatin joins atorvastatin and fluvastatin as the statins that have not demonstrated a health benefit to the patients that use them in terms of reducing serious cardiovascular consequences of high cholesterol such as a first or second heart attack or stroke. Lovastatin, pravastatin, and simvastatin have shown such benefits to patients in addition to their cholesterol-lowering properties, and this is reflected in the professional product labels and advertising for these drugs.

The only reliable, valid indicator of a drug's demonstrated health benefit that consumers can use is if that information is contained in the drug's

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A Reminder About The Dangers Of Aspirin And Reye's Syndrome

The flu season is approaching and with it the risk of Reye's syndrome when aspirin is used to treat the symptoms of an influenza infection.

Reye's syndrome is primarily a children's disease, although it can occur at any age; some cases occur up to age 40. It affects all organs of the body but is most harmful to the brain and the liver — causing an acute increase of pressure within the brain and, often, massive accumulations of fat in the liver and other organs. Reye's syndrome generally occurs in people who have used aspirin in conjunction with a previous viral infection, such as the flu or chicken pox. The disorder commonly occurs during recovery from a viral infection, although it can also develop three to five days after the onset of the viral illness.

The symptoms of Reye's syndrome include persistent or recurrent vomiting, listlessness, personality changes such as irritability or combativeness, disorientation or confusion, delirium, convulsions, and loss of consciousness. If these symptoms are present during or soon after a viral illness, medical attention should be sought immediately. The symptoms of Reye's syndrome in infants do not follow a typical pattern; for example, vomiting does not always occur. The cause of Reye's syndrome remains a mystery. However, studies have shown that using aspirin or salicylate-containing medications to treat viral illnesses greatly increases the risk of developing Reye's syndrome. A physician should be consulted before giving a child any aspirin or anti-nausea medicines during a viral illness.

The Spanish Medicines Agency (Spain's equivalent of our Food and Drug Administration) announced that, effective June 20, 2003 all over the counter (OTC) drug products containing aspirin for use exclusively in children have been withdrawn from the market due to the risk of Reye's syndrome in children with viral illnesses. In addition, the product information for all other OTC aspirin-containing products is to be updated to include a contraindication for use in patients less than 16 years of age. Prescription products will be contraindicated in patients less than 16 years of age when used for the treatment of fever, chickenpox and viral illnesses.

Reye's syndrome is primarily a children's disease, although it can occur at any age.

Here in the United States, aspirin products contain the following warning:

> **Warnings:** Reye's syndrome: Children and teenagers should not use this medicine for chicken pox or flu symptoms before a doctor is consulted about Reye's syndrome, a rare but serious illness reported to be associated with aspirin.

The Health Research Group pushed a recalcitrant Department of Health and Human Services and Office of Management and Budget to require a warning label on all bottles of aspirin, which they did in 1986. Now the number of Reye's syndrome cases is but a fraction of the hundreds of cases a year occurring in the U.S.

What You Can Do

People under 40 who have flu, chickenpox, or flu-like illness and need a drug simply to relieve pain or reduce fever should use acetaminophen (TYLENOL) rather than aspirin.

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FDA-approved product labeling. Advertising claims for drugs can not be made unless research has been submitted to and approved by the FDA that the drug will actually do what a manufacturer claims.

2. Rosuvastatin causes abnormal elevations in urine protein and blood that are signals of serious kidney toxicity; other statins are not associated with this risk.

3. Rosuvastatin is the only statin that has shown life-threatening rhabdomyolysis in pre-approval clinical trials.

In summary, rosuvastatin has no proven health benefit as discussed above, it can cause potentially serious kidney toxicity that is not seen with the other statins, it is the only statin that caused rhabdomyolysis, a life-threatening adverse drug reaction, in pre-approval clinical trials, and there are already three statins on the market that are safer than rosuvastatin and have demonstrated a health benefit to patients.

What You Can Do

There is no medical reason for you to be taking rosuvastatin when there are three safer and more effective statins, in terms of reducing cardiovascular events, on the market.

