PUBLIC CITIZEN HEALTH RESEARCH GROUP

Health Letter

SIDNEY M. WOLFE, M.D., EDITOR JUNE 2002 ◆ VOL. 18, NO. 6

Questionable Doctors Online Disciplined Doctor Resource Debuts on Public Citizen Web Site in June

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* resource is back—with a twist. Or, more accurately, a click. In early June, Public Citizen is launching *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. Also, when the full launch is completed, users will be able to cross check their doctor's record with other states.

"Choosing a doctor is one of the most critical choices consumers make and we believe the public should be armed with as much information as possible when doing so," said Dr. Sidney Wolfe, director of Public Citizen's Health Research Group.

Now that the new *www.questionabledoctors.org* web site has been launched, for a small fee, consumers can obtain information about their doctors in the following states: California, Connecticut, Hawaii, Illinois, Indiana, Maine, Massachusetts, Michigan, New Hampshire, Ohio, Rhode Island and Vermont. Other states will be added throughout the year. (See the ad on page 2 for details about 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. "We've been saying 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," Wolfe said. "There are no

CONTENTS

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."

In addition to *Questionable Doctors Online*, for 2 of the 12 states, California and Hawaii, Public Citizen's Health Research Group has republished the regional edition in print. The following is information on the actions taken by these two states.

The information from California and Hawaii includes disciplinary actions taken from 1992 through 2001 that we received through January 31, 2002. The California reports from both their Medical and Osteopathic Boards contain some minimal information on modifications and terminations of board actions and list the results of some appeals, but we cannot guarantee that all appeals or all court decisions were included. The California Medical Board sent a separate listing of doctors whose actions had been overturned on March 1, 2002. The California Osteopathic Board and the Hawaii Board told us that any such actions would be included in the information we were sent.

The information provided covers disciplinary actions taken against allopathic physicians (MDs) and osteopathic physicians (DOs). See the May 2002 issue of the *Health Letter* for how these states did in our 2002 Ranking of Serious Actions and our report grading state web sites. The tables on pg. 3 give the details of the California and Hawaii Boards' disciplinary actions against doctors. For many of the most serious offenses by California doctors, the disciplinary actions imposed by the board have been dangerously lenient. For example, of 72 cases in which doctors were disciplined for sexual misconduct with patients or other sex-related offenses, most did not result in even a temporary loss of license. Fifty nine percent of the actions against doctors committing these offenses were reprimands or probation, hardly adequate for such serious violations of medical practice. Further examples of such laxity by the California and Hawaii boards can be seen on the web site or book version of *Questionable Doctors*.

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 our report—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 written description of what occurred to the address below or call the phone numbers listed for more information on how to file a complaint.

Medical Board of California
Ronald Joseph, Executive Director
1426 Howe Ave., Suite 54
Sacramento, CA 95825-3236
(916) 263-2389
(800) 633-2322

Osteopathic Medical Board of California
Linda J. Bergmann, Executive Director
2720 Gateway Oaks Drive, Suite 350
Sacramento, CA 95833-3500
(916) 263-3100

Hawaii Board of Medical Examiners
Constance Cabral-Makanani, Executive Director
Department of Commerce and Consumer Affairs
PO Box 3469
Honolulu, HI 96801
(808) 586-3000

California's Disciplinary Actions

The tables below summarize the data that Public Citizen received from California.

Table 1.

Disciplinary Actions Against MDs and DOs 1992 through 2001*

Actions	Number	Percent**
Revocation	524	17.95
Surrender	501	17.16
Suspension	250	8.56
Probation	1195	40.94
Practice Restriction	2	0.07
Action Taken Against Controlled Substance License	2	0.07
Other Actions	445	15.24
Total Actions	**2919**	**100.00**

* This table lists only the two most serious disciplinary actions taken against a physician.
** Percentages may not total 100% due to rounding.

Table 2.

Offenses for which MDs and DOs were Disciplined 1992 through 2001*

Offense	Number	Percent
Criminal Conviction	262	13.56
Sexual Abuse of or Sexual Misconduct with a Patient	59	3.05
Substandard Care, Incompetence or Negligence	455	23.55
Misprescribing or Overprescribing Drugs	104	5.38
Substance Abuse	36	1.86
Disciplinary Action Taken Against License by Another State or Agency	485	25.10
Other Offenses	531	27.48
Total Records with Offense Listed	**1932**	**100.00**

* Includes only those actions for which an offense was listed and for which we had a corresponding term in our database.

Hawaii's Disciplinary Actions

The tables below summarize the data that Public Citizen received from Hawaii.

Table 1.

Disciplinary Actions Against MDs and DOs 1992 through 2001*

Action	Number	Percent**
Revocation	21	15.67
Surrender	5	3.73
Suspension	11	8.21
Probation	10	7.46
Practice Restriction	11	8.21
Action Taken Against Controlled Substance License	1	0.75
Other Actions	75	55.97
Total Actions	**134**	**100.00**

* This table lists only the two most serious disciplinary actions taken against a physician.
** Percentages may not total 100% due to rounding.

Table 2.

