PUBLIC CITIZEN HEALTH RESEARCH GROUP

Health Letter

SIDNEY M. WOLFE, M.D., EDITOR

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A Conversation With Sheldon Krimsky

Uncoupling Campus and Company

By Melody Petersen

This article appeared in the September 23, 2003 issue of The New York Times.

In the late 1970's, Dr. Sheldon Krimsky was a young assistant professor at Tufts — politically naive, by his own admission — when he was asked to lead a team of students investigating whether a chemical company had polluted water wells in a nearby town.

When the company, W.R. Grace, learned that Dr. Krimsky and his students would soon be releasing a report that it would not like, a top executive visited the president of the university to ask him to stop its publication, Dr. Krimsky says in a new book. (The company says it cannot offer a perspective on the account because it was so long ago.)

The president said no.

But the possibility that such an effort could have succeeded disturbed Dr. Krimsky deeply. What if the company had given large financial grants to Tufts or had selected a faculty member to sit on its board? Would he, an untenured professor, still have been allowed to publish the report?

The experience prompted Dr. Krimsky to begin studying the growing number of financial ties between universities and their scientists and corporations.

Today, biotechnology and pharmaceutical companies regularly give universities multimillion-dollar grants.

In medical schools, dozens of faculty members may be earning significant sums as corporate consultants. At the same time, universities and their professors are plunging into the business world themselves, creating companies to sell products discovered in academic laboratories.

In his book, "Science in the Private Interest" (Rowman & Littlefield), Dr. Krimsky documents the growing entanglement between commerce and academic science. He argues that the lure of profits is transforming universities so that they are no longer independent, disinterested centers of learning that the public has long depended on.

The subject is not new, but it is gaining increased attention. Dr. Derek Bok, the former president of Harvard, also tackles the subject in his recent book, "Universities in the Marketplace: The Commercialization of Higher Education" (Princeton University Press).

Dr. Krimsky argues that the trend has accelerated in the last 25 years as universities look to corporations to fill holes in their budgets and with new federal incentives for university-industry partnerships.

Q. You write that in the 1940's and 50's some scientists opposed patenting their medical discoveries. You note that neither Jonas Salk nor the March of Dimes, which supported his work, decided to patent or receive royalties from the discovery of a polio vaccine. What has changed since then?

A. When Jonas Salk was ques-

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tioned about patenting the vaccine, he replied, "Could you patent the sun?" For him, he was doing something in the public interest. But attitudes changed in 1980. The Supreme Court ruled that patents could be issued on living things *sui generis*, independent of a product or process of development. That meant you could get a patent for a discovery of a virus or by altering a plant or by finding a gene and isolating it. Then a gold rush mentality began.

Universities, seeking new sources of revenue, began turning themselves into engines for economic development. They began establishing intellectual property offices and provided incentives and rewards for faculty who patented their discoveries. In 1965, universities were awarded 95 patents. In 2,000, universities were awarded 3,200.

Q. How have the increasing ties between companies and academic scientists affected the practice of medicine?

A. Increasingly, we are learning that the privatization of research affects both the way that studies are done, as well as the outcome, which appears to have a greater tendency than similar studies by nonprofit sponsors to favor the financial interests of their sponsors. I call this the funding effect in science.

Do we want to trust a physician who makes profit every time we take a pill because he is a founder of the company that manufactures it?

Q. Are ties between researchers and industry affecting patients?

A. If studies are heavily funded by companies that control the data and there is a biasing effect, drugs can get on the market that should not be on the market. There is more than enough documentation to indicate that financial interests have brought dangerous drugs to the marketplace.

Q. In what scientific areas, besides medicine, do you see the effects of private financial interests?

A. We can find the commercialization of research in almost any area where there are high financial stakes in the outcome. Historically, this has been true in tobacco research. For decades, companies funded research to give them what they wanted the public to hear, namely that tobacco was not dangerous.

More generally, we see commercial effects in the evaluation of toxic chemicals such as lead, pesticides, dioxin. Also, the commercial interests are manifest in atmospheric science related to the global warming controversy, biotechnology and even in criminology when for-profit prisons were first introduced.

Q. With the growing mix between commerce and science, how have scientists changed their definition of a colleague who should be admired?

A. It was once considered unseemly for a biologist to be thinking about some kind of commercial enterprise while at the same time doing basic research. The two didn't seem to mix. But as the leading figures of the field of biology began intensively finding commercial outlets and get-rich-quick schemes, they helped to change the ethos of the field.

Now it is the multivested scientists who have the prestige. You can publish in the good journals, and you can start a company. Then you have reached your fulfillment as an academic scientist. The traditional negative attitudes toward commercialization disappeared over a fairly short period of time.