Product Recalls

August 16, 2003 — September 16, 2003

This chart includes recalls from the Food and Drug Administration (FDA) Enforcement Report for drugs, dietary supplements and medical devices, 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.*

Class I Recall

Name of Drug or Supplement; Class of Recall; Problem	*Lot #; Quantity and Distribution; Manufacturer*
Viga Tablets (Naturalviagra), 200 mg, 20 and 30 count bottles and 4 tablet sample packets, Class I; Unapproved new drug; product contains undeclared prescription drug Sildenafil	Numerous lots; Approximately 6 million tablets distributed nationwide; Health Nutrition Inc., Torrance, CA. and/or Best Life International, Inc., Mayaguez, PR
Vinarol with VASX Tablets, 500mg, blister packages of 2 or 7 tablets, Class I; Unapproved new drug; product contains undeclared prescription drug Sildenafil	Lots 030060 and 020245, Exp 11/2006 through 3/2007; 1-6 million tablets distributed nationwide; Bionate International, Inc., Scottsdale, AZ

Name of Drug or Supplement; Class of Recall; Problem	*Lot #; Quantity and Distribution; Manufacturer*
Accutane Capsules, (Isotrentinoin) 10 mg, 20 mg, and 40 mg prescription pack of 10 capsules, Rx only; Class II; Mislabeled; the yellow qualification sticker does not contain the words "No refills allowed"	Numerous lots; Unknown number distributed nationwide; Roche Laboratories, Inc., Nutley, NJ
Combipatch Transdermal System, (estradiol/norethindrone acetate transdermal system) 0.05/0.25 mg per day, 3 Patient Calendar Packs of 8 Systems, Rx only; Class II; Subpotency (estradiol/NETA) and degradation failure (excess primary estradiol degradant)	Lot 61921011, Exp. June 2004; 256,608 patches distributed nationwide; Novartis Pharmaceuticals Corporation, East Hanover, NJ
Levoxyl Tablets, (Levothyroxine Sodium Tablets), 75mcg, 100 and 1000 tablet bottles and physician sample packets of 7, Rx only; Class II; Subpotent (stability)	Numerous lots; 175,658 bottles distributed nationwide; King Pharmaceuticals, Inc., Bristol, TN
Levoxyl Tablets, (Levothyroxine Sodium Tablets), 112 mcg, 100 count bottles, Rx only, Class II; Tablet mix-up: bottles labeled as Levoxyl 112mcg tablets were found to contain Soloxine 0.2mg tablets (Vet/Animal brand-Levothyroxine)	Lot #024737, Exp. May 31,2004; 4,218 bottles distributed nationwide; Jones Pharma Inc, (a wholly owned subsidiary of King Pharmaceuticals, Inc.), St. Louis, MO

DRUGS AND DIETARY SUPPLEMENTS *cont.*

Name of Drug or Supplement; Class of Recall; Problem	*Lot #; Quantity and Distribution; Manufacturer*
Nortrel 7/7/7 Oral Contraceptive Tablets (norethindrone and ethinyl estradiol tablets), 28-day regimen, 6 blister card, 28 Tablets Each, Rx only, Class II; Each light yellow tablet contains 0.5mg norethindrone and 0.035mg ethinyl estradiol. Each blue tablet contains 0.75mg norethindrone and 0.035mg ethinyl estradiol. Each peach tablet contains 1mg norethindrone and 0.035mg ethinyl estradiol. Each white tablet contains inert ingredients. Class II; Mispacked; color-coded tablets are packaged in improper sequence as white, peach, blue, yellow rather than in correct sequence as yellow, blue, peach, white.	Lots 290122001, 290122002, 290122003; 469,938 blister cards distributed nationwide and in Puerto Rico; Barr Laboratories, Inc., Pomona, NY
Pain Relieving Rub, (Menthol 10% and Methyl salicylate 15%), Class III; Subpotent (methyl salicylate) 12 month stability	Numerous lots; 24,315 tubes distributed nationwide; G & W Labs, Inc., South Plainfield, NJ
Premarin Tablets (conjugated estrogens tablets) 0.625mg, 100 and 1000 tablet bottles, Rx only; Class III; Dissolution failure; 100-count bottles	Lots 011765A , 011895A, 011895B, 1000- count bottles: Lots 011765B, 011897, 1J00088; 22,060 bottles distributed nationwide; Ayerst Laboratories, Inc., Philadelphia, PA
Senokot-S Tablets (sennosides 8.6mg and docusate sodium, The Purdue Fred 50mg) Natural Vegetable Laxative Plus Softener, standardized senna concentrate and docusate sodium, 10-count carton; Class III; Subpotent (sennosides)	141,408 10-count cartons distributed nationwide; The Purdue Frederick Company, Stamford, CT

