PUBLIC CITIZEN HEALTH RESEARCH GROUP

Health Letter

SIDNEY M. WOLFE, M.D., EDITOR

OCTOBER 2002 ◆ VOL. 18, NO. 10

ADAPT Trial for Alzheimer's Disease Prevention Should Be Canceled

On September 4, 2002, Public Citizen sent a letter to Health and Human Services (HHS) Secretary Tommy Thompson asking that an Alzheimer's Disease (AD) prevention trial be immediately stopped and that the patients be provided with information on the risks to which they may already have been exposed.

The "Alzheimer's Disease Anti-Inflammatory Prevention Trial" (ADAPT) is sponsored by the National Institute of Aging (NIA), part of the National Institutes of Health (NIH), and led by Dr. John Breitner at the University of Washington in Seattle. The trial is testing two nonsteroidal anti-inflammatory drugs (NSAIDs) against placebos. The aim is to treat 2,625 healthy elderly people (70 or older) who have a parent or sibling with serious age related memory loss, senility, dementia, or AD, for seven years.

The ADAPT trial is being conducted in six centers across the U.S.: Johns Hopkins University (Baltimore, MD), Boston University, University of Rochester, University of Washington (Seattle, WA), Sun Health Research Institute (Sun City, AZ), and the University of South Florida (Tampa, FL). Pharmacia and Bayer pharmaceutical companies are providing the two NSAIDs: Celebrex (Pharmacia) and Naprosyn (Bayer) and matching placebos. The study has been ongoing since January 2001, with about 1,000 enrolled to date, but new patients are still being recruited.

However, Public Citizen discovered in our search of the medical literature on AD, that there were serious problems with the scientific rationale for this trial so that, instead of helping patients, the NSAIDs being used have the potential to inflict harm on otherwise healthy individuals. This information has not been provided to patients and may not even be realized by some of the investigators involved in the trial.

There have been many hypotheses as to the cause(s) of AD. At one time, AD was thought to be due to an inflammatory reaction in the brain after finding in the brain chemicals typical of an anti-inflammatory response. There also appeared to be a lower incidence of AD in people who, for other reasons, had been on NSAIDs. However, a key paper published in the November 2001 issue of *Nature* magazine, using cell culture and animal models, established that only certain NSAIDs (ibuprofen, indomethacin, and sulindac) were effective in preventing the formation of the amyloid protein thought to be responsible for AD. Other NSAIDs tested had no such

continued on page 2

CONTENTS

ability, including the two chosen to give to patients in the ADAPT trial (Celebrex and Naprosyn).

A recent reanalysis of a major observational study on NSAID use, reported in July 2002 by the International Alzheimer Congress, showed that the apparent protective effect was restricted to ibuprofen, indomethacin, and sulindac and, again, did not include Naprosyn. The ADAPT researchers have acknowledged that a reason they selected these drugs was that they were received free from the manufacturers.

The use of long term NSAIDs is putting patients at risk for many adverse events. Yet, patients are not informed fully (or at all) about many of these risks.

Gastrointestinal (GI) Effects

Even the senior investigator for the ADAPT trial, Dr. Breitner, expressed concern over "the potential to cause serious side effects when [NSAIDs were] used at high doses or over prolonged periods." Patients are only told, "The study drugs can cause stomach irritation. This can range from mild stomach upset to ulcers" which "very rarely ... bleed." The consent form never mentions perforation of the GI tract. The Celebrex and Naprosyn labels give the frequency of upper GI ulcers, gross bleeding, or perforation caused by NSAIDs as 1 percent. These FDA-approved labels go on to say that this is true only for those treated for three to six months. However, this study will continue for seven years. The label also states that this rate increases to 2-4 percent at one year (with even higher incidences expected over longer durations of use). Furthermore, the Celebrex label states that *only 20% of serious upper GI events are symptomatic*. Thus, the promise in the Informed Consent sheet, "We will monitor you for any problems of this sort" does not protect patients from harm.

Kidney Effects

The FDA-approved Celebrex label warns that the elderly are at greater risk for kidney problems and that "Long term administration of NSAIDs has resulted in renal papillary necrosis and other renal injury" (the Naprosyn label also warns patients of possible serious kidney pathology). However, ADAPT patients are not told that being elderly (as they all are) is an extra risk factor even if they have no problems with kidney, liver, or heart functions; they are only told that they will have lab tests and stop taking study drugs if problems develop.

Liver Effects

Although the FDA-approved labels warn of rare, severe liver reactions that can lead to death, ADAPT patients are told only that if they develop liver problems, they will be told to stop taking the drug.

Effects in the Blood

Although the FDA-approved Celebrex label warns of anemia, the ADAPT consent form says nothing about this.

Fluid Retention, Edema, and Blood Pressure

Although the FDA-approved labels warn of the need for caution in patients with high blood pressure, fluid retention, or heart failure, ADAPT patients are only told that if they develop water retention, they will be told to stop taking the drug.

Aspirin-sensitive Asthma

Although the FDA-approved labels warn of aspirin-sensitive asthma that can be fatal in susceptible individuals, ADAPT patients are told nothing about this potentially serious adverse effect.