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THE PUBLIC CITIZEN HEALTH RESEARCH GROUP
Health Letter

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

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

Advertising Dietary Supplements on the Internet: Supplementing Income Rather than Health

In retrospect, it all seems so predictable. Put an unregulated industry hawking largely ineffective or unproven products on a free-wheeling medium, and false claims are sure to proliferate. In this case, the industry is dietary supplements and the medium the Internet.

Dietary supplement consumption is increasing massively in the U.S. Sales in 2001 totaled $18 billion. The increase in use — 380% between 1990 and 1997 — didn't just happen because consumers suddenly recognized the usefulness of these products. It is instead the result of the deliberate deregulation of the industry under the Dietary Supplement Health Education Act of 1994 (DSHEA). This law allows producers to make claims of a supplement's impact upon bodily "structures and functions," but not to make specific health claims for the product. So, according to the framers of this act, it is now okay for a dietary supplement manufacturer to claim that its product "builds healthy bones," but not that it "prevents osteoporosis." This is the kind of distinction only a lawyer could love. Under DSHEA, structure/function claims require no evidence of safety or effectiveness whatsoever (although they are supposed to include a disclaimer noting that the Food and Drug Administration has not evaluated them). Health claims, by contrast, require pre-approval from the FDA.

The result of this profusion of misleading, unsupportable and just plain false claims is that consumers are left in the lurch.

What better place to make baseless claims than the largely lawless Internet, used by 140 million in the U.S., about two-thirds of whom have sought health information. It was a match made in heaven.

Recently, researchers at Harvard decided to examine the claims made by dietary supplement manufacturers on the Internet (*Journal of the American Medical Association* 2003; 290:1505-9). They used the five most common Internet search engines to identify web sites on the eight dietary supplements with the largest sales in 2000. They then analyzed the health content of all sites on the first page of their search results. The

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Q. With more scientists focused on research areas where there are commercial opportunities, what scientific areas are languishing?

A. Areas that struggle to get funds, the ones that don't have this potential for great commercial value, are those that pursue the causes of disease. For example, research that seeks to find the environmental, social, or lifestyle factors responsible for illness or reduced quality of life.

Public health research has saved countless lives when scientists discovered that lead and mercury destroyed the brains of workers, that vinyl chloride and benzene produced cancer, that fluorocarbons created an ozone hole in the atmosphere that lets in dangerous amounts of ultraviolet light that inflicts skin cancer. But the solutions to those problems did not make scientists or companies wealthy.

Q. How has the commercialization of science affected the makeup of federal advisory boards that recommend whether experimental drugs should be approved and provide other advice?

A. There are two rules that guide federal advisory committees. Rule No. 1 is that no scientist with a substantial conflict of interest should be permitted to serve on an advisory committee. Rule No. 2 is that Rule No. 1 can be waived. And the number of waivers has been extraordinary.

Q. Why should the public worry about the entanglement of university science with entrepreneurship?

A. We are exposed to new drugs, new chemicals, new technology, new foods. Sometimes these products are introduced into the market without adequate testing. They are withdrawn years later, after there are casualties. Many times the scientists who place their testimony behind a product have an undisclosed financial interest in its success.

We need to know where to place our trust. Do we want to trust a physician who makes profit every time we take a pill because he is a founder of the company that manufactures it? That decision should be made with informed consent of the patient. Medical research and commerce must be separated.

Product Recalls

September 16, 2003 — October 15, 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.*

Name of Drug or Supplement; Class of Recall; Problem	*Lot #; Quantity and Distribution; Manufacturer*
Albuterol Sulfate 0.083%, unit-dose vial containing Albuterol Sulfate Inhalation Solution, Rx only, Pre-mix solution for inhalation only; Ipratropium Bromide 0.02%, unit-dose vial, pre-mixed solution for inhalation only, Rx Only; Class II; Good Manufacturing Practice deviations; including, but not limited to, lack of testing for approval or release, stability data, and validation for cleaning/manufacturing operations	Numerous codes; 44,000 distributed in Puerto Rico; Monserrat Pharmaceuticals, Inc., Aguas Buenas, PR
Amaryl tablets (Glimepiride), 4 mg, 100 tablet blister pack, Rx Only; Class III; Dissolution failure: stability (18 month test station).	Lot number 1054540; 7,032/100-tab boxes distributed nationwide; Aventis Pharmaceuticals Inc., Kansas City, MO

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results demonstrate the ugly and dangerous consequences of reckless deregulation.

Seventy-six percent of the sites either sold a product or provided direct links to a site that did. Only 22% of those sites provided a medical reference of any kind. Eighty-one percent made some claim regarding health and 55% of these claimed to prevent, diagnose, treat or cure a specific disease — precisely the kind of claim banned by the FDA. Half of those making health claims omitted the FDA-required disclaimer.