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	*Lot #; Quantity and Distribution; Manufacturer*
Baby Walkers. The walkers will fit through a standard doorway and are not designed to stop at the edge of a step. Babies using these walkers can be seriously injured or killed if they fall down stairs.	"SUN KIDS" or "HAPPY BABY" labels appear on walkers; 4,100 sold in Texas and California from November 2002 through April 2003; SunTech Enterprises Inc., Commerce, CA; (866) 992-5766
Computer monitors. The monitor's circuit board can overheat and smoke, posing a fire hazard to consumers.	G51 CRT and G51t Touch Screen CRT models; 63,000 sold nationwide; IBM, Armonk, NY; (860) 644-3155; www.ibm.com/pc/g51recall
Easter Oil Lamps. The oil lamp can tip over easily, posing a fire hazard.	Item numbers 054-03-1843 or 054-03-1844 printed on tag; 500 sold at Target stores nationwide from February 2003 through March 2003; DesignPac Inc., Northlake, IL; (800) 440-0680; www.target.com
Falcon Action Toy Jets. Small parts of the toy jet can detach, posing a choking hazard to young children.	Model CDL-22338D; About 1,500 sold in the New York and New Jersey region from November 2002 through December 2002; C.D.X. Trading Inc., Ridgewood, NY; (718) 821-1600
Fire Escape Hoods. These fire escape hoods do not provide protection against certain chemical warfare agents (Sarin, Tabum and Soman), as previously claimed in marketing materials and on the firm's Web site.	Sold as "Plus 10(r) Filter Breathing Unit;" 2,000 sold nationwide from January 1993 through August 2003; Essex PB&R Corp, Edwardsville, IL; (800) 296-7587

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Name of Product; Problem	*Lot #; Quantity and Distribution; Manufacturer*
Gas Grills. Certain wind conditions blowing at these grills can cause overheating or flashbacks under the control panel. Flames could damage the hose that supplies gas to the burner, causing an uncontrolled flame. Also, flames could come in contact with user's hands, resulting in burns.	Horizon Model numbers GH450SBP and GH450XBP; About 1,500 sold at True Value stores nationwide from February 2003 through June 2003; CFM Keanall, Mississauga, Ontario, CA; (888) 532-6255; www.cfmcorp.com
Gas Grills. The glass cover and components on the grill's thermometer can break, posing a risk of injury to the user or those nearby.	Summit Gas Grills model numbers 5210001, 5310001, 5220001, 5320001, 5230001, 5330001, 5260001, 5360001, 5270001, 5370001, 5290001, and 5390001, with serial numbers beginning with the letters DT; Vieluxe Gas Grills model numbers 360201, 360102, 370201, 370102 and 370299, with serial numbers beginning with the letters DA, DU, and DT; 43,000 (Summit) sold nationwide from August 2002 through August 2003 ; 1,450 (Vieluxe) sold nationwide from January 2001 through July 2003; Weber-Stephen Products Co., Palatine, IL; (866) 249-3237; www.weber.com
Pool Heaters. A malfunctioning circuit board can cause these gas pool heaters to fail to ignite, allowing gas to accumulate in the heater cover. Delayed ignition of built-up gas can result in a fire or explosion causing property damage and injuries.	Model numbers H150ED2, H150PED2, H200ED2, H250PED2, H250PEDH2, H300ED2, H200PED2, H250ED2, H350PED2, H400ED2, H400PED2, H300PED2, H3503D2; About 15,800 sold nationwide from December 2002 through June 2003; Hayward Pool Products Inc., Elizabeth, NJ; (888) 429-9273; www.haywardnet.com
Propane Heaters. The heaters can emit high levels of carbon monoxide (CO), posing a risk of CO poisoning to consumers if used indoors.	About 40,400 sold exclusively at "Academy Sports and Outdoors" stores in Alabama, Florida, Louisiana, Mississippi, Oklahoma, Tennessee and Texas from September 2001 through May 2003; Academy Sports and Outdoors, Katy, TX; (800) 577-8684; www.academy.com
Puzzibilities Recycling Truck. One of the puzzle pieces (a stack of newspapers) poses a small parts choking hazard to young children.	Nine wooden pieces form a green recycling truck, three workers, a container for plastics, a bundled set of newspapers, and a recycling bin; About 3,000 sold nationwide between February 2003 and August 2003; Small World Toys(r), Culver City, CA; (800) 421-4135; www.smallworldtoys.com
"Sandy Claws" Swim Trainers. The nylon body strap on the swim trainer can detach or tear from the flotation device and release a child into water, posing a serious drowning hazard to young children.	Red and yellow colored fabric crab with eight stuffed legs and two eyes covering a styrofoam buoyancy float; 3,400 sold nationwide from January 2003 through July 2003; Swimways Corp., Virginia Beach, VA; (800) 889-7946
Telephone Line-Sharing Devices. A security system connected to this device could be prevented from notifying emergency personnel of a hazard. The delay could cause consumers to suffer injuries.	Labeled "OnQ" and "1x8 ENHANCED TELECOM w/SURGE;" 3,000 sold nationwide and in Canada from November 2002 through June 2003; OnQ Technologies, Middletown, PA; (800) 321-2343; www.onqtech.com.
Toy necklaces. The necklace's pendant contains high levels of lead, posing a risk of poisoning to young children.	Ten-inch black cord with a 7/8-inch-diameter gray metal pendant; 1.4 million sold nationwide from March 2002 through April 2003; L.M. Becker & Co. Inc., Kimberly, WI; (888) 869-6569; www.tognjog.com