Additional potential adverse events derived from the medical literature but not yet in either the FDA approved label or in the Informed Consent sheet include: thrombotic (blood-clotting) tendency; delay in bone healing; and delay in ligament healing.

AD presents a frightening prospect because it involves loss of mental functioning. Because the public has come to expect pharmaceutical solutions to every disease, there is a great demand for preventive therapies for AD. Unfortunately, this trial is based on a hypothesis that is not supported by the latest research, thereby putting patients at risk of severe adverse reactions with little, if any, likelihood of a positive outcome. An especially vulnerable group is being exposed, i.e., the aged population (in this case, those 70 years old and older), who are apt to be at greater risk than younger people are. They will be exposed to a group of drugs (NSAIDs) for periods much longer than any period heretofore studied experimentally in any age group (most studies have ranged from three months to one year in duration). Thus, there may be additional adverse events about which we are currently ignorant or those we currently recognize may be more frequent or serious. More recently, the discoveries that COX-2 inhibitors like Celebrex block bone and ligament healing and may cause increased heart attack rates have added additional causes for concern, especially in the elderly. The risks to which patients are exposed are either not clearly spelled out or are missing entirely in the patient consent forms.

Even if there was a basis when the ADAPT trial was first proposed for believing that Naprosyn or Celebrex might have worked in preventing AD, there is no longer a scientific basis to support that hypothesis. We now know that only certain NSAIDs are candidates for a protective effect. Nevertheless, the Consent Statement for Enrollment states that, "Recent research suggests that they [Celebrex and Naprosyn] might [prevent AD]".

We feel strongly that the ADAPT trial should be stopped and the patients enrolled should be fully informed about the extremely unlikely probability of efficacy of these two NSAIDs as well as the properties of these drugs that might put volunteers at risk of serious adverse reactions. There is no justification for continuation.

Will a Vitamin a Day Keep the Doctor Away?

A June 20, 2002 press release from the Council for Responsible Nutrition (CRN) proclaimed: "Harvard Researchers Publish *JAMA [Journal of the American Medical Association]* Articles Recommending Vitamin Supplements For All Adults." The studies concerned vitamins for chronic disease prevention. The press quoted the authors of the studies saying "we recommend that all adults take one multivitamin daily." This research was published in the June 19, 2002 issue of *JAMA*.

CRN is one of the dietary supplement industry's leading lobbying groups and operates under a thin veneer of scientific rigor. Their credo: if you don't have it (scientific evidence), advertise that you do; it's cheaper.

Only two months later, on August 14, 2002, *JAMA* published research on the effect of daily multivitamin-mineral and vitamin E use on acute respiratory tract infections in the elderly. This study concluded that neither daily multivitamin-mineral use nor 200 milligrams of vitamin E showed a beneficial effect on the incidence and severity of acute respiratory tract infections in well-nourished noninstitutionalized elderly persons. In fact, these researchers observed adverse effects of vitamin E on the severity of illness.

CRN did not issue a press release about the results of this most recent *JAMA* publication. More vitamins are sold if the negatives are not mentioned.

In their June 20th press release CRN was selective in their praise of vitamins. There were several observations made by the authors of the June 19th *JAMA* studies that add important context to the debate about the benefits of vitamins not highlighted by CRN:

> *The science of vitamin supplementation for chronic disease prevention is not well developed, and much of the evidence come from observational studies.*

The *JAMA* authors went on to say:

> *Foods contain thousands of compounds that may be biologically active, including hundreds of natural antioxidants, carotenoids, and flavonoids.* ***For these reasons, vitamin supplementation is not an adequate substitute for a good diet*** *(emphasis added).*

Why are there such conflicting results between the June and August studies?

First, the June study addressed vitamins for chronic disease prevention in adults and the August publication was about the effect of vitamins on the development of acute respiratory tract infections in the elderly. These are two very different situations.

Second, the June study was a review of the published literature, a type of summary of studies, while the August study was an experiment, the scientific gold standard, a randomized controlled trial. Literature reviews are important and useful, but one of their most important uses is to develop research questions that ultimately must be tested using a randomized controlled trial.

It is too soon to forget the lesson of hormone replacement therapy (HRT). Studies other than randomized controlled trials were the basis for prescribing HRT to millions of women to prevent cardiovascular disease. When a randomized controlled trial of HRT was undertaken it was stopped early because of increases in breast cancer, cardiovascular disease, stroke, and blood clots that were found in the women using HRT (see the September 2002 issue of *Worst Pills, Best Pills News).*

Third, literature reviews are prone to a type of bias that can incorrectly lead to a conclusion that a particular treatment or behavior such as taking vitamins is beneficial. This is known as publication bias and occurs because journal editors are more likely to publish favorable studies than those that are unfavorable. Also, because so much research is currently being sponsored and controlled by companies that are selling the treatment, only those studies that reflect favorably on the product may even be submitted for publication.