Critical safety information was frequently omitted. For example, only 39% of sites for kava kava, a plant from the South Pacific used for relaxation, insomnia and menopausal symptoms, mentioned the life-threatening liver toxicity caused by the drug. Others made long strings of fanciful claims: "The herb valerian is most effective in treating a wide range of stress conditions such as irritability, depression, fear, anxiety, nervous exhaustion, hysteria, delusions, and nervous tension...The herb is especially useful for treating shingles, sciatica, neuralgia, multiple sclerosis, and epilepsy." No wonder it's selling like hot cakes.

The result of this profusion of misleading, unsupportable and just plain false claims is that consumers are left in the lurch. DSHEA does not require dietary supplement manufacturers to register with the government, let alone to prove safety, effectiveness or even that the amount of "active" ingredient claimed is actually in the product. Even if the FDA had the will to enforce the little authority it has (see related story, p. 12 about non-enforcement regarding prescription drug ads), the sheer number and variety of claims makes the task insurmountable.

The time has long passed for DSHEA to be repealed. It has proved unworkable (except for filling the ever-deepening pockets of conscienceless profiteers) and in some cases it has proved dangerous: over 100 deaths have been linked to the dietary supplement ephedra alone. In the meantime, consumers are best served by simply avoiding these products (other than vitamins and minerals) and by sticking with products that actually offer proof of safety and efficacy, when they need a drug at all: FDA-approved, over-the-counter and prescription medications (except for those for which we advise Do Not Use).

DRUGS AND DIETARY SUPPLEMENTS *cont.*

Name of Drug or Supplement; Class of Recall; Problem	*Lot #; Quantity and Distribution; Manufacturer*
Duradryl Jr. Capsules, each capsule contains: Phenylephrine HCl 10mg, Chlorpheniramine Maleate 4.0mg, Methscopolamine Nitrate 1.25mg, 100 capsule bottles, Rx Only, Class III; Dissolution failure; Phenylephrine HCl and Methscopolamine Nitrate	Lot No. 046G3002; 4,992 bottles distributed nationwide; Breckenridge Pharmaceuticals, Inc., Boca Raton, FL
Evista Tablets (Raloxifene HCl), 60 mg, 7 tablets blister pack, Rx Only. Class III; Mislabeling; Lot number and expiration date are not printed on the external carton labeling.	Numerous lots; 13 sample pack lots distributed nationwide and in Cyprus, Lebanon, and Malta; Lilly, Eli & Co., Indianapolis, IN
Glucophage XR tablets (metformin HCl extended release), 500 mg, 100 count bottles, Rx only, Class III; Subpotency; some tablets may contain less than the minimum specification for potency (blend validation).	Numerous lots; 205,655 units distributed nationwide; Bristol-Myers Squibb Company, Princeton, NJ
Haloperidol Injection, USP, 5 mg/mL, 1 mL vial, Rx Only, For Intramuscular Use, Sterile; Class III; Manufacturing Validation: The bulk solution mix time was not completed as per the validated process time.	Lot No. 852072E25, Exp. June 2004; 58 bottles of 180 capsules distributed nationwide; Abbott Laboratories, North Chicago, IL
Kaletra Capsules (lopinavir/ritonavir) capsules, Each soft gelatin capsule contains: lopinavir 133.3mg, ritonavir 33.3mg, 180 capsule bottles, Rx only; Class II; Counterfeit; bottles labeled as containing Kaletra Capsules may contain Kaletra Capsules and/or Agenerase Capsules or a mix of both, as well as, bottles of Kaletra Capsules have been repackaged/relabeled by an unknown source with an extended expiration date/counterfeit lot number.	Numerous lots; 2,256,625 distributed nationwide and in Puerto Rico; American Pharmaceutical Partners, Inc., Schaumburg, IL
M.T.E. — 6 Concentrated, Mixture of Six Trace Elements Additive (Each mL providing: Zinc 5 mg, Copper 1 mg, Manganese 0.5 mg, Chromium 10 mcg, Selenium 60 mcg, Iodide 75 mcg), 10 mL Multiple Dose Vial, Must Be Diluted Before IV Use, Rx only, Class III; Subpotent (Iodide)	Lot numbers 100669 Expiration Date 8-30-03, 110316 Expiration Date 3-30-04 and 111223 Expiration Date 12-30-04; 68,650 vials distributed nationwide, Puerto Rico, and Canada; American Pharmaceutical Partners, Inc., Schaumburg, IL
Mylanta Antacid Anti-Gas (Aluminum Hydroxide equivalent to dried gel, USP 200 mg, Magnesium Hydroxide 200 mg, and Simethicone 20 mg) 5 Fl Oz (150ml) bottles; Class III; Defective container, tamper evident cap does not engage properly.	Lot number HDF041; 24,360 bottles distributed nationwide and in Trinidad and Tobago; Johnson & Johnson Merck, Fort Washington, PA
Non-Aspirin Sinus Gelcaps, (Acetaminophen, 500mg and Pseudoehedrine HCl, 30mg), 24 Gelcaps blister packed cartons, Extra Strength, Pain Reliever/Nasal Decongestant, Pharmacist Formula; Also sold under brand names Eckerd, American Fare, Longs, Pharmacist Formula and ElectHealth; Class III; Mislabeling; Extended expiration date-product incorrectly bears expiry as 11/2005 rather than correct date of 12/2004	Lot Numbers 3EB1154 (Eckerd), 3EB1156 (American Fare), 3EB0999 (Longs), 3EB1155 (Longs), 3EB1157 (Pharmacist Formula) & 3EB1000 (ElectHealth); 864,000 pills distributed nationwide; Leiner Health Products, Carlson, CA
Oxygen, USP, compressed, steel and aluminum cylinders C, D, E, K, Dey, Class III;Good Manufacturing Practice (GMP's) deviations, including but not limited to, failure to document testing of product purity in batch records.	Numerous lots; 573 cylinders distributed in Georgia and South Carolina; Southern Welding Supply, Inc., Savannah, GA