DO NOT USE!

Strong New Safety Warning Added For The Asthma Inhaler Salmeterol (SEREVENT)

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

In the March 2003 *Worst Pills, Best Pills News* we listed the asthma drug salmeterol (SEREVENT) as a DO NOT USE drug after the Food and Drug Administration (FDA) announced on January 23, 2003 that a large safety study involving the drug had been halted prematurely 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.

Salmeterol belongs to a family of asthma medications known as lone acting beta2-receptor agonists, or just beta agonists. Salmeterol is a long-acting beta agonist, in contrast to others in this family, such as albuterol (PROVENTIL, VENTOLIN), metaproterenol (ALUPENT) and pirbuterol (MAXAIR), which are short-acting.

Salmeterol is produced by GlaxoSmithKline of Research Triangle, NC.

On August 14, 2003, the FDA announced that a box warning is now required on the professional product labeling or package inserts for drug products containing salmeterol. This requirement applies to both Serevent and the combination of salmeterol with the steroid fluticasone sold as AdvAir. The FDA has the regulatory authority to require 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 box warning is the strongest type of safety warning that the FDA can mandate in a drug's professional product labeling.

The text of the new warning reads:

> **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 13,174 patients treated for 28 weeks) versus those on placebo (4 of 13,179). Subgroup analyses suggest the risk may be greater in African-American patients compared to Caucasians.

The terminated safety study was called the Salmeterol Multi-center Asthma Research Trial, or SMART for short. This study was initiated by GlaxoSmithKline in 1996 and 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 after reports of death had been submitted to the FDA.

Unfortunately, information about the SMART study is only fragmentary. GlaxoSmithKline has not published a full description of the study and its outcomes in a medical journal. The Health Research Group has filed a Freedom of Information Act request with FDA to obtain more information but it may be months before this request is granted because of the FDA's demonstrated lack of interest in making important information available to the public in a timely manner.

What is known about the SMART study is contained in the FDA's January 23, 2003 announcement and the new additions to salmeterol's professional product labeling. A very troubling aspect of the FDA's announcement was the number of patients in the trial not using an inhaled steroid as the foundation of their asthma treatment. The National Asthma Education and Prevention Program (NAEPP) guidelines published in 1997 recommend that patients requiring more medicine than needed for simply treating an acute attack with short-acting beta agonists should be using regular and adequate doses of an inhaled steroid for optimal management of their asthma. There are a number of inhaled steroids on the market in the U.S., including beclomethasone (BECLOVENT, VANCERIL), budesonide (PULMICORT), flunisolide (AEROBID), fluticasone (FLOVENT) and triamcinolone (AZMACORT).