The June literature review looked primarily at vegans (strict vegetarians), alcohol dependent individuals, patients with malabsorption problems and the elderly. The review concluded that inadequate intake of several vitamins is linked to, but does not cause, some chronic disease in these groups of patients, if the elderly are malnourished. This is not unreasonable.

Turning to the August randomized, controlled trial. This trial was conducted in the Netherlands and involved 652 individuals aged 60 years or older most of whom lived at home. They were randomly assigned to four groups: 1) multivitamin-mineral, 2) vitamin E alone, 3) multivitamin plus vitamin E, and 4) a dummy placebo. The 652 individuals were followed for a maximum of 15 months and kept track of the number and severity of acute respiratory tract infections under the supervision of a nurse.

The multivitamin-mineral group had 240 episodes of acute infections with 71 percent experiencing at least one episode; the vitamin E alone group developed 280 episodes of infection among 68 percent; the multivitamin-mineral plus vitamin E group experienced 274 infections among 66 percent; and the placebo group had 230 infections among 67 percent of the individuals.

The number and severity of acute respiratory tract infections were not lowered in those taking multivitamin-minerals alone or with vitamin

continued on page 4

Questionable Doctors Online

Disciplined Doctor Resource Adds 14 More States on Public Citizen Web Site

Because consumers can find out more about a car they plan to purchase than a doctor they plan to visit, Public Citizen's invaluable *Questionable Doctors Online* database has added 14 more states bringing the total to 27 states for which we have updated information through 2001. In early June, Public Citizen launched *Questionable Doctors Online* onto the World Wide Web in an attempt to make this valuable consumer resource available to as many people as possible.

It contains information about physicians who have been disciplined by state medical boards and other agencies for incompetence, misprescribing drugs, sexual misconduct, criminal convictions, ethical lapses and other offenses. But unlike the previous print editions of *Questionable Doctors*, Public Citizen will be able to provide more timely information soon after it becomes available. Also, when the full launch is completed, users will be able to cross check their doctor's record with other states.

For free consumers can learn whether their doctors in the following states have been disciplined: Alabama, Alaska, California, Colorado, Connecticut, the District of Columbia, Florida, Georgia, Hawaii, Idaho, Illinois, Indiana, Maine, Maryland, Massachusetts, Michigan, Montana, Nevada, New Hampshire, New Mexico, Ohio, Oklahoma, Rhode Island, Texas, Utah, Vermont, and Virginia. Other states will be added throughout the year. For $10 consumers can get details about the actions taken. (See the ad on page 10 prices and ordering information.)

Public Citizen has long sought greater consumer access to information about doctors, and there have been improvements in making that information available. Most state medical boards, for example, now provide some physician information on the Internet, but the information about the disciplinary actions varies greatly, is often inadequate and can be difficult for people to access.

The most complete database on doctors is the National Practitioner Data Bank, which contains state medical board sanctions in addition to hospital disciplinary actions and medical malpractice awards. But neither consumers nor their doctors have access to it. Public Citizen's position has been for years that it's time for Congress to respond to the needs of citizens and open the National Practitioner Data Bank to the public. There are no excuses for allowing this data to be viewed by HMOs, medical boards and hospitals but not by the people who must put their lives in the hands of these practitioners.

If you feel that your doctor has not given you proper medical care or has mistreated you in any way—whether or not he or she is listed in the database—it is important that you let your state medical board know. Even if they do not immediately act on your complaint, it is important that the information be recorded in their files because it is possible that other people may have filed or will file complaints about the same doctor. Send a brief

continued on page 9

VITAMINS, *from page 3*

E. However, among those receiving vitamin E alone and experiencing an infection, the duration of illness and the total number of symptoms were significantly higher, and fever and restriction of activity occurred more frequently, than those in the no-vitamin groups.

The results of this study have important personal and public health implications. The elderly may be worse off with vitamin E supplementation than without it and the health care system may be unnecessarily being burdened because of vitamin E supplementation.

The authors concluded:

If our results are confirmed and vitamin E exacerbates respiratory tract infections, elderly people, especially those who are already well-nourished, should be cautious about taking vitamin E supplements.

The researchers give the always appropriate scientific response—confirmation of their results is needed and a recommendation of being cautious. A clearer recommendation would be more appropriate. As the authors noted, the only previous studies of vitamin E supplementation in these types of patients did not focus on infectious diseases and no published research could be found on vitamin E supplementation and the severity of respiratory tract infections. It is no longer possible to say, I'll take vitamin E, it might help but it won't harm. The weight of the evidence is, for now, for the use of vitamin E described in the study, more harm than benefit will result.

Will a vitamin a day keep the doctor away? If you are malnourished or a strict vegetarian trying to prevent chronic disease due to a vitamin deficiency maybe, but there is also the possibility of harm. If you are a well-nourished elderly person living at home, taking vitamin E may actually increase the number of times you must see your doctor.

What You Can Do

Your best bet for a long and healthy life is a good diet and exercise. This is also less expensive than buying a lot of costly vitamins.