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DRUGS AND DIETARY SUPPLEMENTS *cont.*

Name of Drug or Supplement; Class of Recall; Problem	*Lot #; Quantity and Distribution; Manufacturer*
Prozac Capsules Weekly (Fluoxetine Hydrochloride), Delayed Release Capsules, 90 mg fluoxetine, 4 capsules blister pack, Rx Only; Class III; Mislabeling; Lot number and expiration date are not printed on the external carton labeling.	Numerous lots; volume distributed nationwide unknown; Lilly, Eli & Co., Indianapolis, IN
Tilade Inhaler (Nedocromil Sodium Inhalation Aerosol), 16.2 g. canister, 104 metered actuations, For oral inhalation only with accompanying mouthpiece; Class II;Tilade Inhaler (Nedocromil Sodium Inhalation Aerosol), 16.2 g. canister, 104 metered actuations, For oral inhalation only with accompanying mouthpiece; Class II; Container defect: misplaced side holes on metering valve stems causing a lower dosage delivery to patient.	Lot A30007A, Exp. Jan 2005; 14,111 canisters distributed nationwide; Aventis Pharmaceuticals, Inc., Kansas City, MO
Zyprexa Tablets (Olanzapine), 5-, 10-, 15-, and 20-mg., 60-tablet bottles, Rx only, Class II; Counterfeit: An unknown number of bottles bearing these lot numbers are counterfeit, in that they have been repackaged, relabeled and/or may contain different strengths or mixed strength tablets differing from their labeled contents and/or bear extended expiration dates, as the source of the repacked and/or relabeled bottles is unknown.	Numerous lots; 31,553/60-tablet bottles distributed nationwide; D & K Healthcare Resources, Inc., Saint Louis, MO

MEDICAL DEVICES

Device recalls are classified in a manner similar to drugs: Class I, II or III, depending on the seriousness of the risk presented by leaving the device on the market. Contact the company for more information. You can also call the FDA's Device Recall and Notification Office at (301) 443-4190. To report a problem with a medical device, call (800) FDA - 1088. The FDA web site is *www.fda.gov.*

Name of Device; Class of Recall; Problem	*Lot #; Quantity and Distribution; Manufacturer*
BD Blood Glucose Test strips. BD Latitude, 100 Test Strips 100 Bandelettes Reactives, Class II; Test strips may not be meeting specifications at the lower range of glucose values.	Catalog # 322002 (fifty count packaging) Lot Number: 2064256; Catalog # 322003 (one hundred count packaging) Lot Numbers: 2064256, 2064273, 2071280; 754,800 strips distributed in Canada; Becton Dickinson Canada, Inc., Oakville, ON
Disetronic D-TRONplus Insulin Pump; Class II; Lack of assurance of reliability and notice to D-tron+ users to examine pump keys for punctures, not to use pumps with punctured keys near water, and to alert users to the possibility of a sticking piston rod.	All units; 8,000 distributed nationwide; Roche Diagnostics, Corp., Indianapolis, IN
Disetronic H-TRON V100 Insulin Pump and **Disetronic H-TRONplus Insulin Pump**, Class II; Lack of assurance of reliability, due to quality system regulations violations, plus notice to users not to expose pump to water.	All units; 2,082 distributed nationwide; Roche Diagnostics, Corp., Indianapolis, IN