In contrast to the recommendations of the NAEPP, the number of patients using inhaled steroids in the SMART study was only 47 percent according to the FDA announcement. Only 50 percent of Caucasian patients were receiving treatment with an inhaled steroid and an even fewer — 38 percent — of African-American patients were using them at the beginning of the study. In the total group of patients not receiving inhaled steroids, there was a statistically significant greater number of asthma-related deaths in all patients taking salmeterol compared to those taking placebo.

The "Clinical Trials" section of salmeterol's professional labeling now has new information about the SMART study. The patients that were enrolled in the study were asthma patients that had never before used a long-acting beta2-agonist such as salmeterol. The average age of the

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MERIDIA — Weight loss or health loss?

Against the better judgment of both the physicians who reviewed the data for the Food and Drug Administration (FDA) and the FDA's external Advisory Committee, the weight loss drug Meridia (sibutramine) has been on the market for over five years. Both the agency's own doctors and its advisors are on record as saying that the benefits (loss of a few pounds in weight) do not outweigh the risks (increased blood pressure and thus increased risk for heart attack and stroke).

Nevertheless, in February 1998 the FDA approved Meridia on the assumption that physicians could identify those patients likely to have dangerous increases in blood pressure. That assumption has not proven valid, either because doctors are not monitoring patients closely enough or because it is not possible to predict who will be at risk. Public Citizen has monitored the drug since its launch. In March 2002, we petitioned the FDA to ban the drug (http://www.citizen.org/publications/release.cfm?ID=7273) and have now updated that petition with a further analysis of the FDA's adverse drug reaction database (http://www.citizen.org/publications/release.cfm?ID=7160).

Through May 2003, there have been a total of 49 cardiovascular deaths, 68% of which were people in their 20s, 30s, and 40s, groups in which such deaths are otherwise rare. One case of cardiac arrest occurred in a 28-year-old woman. There were, in addition, at least 126 serious cardiovascular adverse events such as heart attacks, irregular heartbeats, and hypertension. Fifty percent of these serious events led to hospitalization. One needs to keep in mind that, at most, 10% of adverse events are reported to the FDA, so these numbers are probably ten times too low.

Our latest analysis revealed a new finding: adverse effects on the developing fetus, including cases of cardiovascular birth defects, congenital malformations of the central nervous system, spontaneous abortions, and stillbirths. Much of this could have been predicted from the pre-approval animal data, but the drug's label offers no specific warnings.

The average weight loss in obese people taking a moderate dose of Meridia for one year is only 6 1/2 pounds; no significant additional weight loss occurs after four months of use. Even that trivial weight loss may prove fleeting: up to a third of it vanishes within six weeks of stopping Meridia. There is no justification for continuing to market a drug that provides minimal weight reduction while increasing the likelihood of injury and death. No matter how attractive quick-fix solutions to obesity might seem, we stand by this age-old advice: the only safe and effective way to lose weight is through a calorie-restricting diet and exercise.

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patients was 39 years; 71 percent were Caucasian, 18 percent African-American, and 8 percent were Hispanic. There was a higher number of asthma-related deaths or life-threatening experiences (36 versus 23) and a higher number of asthma-related deaths (13 versus 4) occurred in the patients treated with salmeterol than in the placebo group.

An analysis of Caucasian patients showed no significant increase in respiratory- or asthma-related episodes, including deaths. However, in African-Americans the study showed a statistically significant greater number of respiratory-related deaths or respiratory-related life-threatening experiences (20 versus 7), asthma-related deaths or life-threatening experiences (19 versus 4), and asthma-related deaths (8 versus 1) in patients taking salmeterol compared to those taking placebo. A possible partial explanation offered by Glaxo is that fewer African-American patients were using steroids, but the data provided by the company are too meager to evaluate this claim.