Product Recalls

August 8—September 4, 2002

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*
Clonazepam Tablets, 1 mg and 2 mg, 100, 500, and 1,000 count bottles, Rx only; Class II; Tablet mix up—2 mg tablets may be in bottles labeled as containing 1 mg tablets and/or 1 mg tablets may be in bottles labeled as containing 2 mg tablets	Numerous lot numbers; 160,391 bottles distributed nationwide; Teva Pharmaceuticals, Jerusalem, Israel. Recalled by Teva Pharmaceuticals USA, Sellersville, Pennsylvania
Cortizone 10 Anti-Itch Ointment, 1% hydrocortisone, 30% bonus size, 1.3 oz tube; Class III; Superpotency (24 month stability test point)	Lot 2499604 display, Lot 1899031 packaged within; 110,628 tubes distributed nationwide; Pfizer Inc., Parsippany, New Jersey
Equate Extra Strength Pain Relief PM Gelcaps (acetaminophen 500 mg and diphenhydramine HCl 25 mg) 100 count bottles; Class III; Contamination—gelcaps may contain plastic/gasket material	Lot 1MB1451; 41,040 bottles distributed nationwide; Leiner Health Products, Wilson, North Carolina
Ferrex 150 Forte Capsules, Rx only, 100 unit dose capsules, (iron 150 mg, folic acid 1 mg, vitamin B12 25 mcg), and **Vinate Ultra Prenatal Vitamin and Mineral Supplement Tablets,** Rx only, 100 unit dose tablets, 10 blister packs, 10 tablets per blister pack; Class III; Mislabeled—exterior carton names (Ferrex 150/Vinate Ultra) differs from blister package names (Poly-Iron 150/Ultra Natal)	Lot 021869 EXP 3/04, lot 014247 EXP 10/03; 52,334 blister packs distributed nationwide; Contract Pharmacal Corporation, Hauppauge, New York
GOJO Skin Lotion Medicated (allantoin 0.7%), 5 fl oz tubes NET 148 mL; Class III; Subpotent—active ingredient Allantoin (stability)	Lots 134239, 138256, 147523, 151914, 152499, 153752, 160436, 169565, 170833; 12,719 cases distributed nationwide; GOJO Industries, Inc., Cuyahoga Falls, Ohio
Hydrocortisone Cream 1% and .5% 0.9 gram and 1 gram packets sold under many private labels; Class III; Subpotent	Numerous lot numbers; 1,409,360 packets distributed in California, Colorado, Florida, Illinois, Kansas, Maryland and Missouri; Ultratab Laboratories, Inc., Highland, New York
Imodium Advanced Chewable Tablets (loperamide HCL/simethicone); Class III; Mispackaging by repacking firm. Imodium A-D Caplets containing loperamide HCl were mislabeled as Imodium Advanced chewable tablets containing loperamide and simethicone	Lot Numbers DFC049 and DEC051; 51/2500 count cases distributed nationwide; McNeil Consumer Products, Fort Washington, Pennsylvania. Recalled by Navajo Manufacturing Company, Inc., Denver, Colorado
Iodine Tincture, Solution (sodium iodide 2.4%, iodine 2%) 1 oz. bottle, distributed under Kroger brand; Class III; Labeling—bottles labeled as Iodine Tincture contain Curechrome (benzalkonium chloride)	Lot 2611 EXP 01/04; 4,423 bottles distributed nationwide; Century Pharmaceuticals, Indianapolis, Indiana. Recalled by Rush & Hebble Co., Inc., Edinburgh, Indiana