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*
Air Rifles. The air rifles can discharge unexpectedly when the user closes the barrel, posing a serious risk of injury to consumers and bystanders.	Crosman Model numbers RM177, RM177X, RM677, RM677X, RM877 and RM622; 1,500 sold nationwide from June 2001 through August 2001; Crosman Corporation, East Bloomfield, NY; (800) 724-7486; www.crosman.com
ATVs (all-terrain vehicles). The lower front suspension arm can separate from the steering assembly, resulting in a loss of steering control and posing a serious risk of injury to the rider.	Kawasaki Prairie ATVs; 2-wheel and 4-wheel drive Prairie 200 and 400 models; 75,000 sold nationwide from September 1996 through December 2000; Kawasaki Motors Manufacturing Corp. USA, Lincoln, NB; (866) 802-9381; www.kawasaki.com
Back-Up Power Supply Devices. When used in conjunction with another power protection device, the power supply device can spark, posing a fire hazard to consumers.	Energizer-brand UPS Model ER-PRO1000; 2,100 sold nationwide; Technuity Inc., Indianapolis, IN; (877) 577-0046; www.technuity.com
Batteries. The batteries originally provided with the flashlight may overheat or explode presenting a potential for fire or personal injury.	Fuji Power and A&T Fuji Power CR123A 3-volt lithium batteries originally provided with Galls(r) H.A.L.O. Tactical Flashlight; 10,084 sold nationwide from June 2001 through May 2003; Galls Inc., Lexington, KY; (800) 477-7766
Bicycle Floor Pumps. The bicycle pump can become over-pressurized with air, forcing the handle to quickly and unexpectedly rise upward, possibly injuring the user.	Chrome, with "Park Tool USA" written in white letters on the side; 4,000 sold nationwide from March 2003 through August 2003; Park Tool USA, of St. Paul, MN; (888) 568-4959; www.parktool.com
Board Books. A plastic replica of a balloon attached to the book can detach, posing a choking hazard to young children.	Dora the Explorer heavy-cardboard book has "Whose Birthday Is It?" printed on the cover in yellow letters; 26,000 sold nationwide during August 2003; Simon & Schuster Inc., New York, NY; (800) 223-2336; www.simonsayskids.com
Bottled Water with Push-Pull Sports Cap. When pulled to open, the drinking spout on the sports cap can unexpectedly come off, posing a choking hazard for young children.	Sold under the brand names Dannon Fluoride to Go, Pure American, Enon Springs, Alhambra Junior Sport Drinking Water and Sparkletts Junior Sport Drinking Water; sold as singles and multi- packs in 8-oz., 8.5-oz, and .33-liter sizes; 3.2 million sold nationwide from March 2002 through September 2003; CCDA Waters LLC; Atlanta, GA; (800) 322-4616
Bunk Beds. These bunk beds have openings between the guardrails and between guardrails and the end structures that are too large. A child's body could slide between the opening and become trapped by the child's head. This poses a strangulation hazard to children.	Models S130, S131, S132, S133, S135, S136, S116, and S117 (model numbers on top front railing); 3,600 sold nationwide from September 2002 through May 2003; Home Line Industries, Philadelphia, PA; (800) 523-3310
"Candle and Soap Making For Dummies" Book. The instructions in the book for making lye combine sodium hydroxide and water in an incorrect order. This could cause the mixture to bubble over, posing a burn hazard to consumers.	Paperback, cover is black and yellow with photograph of candlesticks and soap; 5,400 sold nationwide from August 2003 through September 2003; John Wiley & Sons Inc.; Hoboken, NJ; (877) 762-2974; www.wiley.com