The SMART study was designed to treat patients for only 28 weeks, a very short period for assessing a drug for a chronic disease such as asthma, yet serious adverse reactions were seen.

Salmeterol accounted for more than 4.5 million prescriptions in 2002. A large number of patients are taking this drug to treat their asthma and GlaxoSmithKline and the FDA must do much more in disclosing a complete accounting and disseminating the results of the SMART study. This is an important safety issue.

Until much more is known about the SMART study our recommendations remain.

What You Can Do

- You should be reluctant to newly start salmeterol.
- You should not use salmeterol as a replacement for inhaled steroids, which should be continued at the same dose and not stopped or reduced when treatment with salmeterol is started.
- You should not begin treatment with salmeterol if your asthma is significantly worsening or acutely deteriorating. This may be life threatening.
- You should not use salmeterol to treat acute asthma symptoms.
- You should report to your physician any increased need for a short-acting beta agonist. This is a sign of deteriorating asthma.

OUTRAGE, *from page 12*

and deaths are sure to continue.

To take another example, misleading advertising aimed at doctors and patients can make the difference between someone's getting the right drug and the wrong one. But with its practically moribund enforcement of the laws concerning prescription drug advertising, the FDA is again failing to protect against companies giving inaccurate information to consumers and doctors. From a peak in 1998 of 157 actions, the number of prescription drug enforcement actions — letters from the FDA's Center for Drug Evaluation and Research to pharmaceutical companies ordering them to stop specific drug ads that understate risks or overstate benefits — fell to 27 last year. This year, under McClellan's leadership, lax enforcement has continued. With only 14 such actions taken thus far, the agency is on pace to break last year's record low. There is no evidence that the accuracy of drug ads has improved so much that FDA enforcement actions are not needed as frequently as in 1998.

Another step backward on accurate information involves something akin to the snake-oil promotions of years past. The Nutritional Labeling and Education Act of 1990 unequivocally states that any health claim for food must be backed up by evidence based on "significant scientific agreement."

But despite this express requirement, the McClellan FDA recently announced that it would allow food health claims that are supported by far flimsier evidence, including claims supported only by "very limited and preliminary scientific research." This new regulatory scheme, which goes into effect this month, both legitimizes junk science and demonstrates the FDA's disdain for enforcing a federal law.

I agree with Commissioner McClellan that inaccurate health and safety information is a "public health hazard." Yet he and his FDA are failing to practice what he preaches.

The need for congressional oversight of the FDA has never been greater.

Food and Drug Disaster

This article, by Health Letter *Editor Sidney Wolfe, appeared on September 10, 2003 on the editorial page of the* Washington Post.

With gusto, Food and Drug Administration Commissioner Mark McClellan has promoted, in speeches and press releases, one of his priorities: increasing the amount of accurate information conveyed to consumers about FDA-regulated products. "I consider it a public health hazard when people are misled by false claims," he said recently.

Unfortunately, this rhetoric obscures a pattern of FDA actions and inaction under his leadership that decrease the amount of accurate information in the marketplace and, in McClellan's words, create "public health hazards."

For example, in 1996 Congress instructed the FDA to give companies just five more years to start providing written prescription drug information leaflets for distribution to patients at pharmacies. If the companies failed to do so within that time — that is, provide leaflets that set out useful, scientifically accurate information — the FDA could take over the responsibility.

At a recent FDA meeting to evaluate the industry's effort, a University of Wisconsin researcher commissioned by the FDA to do a nationwide study of the content of the patient information leaflets stated that the industry's effort had, quite simply, "failed." In a review of 1,367 patient information leaflets involving four different prescription drugs obtained at drugstores around the country, the study found that, given a possible score of 100 if all the important information was included, the average score of the leaflets was 53 — a failing grade.

Sections of the label with particularly poor performance included precautions, contraindications to using the drug and information about adverse reactions. Nevertheless, although the FDA has allowed these companies more than 25 years to get the leaflets right, the FDA signaled again last month that it will give the private sector yet another chance, rather than switch to government-approved patient leaflets of the kind used in Europe. As a result, millions of patients each year will continue to get dangerously inadequate information about the risks of their prescription medicines. Preventable injuries

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