DRUGS AND DIETARY SUPPLEMENTS *cont.*

Name of Drug or Supplement; Class of Recall; Problem	*Lot #; Quantity and Distribution; Manufacturer*
Lariam Tablets (mefloquine HCl), 250mg; Class III; Potential cross contamination with active ingredients which could include levodopa/benserazide, and/or sulfamethoxazole	Lots B1023-50 EXP 12/03, B1024 EXP 12/03, B1025 EXP 12/03; 69,447 bottles distributed nationwide; F. Hoffmann-La Roche, Basel, Switzerland. Recalled by Roche Laboratories, Nutley, New Jersey
Levothroid Tablets (levothyroxine sodium tablets), 100 mcg, and 125 mcg, 100 count and 5,000 count bottles; Class II; Subpotent prior to expiration date	Numerous lots; 65,427 bottles distributed nationwide; Forest Pharmaceuticals, Inc., Cincinnati, Ohio
Levothroid Tablets (levothyroxine sodium tablets), 25 mcg, 100 tablet bottles, Rx only; Class III; Stability—low potency prior to expiration	Lot #120012 EXP 12/02; 14,415/100-tablet bottles distributed nationwide; Forest Pharmaceuticals, Inc., St. Louis, Missouri
Nasonex Nasal Spray (mometasone furoate monohydrate) 50 mcg, Net Contents: 17 g, 120 Metered Sprays, Rx only; Class II; Defective container—missing part in actuator may cause a narrow stream of product to be dispensed rather than a fine spray	Lot 1-KTL-147 EXP 3/03; 295,620 units distributed nationwide; Schering-Plough Products, Inc., Manati, Puerto Rico. Recalled by Schering Corporation, Kenilworth, New Jersey
North Burn Jel Topical Analgesic, contains lidocaine HCL (2.0%) six-packets 1/8 oz (3.5 g); Class III; Misbranding—Six unit holding carton mislabeled as Burn Jel (lidocaine HCl) but actually contains individual non-medicated packages of Cool Jel	Lot M1G0407 EXP 01/04; 1,200 units distributed nationwide; North Safety Products, Mexacli, BC. Recalled by North Safety Products, Cranston, Rhode Island
Premarin Tablets; Class III; Failure to meet dissolution specifications by manufacturer	Lot 9000481D EXP 01/05; 9,601 bottles distributed nationwide; Ayerst Laboratories, Inc., Rouses Point, New York. Recalled by NationalPharmpak Services, Inc., Zanesville, Ohio
Proventil Repetabs (albuterol sulfate), Rx only; Class III; Dissolution—failures at the sixth and eighth hour (stability)	Numerous lots sold under various formulations; 213,997 bottles distributed nationwide and in Puerto Rico; Schering Corp., Kenilworth, New Jersey. Recalled by AmeriSource Health Services Corp., Columbus, Ohio
Quinaglute Dura-Tabs (quinidine gluconate) (extended-release tablets), 324 mg, 100 count bottles, Rx only; Class II; Metal particles found in tablet (by manufacturer)	Lot #012634 EXP 10/23/03, Lot #012831 EXP 11/27/03, Lot #012263 EXP 9/04/03; 687 bottles distributed nationwide; Berlex Laboratories, Wayne, New Jersey. Recalled by AmeriSource Health Services Corp., Columbus, Ohio
Theo-Dur Extended-release Tablets (theophylline (anhydrous)), Rx only; Class III; Dissolution—failures at the sixth and eighth hour (stability)	Numerous formulations and lots; 818,922 tablets distributed nationwide and in Puerto Rico; Schering Corp., Kenilworth, New Jersey. Recalled by AmeriSource Health Services Corp., Columbus, Ohio
Therevac-SB Mini Enema Gelatin Ampules and **Therevac-Plus Mini Enema w/Anesthetic Ampules**; Class III; Stability—may not meet specifications throughout the labeled expiration date	Numerous lot numbers; 102,807 distributed nationwide; R. P. Scherer Laboratories, St. Petersburg, Florida. Recalled by King Pharmaceuticals, Inc., Bristol, Tennessee
Zerit Capsules (stavudine), 40 mg, bottles of 60, Rx only; Class II; Tablets changed to capsules	Lot 1A36209 EXP 2/03; 26 bottles distributed nationwide; Bristol-Myers Squibb Oncology/Immunology, Princeton, New Jersey. Recalled by Alliance Wholesale Distributor, Richton Park, Illinois

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 1-800-FDA-1088. The FDA web site is *http://www.fda.gov*.

Name of Device; Class of Recall; Problem	*Lot #; Quantity and Distribution; Manufacturer*
Accu Chek Inform Blood Glucose Monitoring System; Class II; May give erroneous results if the temperature icon has ever been displayed with use	All units that have ever displayed a temperature icon in conjunction with patient use; 15,452 units distributed nationwide; Roche Diagnostics Corporation, Indianapolis, Indiana
Choice A.B. Daily Wear Soft Contact Lens (hydrophilic); Class III; Labeling problem	Lot 0313 and 0905; 50 units distributed in California, Massachusetts, Missouri, Oregon and Canada; Specialty Ultravision, St. Hubert, Quebec, Canada. Recalled by Ciba Vision Corp., Duluth, Georgia
Cochlear Implant Guide, CLARION brand; Class II; Firm is recalling due to association of implant guide with meningitis cases	Undetermined quantity distributed nationwide and internationally; Advanced Bionics Corp., Sylmar, California
Manual Resuscitators; Class II; Failures due to air/oxygen leakage	Blue, Pediblue, and Baby Blue; Numerous model numbers, all lots beginning with "D" and "E" 001 through 365 and those beginning with "F" and "H" 001 through 106; 227,580 distributed nationwide and internationally; Vital Signs, Inc., Totowa, New Jersey

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 1-800-638-2772. The CPSC web site is *www.cpsc.gov*.