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CONSUMER PRODUCTS *cont.*

Name of Product; Problem	*Lot #; Quantity and Distribution; Manufacturer*
Ceiling Fans. About 80 of these units were improperly assembled with a metal sleeve that could cause exposed wiring. If this occurs, consumers are at an increased risk of receiving an electrical shock during installation or removal.	Aire Tek ceiling fans, model number 355-6645; 1,200 sold nationwide from January 2002 through May 2002; Vaxcel International Co. Ltd., Glendale Heights, IL; (800) 482-9235
Eddie Bauer Propane Lanterns. The lanterns could produce high levels of carbon monoxide (CO), posing a risk of CO poisoning to consumers if the lantern is used indoors.	Ocean blue with two mantles, the lantern has a glass globe, electric ignition, and an extra-large hood and handle; sits on a plastic base; 12,300 sold exclusively at Target stores nationwide from February 2003 through July 2003; The Wenzel Company, St. Louis, MO; (800) 972-3151; www.wenzelco.com
Gas Grills. The bottom edge on the front control panel is sharp and can cause lacerations to the hands.	Member's Mark(r) Gas Grills; model number Y0005XC-2; 50,000 sold exclusively at Sam's Club stores nationwide from August 2000 through December 2001; Grand Hall Enterprise Co. Ltd., Taiwan; (888) 735-5709
Gas Regulators. Some of these regulators were assembled with an undersized seat disc that could become dislodged and leak propane gas. Propane gas is highly flammable and could ignite causing a fire or explosion. Consumers should immediately close the valve on the service cylinder if LP-Gas leakage is detected.	Marshall Gas Controls Model 451 and 452 LP-Gas regulators on Char-Broil(r), Kenmore(r), and Thermos(r) brand LP-Gas Grills; 35,000 distirbuted nationwide from April 2003 through May 2003; Marshall Gas Controls, S.H. Leggitt Company; San Marcos, TX; (800) 241-7548
Hand-Held Hair Dryers. Some of these hair dryers do not have an immersion protection device on the power cord and could present a serious electrocution hazard if dropped in water.	Blason Turbo Style model 4030; 700 sold nationwide from May 2002 through June 2003; Blason International Trading Corp., Miami, FL; (888) 625-2766
Human Transporters (HT). Under certain operating conditions, particularly when the batteries are near the end of charge, some Segway HTs may not deliver enough power, allowing the rider to fall. This can happen if the rider speeds up abruptly, encounters an obstacle, or continues to ride after receiving a low-battery alert.	All Segway HT i167 ("i Series") models; approximately 6,000 sold nationwide from March 2002 through September 2003; Segway LLC, Manchester, NH; (877) 889-9020
Lawnmowers. If the lawnmower strikes an object with sufficient force, the crankshaft can bend. Vibration created by a bent crankshaft can eventually result in a fatigue failure of the Roto-stop(tm) blade brake control assembly. This can allow the cutting blade to continue rotating after the blade control lever is released, posing a risk of injury to consumers.	Honda Harmony Walk-Behind Lawnmowers; 30,000 sold nationwide from November 2000 through June 2003; Honda Power Equipment Manufacturing Inc., Swepsonville, NC; (800) 426-7701; www.hondapowerequipment.com
Melting Pot Gift Sets. The melting pots can produce excessive flame and/or ignite presenting a fire and burn hazard to consumers.	Packaged in a heart-shaped paperboard gift box with a ceramic melting pot (simmer pot), four individually wrapped scented wax melters of various scents, and six tea light candles that have "Lang" printed on the top; 9,000 sold nationwide from May 2003 through August 2003; Lang Candles Ltd., Delafield, WI; (888) 526-4011
Notebook Computers. Users could receive a mild electric shock when the recalled computers are connected to a phone line and the phone rings.	Sony VAIO notebook computers with model numbers PCG-FRV25 or PCG-FRV27; 5,600 sold nationwide from June 2003 through July 2003; Sony Corporation;Tokyo, Japan; (800) 880-9743; www.sony.com/pcsupport
Pacifiers. These pacifiers fail federal safety tests, come apart, and can pose a choking hazard to infants and small children.	Model numbers 35826, 35827, 35828, 35829; 154,000 sold in Kroger-owned stores nationwide from August 2002 through August 2003; Apothecary Products Inc., Burnsville, MN; (800) 632-6900

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DO NOT USE!
Asthma Drug Montelukast (SINGULAIR) For The Treatment Of Hay Fever

The Food and Drug Administration (FDA), on January 23, 2003, approved the asthma drug montelukast (SINGULAIR) for the relief of symptoms of seasonal allergic rhinitis (hay fever) in adults and children two years of age and older. Montelukast is a member of a family of drugs known as leukotriene inhibitors.

Montelukast is marketed by Merck & Company of West Point, PA and was originally approved for asthma in February 1998.

We already listed montelukast as a Do Not Use drug for asthma in the *Companion* to the 1999 edition of *Worst Pills, Best Pills* for two primary reasons.

First, the National Institutes of Health's 1997 Guidelines for the Diagnosis and Management of Asthma said of the leukotriene inhibitors that "further clinical experience and study are needed to establish their roles in therapy." At this time, the role of the leukotriene inhibitors in the management of asthma is still far from established.

Second, the leukotriene inhibitors are promoted as useful in helping patients reduce their dosages of steroid drugs, for example triamcinolone (AZMACORT). The Cochrane Database of Systematic Reviews published in 2002 found, in comparing leukotriene inhibitors to placebo in people also using steroids, that the dosage of inhaled steroids can be safely reduced without requiring the use of leukotriene inhibitors.

...the drug has not been shown to be more effective than the oral antihistamine loratadine, at almost eight times loratadine's cost.