Name of Product; Problem	*Lot #; Quantity and Distribution; Manufacturer*
All-terrain Vehicles; Ball joints on the front suspension can fail, resulting in a loss of control	Red or green Artic Cat brand; 45,000 sold nationwide from June 2001 through June 2002; Arctic Cat Inc., Thief River Falls, Minnesota (800) 210-5941 www.artic-cat.com
Bicycles; Stem can break, causing a loss of control	Model 3T ZEPP XL; 1,300 sold nationwide from March 2001 through July 2002; Cannondale Corp., Bethel, Connecticut (800) BIKEUSA www.cannondale.com
Cordless Drill/drivers; Switch can malfunction and overheat, posing the possibility of a fire hazard	Firestorm and Quantum Pro, numerous models; 950,000 sold nationwide, and in Puerto Rico and Canada from March 1999 through December 2001; Black & Decker (U.S.) Inc., Towson, Maryland (866) 821-5444 www.blackanddecker.com
Digital Cable Boxes; Pins that connect to the power cord could break, which could pose an electric shock hazard	DCT2000; 1 million distributed in conjunction with digital cable service from March through June 2002; Motorola Inc. Broadband Communications Sector, Horsham, Pennsylvania (866) 281-1588 www.motorola.com/broadband
Digital Multimeters; Users can misinterpret delayed reading to mean that high voltage is not present. If high voltage is present, users could be exposed to a risk of shock, electrocution, and thermal burns	Serial number below 79000000; 17,200 sold nationwide from January through October 2001; Fluke Corp., Everett, Washington (800) 260-4819 www.fluke.com/170recall

CONSUMER PRODUCTS *cont.*

Name of Product; Problem	*Lot #; Quantity and Distribution; Manufacturer*
Floor Pumps; Pressure gauge lens can separate from the pump and strike a consumer—used for bicycle tires	Topeak Joe Blow Comp; 10,000 sold nationwide from March 2000 through August 2001; Todson Inc., Foxboro, Massachusetts (800) 250-3068 www.topeak.com
Freestyle Bicycles; Length of the crank arm fails to allow sufficient space between the rider's foot and the front wheel. The rider's foot could come in contact with the front wheel, causing the rider to lose control	2003 model BMX; 1,100 sold nationwide from May through August 2002; Haro Bicycle Corp., Vista, California (800) 289-4276 www.harobikes.com
Hairdryers; Do not have an immersion protection device on the power cord and could present a serious electrocution hazard if exposed to water	Model BAB2002BLX; 23,000 sold in Miami, Florida and Reseda, California from December 2000 through January 2002; Babyliss Pro, Stamford, Connecticut (800) 726-4202
Hedge Trimmers; Catalytic muffler can overheat and damage the fuel tank, posing a fire hazard	Gasoline powered professional Model HT231 and model DH231; 3,100 sold in California from April through September 2001; Shindaiwa Inc., Tualatin, Oregon (800) 521-7733
Key Chains; Miniature Coca-Cola bottle that attaches to the body of the plush bear key chain can come off, posing a choking hazard to young children	Bottle Cap Bear; 8,000 sold nationwide from January through July 2002; Team Bears LLC, East Brunswick, New Jersey (800) 450-5585
Mountain Bikes; Steer tube can break off from the two main tubes of the frame causing the rider to lose control	Marin-brand, aluminum-framed; 1,000 sold nationwide from August 1998 through July 2002; Marin Mountain Bikes, Novato, California (800) 876-9840
Plastic Folding Chairs; Legs were mis-assembled by the installer and a piece of the chair could be bent out of shape, which can allow the chair to collapse during use	Adams Quik Fold Chair and Quik Fold Café Set; 2,740 sold nationwide from February through March 2002; Adams Manufacturing Corp., Portersville, Pennsylvania (800) 237-8287 www.adamsmfg.com
Slicers/corers; Cutting blade can separate from the center-coring ring during use causing cuts to consumers' hands and fingers	Pro Line; 31,000 sold nationwide from January 2001 through July 2002; Leifheit International USA Inc., Melville, New York (866) 695-3434 www.leifheitusa.com
Table Saws, Recall to Repair; Motor housing on saw may crack, posing a risk of electric shock	10 inch table saws BT2500 and date codes 200128-CT through 200148-CT; 6,100 sold nationwide from August 2001 through April 2002; Black & Decker (U.S.) Inc., Towson, Maryland (866) 357-0324 www.blackanddecker.com
Toy Chests; Screws in the lid support hinges can loosen over time, and come out from the base of the toy chests	Blue, sold under Playskool name; 3,300 sold at Target stores nationwide from October through December 2001; XL Machine Ltd., Eden Prairie, Minnesota (866) 746-8097
Walk-behind Mowers; Vendor who manufactured the mulch plates for Lawn-Boy used the wrong material, making the plates brittle and easy to crack or break. Objects coming through a broken plate could injure the operator or bystanders	21-inch Lawn Boy Easy Mulch Silver, Silver Pro and GoldPro Series; 36,000 sold nationwide from February through August 2002; Lawn-Boy Inc., Bloomington, Minnesota (866) 336-5207 www.lawnboy.com
Wooden Toys; Small parts present a choking hazard	Star Clacker and Ride-On Duck; 6,800 sold nationwide from April through July 2002; Pottery Barn Kids, San Francisco, California (866) 428-6467 www.potterybarnkids.com

QUESTIONABLE DOCTORS ONLINE, from page 4

written description of what occurred to the board for your state or call them for more information on how to file a complaint. The addresses of the 27 states updated in our database are available at our Web site.

Doctors Still Practicing

For many of the most serious offenses by doctors, the disciplinary actions imposed by state medical boards have been dangerously lenient. Choosing a doctor is one of the most critical decisions a consumer will make, but unfortunately, finding good, reliable information about physicians has been exceedingly difficult. We believe that to make the right choices about health care, consumers need to know whether their doctor has been disciplined for any offense and the details of the offense.

The majority of doctors disciplined for the five most serious offenses—sexual abuse or sexual misconduct; substandard care, incompetence or negligence; criminal conviction; misprescribing or overprescribing drugs; and substance abuse—were not required to stop practicing even temporarily. Therefore it is likely they are still practicing and that their patients are unaware of their offenses.

Following are some doctors still practicing in some of the added states.

Georgia

• A doctor who previously abused alcohol had his license suspended temporarily in West Virginia and Georgia because he had a relapse and was charged with driving under the influence. He was then placed on probation by Georgia, which has ended.

• Six Georgia physicians, currently practicing, were disciplined for having sex with patients or other sexual offenses. Five were put on probation and one was reprimanded.

Oklahoma

• A doctor who had inappropriate sexual relationships with mothers of three of his pediatric patients while treating their children and became the father of a child born to one of the mothers was merely reprimanded by the Oklahoma board. The board's Web site mentions the 1997 reprimand but gives no reason for it.

• A doctor who was reprimanded by the board for being the acting anesthesiologist for numerous procedures during which patient care was jeopardized due to his acts of negligence or his inability to perform the required anesthesia procedures with appropriate skill or knowledge. He can no longer practice as an anesthesiologist but can practice as a general practitioner. The board's Web site mentions his reprimand and the restriction on his practice but fails to mention any reason for these.

• A doctor whose license was suspended in 1999 for engaging in sexual misconduct with a patient, after she was discharged from a psychiatric hospital where he was treating her, had his license reinstated later that year and was put on probation. The Oklahoma board Web site merely describes the reason as "unprofessional conduct" and incompetence.

Maryland

• A doctor who breached the standard of care by operating on the wrong leg. He also filed a false report by making changes in the patient's medical record. His license was suspended for two years, but that suspension was stayed for all but three months, after which he was put on probation for 36 months.

• A doctor who breached the standard of care for the delivery of quality anesthesiology to 21 patients out of 23 cases reviewed by peers. He was reprimanded and some restrictions were placed on his practice.

• A doctor who had inappropriate physical and sexual conduct with four patients during psychiatric therapy. He surrendered his license but it later was reinstated and he was put on 60 months of probation.

Virginia

• A doctor who surrendered his license in North Carolina and whose South Carolina license was suspended because of unethical practice. Virginia merely reprimanded him for

continued on page 10

Editor.....*Sidney M. Wolfe*
Acting Editor.....*Peter Lurie*
Managing Editor.....*Phyllis McCarthy*
Staff Researchers..... *Larry Sasich*
Benita Marcus Adler
Elizabeth Barbebenn
Peter Lurie
Information Specialist.....*John Paul Fawcett*
Proofreader..... *Benita Marcus Adler*
Production Mgr.....*Kristy I. Jackson*

President.....*Joan Claybrook*
Founder.....*Ralph Nader*

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.

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

QUESTIONABLE DOCTORS ONLINE, from page 9
lying.

• A doctor who—without arranging for another physician to assume care—left a patient, upon whom he had made an incision in preparation for surgery, at one hospital so he could attend the medical needs of a patient at another hospital. Virginia merely reprimanded him.

Florida
• Last October, a Florida surgeon operated in the wrong place in the body, an act judged to be substandard care. He was fined $5,000 and required to give a one hour lecture on wrong site surgery and to take five hours of courses in risk management.

• In 1995, New York revoked the license of this physician because he was practicing negligent, substandard care. In 1997, based on the New York action, the Florida board merely put him on probation for 60 months and required him to take classes and be monitored.

Alaska
• A doctor who was put on probation because of sexual misconduct with a female patient. His probation included a requirement for education on the topic and a restriction on his license.

• A doctor whose license was suspended for one month and who was placed on probation for five years for sexual contact with a patient and excessive use of controlled substances.

Nevada
• A doctor who was merely put on probation and fined $4,000 for gross malpractice concerning abortion.

Utah
• A doctor who committed a pattern of negligent acts, engaged in unprofessional conduct and violated a probation order. For all this, he was merely put on probation again.

OUTRAGE, *from page 12*
humectants (chemicals used to keep tobacco moist) from Dow. Philip Morris quickly realized that it could use these purchases as a cudgel to modify Dow/Merrell's promotional campaign for Nicorette, whatever the public health consequences. An internal Philip Morris memo explains: "[T]hey cannot realistically expect a customer to spend millions of dollars for materials, when the profits from those sales, directly or indirectly, are used to attack that customer's product and perhaps reduce the customer's sales."

Philip Morris complained about efforts by Dow to induce its workers to quit smoking

What had Dow done to so inflame its customer? In the same memo, Philip Morris complained about efforts by Dow to induce the workers at the plant producing the humectants to quit smoking, an economic analysis funded by Dow to assess the impact of smoking and "Dow literature appearing in doctors' offices encouraging smokers to quit by using Nicorette." Kvetched the addiction purveyors: "We had been assured that Nicorette would have a low-key introduction and would be aimed only at those smokers who had to stop for medical reasons." In protest, Philip Morris stopped purchasing the humectants in May 1984.