Furthermore, the dose of leukotriene inhibitors required to achieve a significant reduction in steroid dosage is several times the currently approved maximum dosage.

In a triumph of advertising over science, despite these serious questions about its effectiveness, almost 13.5 million prescriptions were dispensed for montelukast in U.S. pharmacies in 2002 at a cost of almost $1.2 billion.

The recent approval of montelukast for seasonal allergic rhinitis was based on five clinical trials. All of the trials were similar in design. There was a total of 5,029 patients involved, of whom 1,799 were treated with montelukast. Patients in the trials were 15 to 82 years of age with a history of seasonal allergic rhinitis, a positive skin test to at least one allergen, and active symptoms of seasonal allergic rhinitis.

The effectiveness of montelukast in the five trials was assessed using the average change from the beginning of the study in daytime nasal symptoms score. This score is the

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CONSUMER PRODUCTS *cont.*

Name of Product; Problem	*Lot #; Quantity and Distribution; Manufacturer*
Pocket Knives. The black plastic handles of the pocket knives can crack, posing a risk of injury from the blade.	Model 425BK MiniBuck Black Knives; 2,000 sold nationwide from July 2003 through September 2003; Buck Knives Inc.; El Cajon, CA; (800) 215-2825
Treadmills. Fire hazard because of overheating and ignition of dust inside the treadmill's hood. The dust accumulates because of lack of regular maintenance.	Cybex or Trotter Treadmills, models Cybex 400T, Cybex 410T, Trotter 510, Trotter 525, Trotter 535 and CXT+; 33,719 sold natiowide from September 1993 through October 2001; Cybex International, Inc., Medway, MA; (888) 678-3846; www.cybexintl.com
Wooden Toy Cars. The wheels on the toy car can come off, posing a choking hazard to young children.	Sonato wooden toy cars, part of Wooden Baboy Toys Set of 5; item #828143; 600 sold at Magic Cabin catalogs and web site from December 2002 through August 2003; Magic Cabin Inc., Dayton, OH; (888) 623-3655; www.magiccabin.com

MONTELUKAST, *from page 9*
average of individual scores of nasal congestion, rhinorrhea (runny nose), nasal itching, and sneezing as assessed by patients in the trial on a 0 - 3 point scale.

Four of the five trials found montelukast superior to a placebo (an inactive "dummy" drug). In the fifth trial, montelukast was compared to an active antihistamine, loratadine (CLARITIN). In this trial, the score for loratadine was superior to that of montelukast.

The Medical Letter On Drugs and Therapeutics, a highly respected, independent source of drug information written for health professionals, reviewed montelukast for hay fever in their March 17, 2003 issue, and concluded:

> Montelukast (Singulair) might be as effective as an oral antihistamine for treatment of seasonal allergic rhinitis (more data are needed), but it is less effective than an intranasal corticosteroid, and more expensive than either.

We agree. Intranasal corticosteroids, or steroids, are also effective for hay fever. The *Medical Letter* was referring to studies showing that fluticasone (FLONASE) was better than either montelukast or loratadine for hay fever. Some other intranasal steroids on the market are beclomethasone (BECONASE AQ) and budesonide (RHINOCORT AQUA).

Overall, montelukast is an unremarkable treatment for hay fever, as is loratadine or its close chemical relative desloratadine (CLARINEX), for that matter. We wrote about desloratadine in the March 2002 *Worst Pills, Best Pills News.*

Our recommendation, as it has been for years, for the initial treatment of hay fever remains generic chlorpheniramine on the basis of both effectiveness and cost. The non-prescription antihistamines such as generic chlorpheniramine (brand name CHLORTRIMETON) are effective, perhaps equally or more so, than prescription antihistamines. The drowsiness that may be experienced by some people using generic chlorpheniramine can be avoided in many people by starting with a low dose and slowly working up to a dose that relieves symptoms without sedation.

Cost is always an important consideration, particularly when the effectiveness of a drug such as montelukast is only marginal. The table above lists the retail prices of a month's supply of some of the drugs mentioned in this article for comparison. The prices were obtained from a Washington, DC chain pharmacy.

Drug	Retail Cost of a 30-Day Supply	Notes
montelukast (SINGULAIR)	$95.59	
desloratidine (CLARINEX)	$77.59	
budesonide (RHINOCORT AQUA) nasal spray	$74.59	a dose of two sprays in each nostril once daily would last 30 days
Non-prescription loratadine (CLARITIN)	$12.49	based on the cost of 24 tablets of $9.99
Non-prescription generic chlorpheniramine, 4-milligram tablets (CHLORTRIMETON)	$8.09	based on the cost of 100 tablets of $8.99 and a dose of one tablet three times a day

In summary, there are two reasons why we have listed montelukast as a Do Not Use drug for the treatment of hay fever symptoms. First, the drug has not been shown to be more effective than the oral antihistamine loratadine, at almost eight times loratadine's cost. Second, the price discrepancy is even more outrageous when the comparison is with generic chlorpheniramine, which is as effective as prescription products like SINGULAIR and CLARINEX.