But because Dow was one of the only sources for these crucial chemicals, Philip Morris soon resumed purchases—and its influence over Dow. Minutes from a meeting between Marion Merrell Dow, Dow itself and Philip Morris indicate that "[David] Sharrock [president of Marion Merrell Dow] said he has been carefully screening advertising and promotional materials to eliminate any inflammatory anti-industry statements. He intends that sales be maintained on a basis of Nicorette being a product for those who want or need to stop smoking. Examples were cited where ad agencies pushed anti-smoking themes and Sharrock vetoed the ideas." Subsequently Dow caved in to pressure from Philip Morris and ended its contributions to the National Interagency Council on Smoking and Health, a mainstream alliance including such members as the American Lung Association and several U.S. Government agencies.

Exit Dow/Merrell, stage right, tail between its legs. Enter CIBA-Geigy, the next to succumb to bullying threats from Philip Morris, still firmly at center stage.

In 1991, CIBA-Geigy released the nicotine patch Habitrol for marketing. Analysts at Philip Morris were alarmed, predicting a loss in sales due to patches of $11.2 billion by 1996. But Philip Morris soon realized that CIBA's Achilles Heel was its diverseness—it has both agricultural and pharmaceutical divisions—and set about turning CIBA against itself.

Philip Morris objected particularly to a campaign entitled "Smokebusters," which it said in an internal memo shortly after Habitrol was released "bordered on being anti-tobacco." It approached CIBA's agricultural division, which manufactures pesticides for tobacco production and conducts tests of plants and cigarettes for pesticide residues. Internal negotiations between the agricultural and pharmaceutical divisions followed, producing the following internal CIBA ground rules: "No antismoking theme ... Our product is not a tobacco substitute ... We do not endorse positions which would take away the freedom of choice for smokers."

"We do not endorse positions which would take away the freedom of choice for smokers" — CIBA-Geigy

CIBA agricultural division internal correspondence explained the impact of the ground rules: "[T]he Smoke Buster program would end February 1 and not be repeated. Habitrol consumer advertising in newspapers and magazines and on television would be aimed at smokers who are committed to quitting smoking ... [We have] informed tobacco companies, the Tobacco Leadership Group and tobacco growers about the outcome."

It is in the nature of current consolidations in the pharmaceutical industry and elsewhere that, soon enough, the swallower will be swallowed, creating hitherto unimagined opportunities for new conflicts of interest. In 1996, CIBA merged with Sandoz to form a new pharmaceutical company, Novartis. The even-more-mega-company's slogan is "Think What's Possible." Might the new company see this as an admonition against conflict of interest? Smokers who didn't quit because CIBA and Dow/Merrell never fully promoted their products, and those involuntarily exposed to these smokers' second-hand tobacco smoke, won't be holding their breaths.

Strange Bedfellows: How the Tobacco and Drug Industries Collaborated to Undermine Anti-Smoking Efforts

At first take it seems impossible. How could it come to pass that pharmaceutical companies, supposedly dedicated to curing people of life-threatening diseases, would come to join hands with the tobacco industry—which annually is responsible for the deaths of more than 400,000 Americans and a total of 3.5 million people worldwide? The answer: corporate mergers, acquisitions and diversifications have placed the tobacco industry in a position where it can have influence over pharmaceutical companies, including those who make smoking cessation aids.

In the August 14, 2002 issue of the *Journal of the American Medical Association*, Bhavna Shamasunder and Lisa Bero of the University of California, San Francisco clearly demonstrate that these conflicts of interest have had a powerful impact on the promotion of smoking cessation products—endangering the lives of American smokers who might otherwise have quit.

Litigation brought by individuals damaged by tobacco products and the 1998 settlement agreement between the tobacco companies and most U.S. states have shaken loose a veritable treasure trove of documents that have confirmed how deeply the tobacco industry had sunk its avaricious tentacles into a variety of institutions ranging from the World Health Organization to Hollywood. But, in two case reports derived from these documents, the researchers have provided the clearest evidence to date of the unseemly partnerships between the drug industry and the industry making the most dangerous drug of them all—tobacco.

The first case began in 1980 and involved Nicorette gum, manufactured by Marion Merrell Dow, then a subsidiary of the Dow Chemical Company. At the time, Philip Morris, the world's largest tobacco company, was buying about $8 million of

continued on page 11

Printed on recycled paper.

MOVING? SUBSCRIPTION? ADDRESS CORRECTION?
Please enter corrections or subscription information below. Return current mailing label. Mail to ####

NAME

ADDRESS

CITY, STATE ZIP

SUBSCRIPTION

☐ One year $18 ☐ Two year $30 ☐ Three year $42

Enclose your check or money order made out to *Health Letter*.

CHAA44

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

Non-Profit Org.
U.S. POSTAGE
PAID
Wash., DC
Permit No. 8314