What You Can Do

You should not use montelukast for the treatment of hay fever symptoms because of its meager effectiveness and exorbitant cost.

OUTRAGE, *from page 12*
is actually housed on the FDA's own web site.

From there it is downhill all the way. In 1997, the FDA agreed that all information for consumers should be based on material that is provided to doctors, which itself sometimes includes FDA-approved information for patients. So we took the agency at its word and compared the new web site to the FDA-approved patient information on PREMARIN (conjugated estrogens), a Wyeth-Ayerst Laboratories product that is the leading brand of HRT. This comparison shows several gaping holes in the web site information.

For starters, although FDA regulations regarding prescription drug information for consumers mandate that the information in the "black-box warning" (the strongest type of warning the FDA can require) must appear at the beginning of written information intended for patients, the Collaborative Campaign relegates this material to its sixth topic, after the benefit information and other data about hormones and menopause.

The Collaborative Campaign web site lists conditions under which

OUTRAGE, *from page 10*

women should never use HRT (contraindications), but these are displayed in a sidebar under yet another listing of the benefits of the hormones. In contrast, the FDA-approved Premarin information for patients prominently advises women not to take Premarin if they have certain conditions such as cancer, vaginal bleeding, heart attack or stroke.

Moreover, the web site makes no mention of the symptoms of hormone-induced illness or of steps to take if such symptoms occur. References to alternative therapies for osteoporosis are similarly missing in action. Both are present in the FDA-approved patient information.

Why would the FDA go to such effort to create this grossly misleading information, when it simply could have linked users to its own generally well-crafted information for patients? A possible explanation can be found in a *Washington Post* report, which noted that, "... there was direct and indirect pressure on the FDA ... from the largest maker of hormone products, Wyeth Pharmaceuticals" during the development of the Collaborative Campaign.

Recently, FDA Commissioner Mark McClellan said: "I consider it a public health hazard when people are misled by false claims." But a man cannot (or, at least, should not) survive on rhetoric alone, and the facts speak otherwise. Since 1998, when the FDA's drug advertising division took 157 enforcement actions for false or misleading ads, the number of such actions has plummeted an astonishing 86% to a projected 22 actions so far in 2003. How come? This is not because the drug industry has cleaned up its act, but in part because the FDA has quietly changed the rules. The agency now requires an additional layer of internal legal review before actions can be issued. And its chief lawyer, at one time a hatchet man for various industries, including tobacco, has long been hostile to many attempts to regulate commercial speech.

So, Dr. McClellan, we have a modest proposal for you: In order to pump up your agency's flagging enforcement statistics, why don't you launch an investigation into why the FDA permitted this misleading web site? Maybe you'll consider bringing an action against yourselves, the way you would against any company that produced information as contrary to FDA regulations as the Collaborative Campaign has turned out to be. The enemy, indeed, seems to be "us" — or at least those charged with protecting us.

We Have Met the Enemy and He is Us

When Pogo, the late-lamented comic-strip denizen of the Okefenokee Swamp, remarked that "we have met the enemy and he is us," he might well have been talking about one of the country's key guardians of health, the Food and Drug Administration (FDA).

Over the past several months, medical journals and the popular press have been awash in a tide of bad news on hormone replacement therapy (HRT). HRT causes blood clots. HRT causes breast cancer. HRT increases the risk of cardiovascular disease instead of preventing it. HRT does not prevent Alzheimer's disease or memory loss, but may instead cause dementia. Women, after decades of being persuaded by physicians on the receiving end of drug company propaganda to take this now largely discredited therapy, have every right to be confused.

So the FDA's announcement on September 9 of a "Collaborative Campaign to Inform Women About Menopausal Hormone Therapy" sounded as though it might hold some promise; that is, until you actually went to the Collaborative Campaign web site (www.4woman.gov/menopause). Instead of the dry, fact-filled explanation of the risks and benefits of HRT one might expect from the FDA, the opening page on the site contained no substantive information whatsoever. Instead, the page, which is entitled "Menopause and Hormone Therapy" and is completely unnecessary from a web design perspective, offers only a collage of photographs of attractive seniors frolicking in sun-drenched fields and riding bicycles. One must then click on this image to reach the information on HRT, which

continued on page 10

Moreover, the web site makes no mention of the symptoms of hormone-induced illness or of steps to take if such symptoms occur.

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

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