Offenses for which MDs and DOs were Disciplined 1992 through 2001*

Offense	Number	Percent
Criminal Conviction	5	6.02
Sexual Abuse of or Sexual Misconduct with a Patient	5	6.02
Substandard Care, Incompetence or Negligence	6	7.23
Misprescribing or Overprescribing Drugs	1	1.20
Substance Abuse	3	3.61
Disciplinary Action Taken Against License by Another State or Agency	38	45.78
Other Offenses	25	30.12
Total Records With Offense Listed	**83**	**100.00**

* Includes only those actions for which an offense was listed and for which we had a corresponding term in our database.

Editor ..... *Sidney M. Wolfe*
Managing Editor ..... *Phyllis McCarthy*
Staff Researchers ..... *Benita Marcus Adler, John Paul Fawcett, Bob Goodman, Jeff Vinson, Larry Sasich*
Information Specialist ..... *John Paul Fawcett*
Production Mgr. ..... *Kristy I. Jackson*
Proofreader ..... *Benita Marcus Adler*

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

THE PUBLIC CITIZEN HEALTH RESEARCH GROUP
Health Letter

Published Monthly by
Public Citizen Health Research Group

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.

Material in the *Health Letter* may not be reprinted without permission from the Editor. Send letters and requests to HEALTH LETTER, Editor, 1600 20th St., NW, Washington, D.C., 20009.

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**

Understanding Risks—and the Risks You Run By Misunderstanding Them

Imagine you're a 70-year-old woman with osteoporosis talking with your doctor about the potential benefits (and risks) of several different available drug treatments to prevent hip fractures in elderly female patients. One treatment, you are told, will reduce your risk of fracture by about 25 percent; another treatment will reduce this risk by about 1 percent. With yet another treatment, 97 percent of women are free of fractures after two years of treatment, compared to 96 percent of those who go untreated. Which therapy would you choose?

Chances are, you would choose the first.

As a matter of fact, all of these alternatives refer to the same treatment and the same treatment effect, but express the risk in different ways. The first (the 25 percent number) refers to what is called the "relative risk reduction." If a treatment reduces the risk of hip fracture from 4 in 100 (4 percent) to 3 in 100 (3 percent), the risk is reduced by 1/4, or 25 percent. However, in "absolute" terms, the risk is reduced by 1 percent (from 4 percent to 3 percent). Improving the percentage of women free of fractures after two years from 96 percent to 97 percent (1 percent improvement) is yet another way of describing the same result. Even though all three expressions are "correct," expressing risk reductions in relative, rather than absolute, terms can make treatment effects seem larger than they really are.

Take another example; if a middle-aged man with a history of a heart attack takes a "statin" drug for five years to lower his cholesterol, his risk of having a heart attack during this time is reduced from 12 percent to slightly less than 8 percent. The relative risk reduction here is 33 percent, but in this case the absolute risk reduction is 4 percent. Patients are likely to overestimate benefits—and probably are more likely to undergo treatments—when these benefits are expressed in relative rather than absolute terms.

But it is not just patients who may misinterpret these measures—doctors do, too. For example, a study of Italian physicians presented the same results to doctors five different ways (similar to the example above) as if they were from different studies. Doctors were much more willing to prescribe a cholesterol-lowering drug when results were expressed in terms of relative risk reduction compared to other measures.

This might not be much of a problem if both absolute and relative risk reductions were presented together. However, this is most often not the case. Drug companies use relative risk almost exclusively in their ads—for obvious reasons: they are usually much bigger. "Reduces your risk of hip fracture by 25 percent" sounds much more impressive than "reduces your risk by 1 percent." And, unfortunately, far too many doctors get their information from promotional literature rather than from the medical literature. Media reports, too, have been found to focus on relative, rather than absolute risks, for similar reasons. Even medical journals frequently seem to prefer relative to absolute reductions.

We often use terms such as "likely" or "rarely," and while we all understand (more or less) what these terms mean, different people may interpret these terms quite differently—one person's "probably" may be another's "unlikely." And in fact, for some diseases, a risk of 5 percent might be considered quite high, while for other conditions it might be considered low. Important, of course, is how life threatening the condition is. Clearly, expressing risk quantitatively, i.e., using numeric estimates, is preferable to using terms like "unlikely." But even this can create confusion, as can be seen above.

What is the best way to express risk? There is no clear answer to this, though what is perhaps best is to describe results in *both* relative and absolute terms, rather than solely in terms of relative reductions. Relative risk reductions by themselves can be deceiving and difficult to interpret. The so-called "number needed to treat" ("NNT"), has also become a popular measure in the medical literature. It is the number of patients that would need to be treated in order to prevent one outcome, be it hip fracture, heart attack, or stroke. In the example of osteoporosis above, where the absolute risk reduction was 1 percent over two years, 100 patients would need to be treated for 730 days to prevent one hip fracture. Likewise, a "number needed to cause harm" related to the risks of the treatment, can also be calculated. Visual presentations of risks may be helpful, and some studies suggest that patients prefer "bar charts" to other types of display of risk.

Three things you should ask your doctor about a treatment or a screening test:

What is my risk of having the medical problem at which the treatment is directed?

Baseline risks can vary a great deal depending on your age and presence or absence of "risk factors"—for example, diabetes and smoking increase your risk of heart attack and stroke. The chance that you will benefit from a given treatment will depend to a large extent on your baseline risk: the greater the risk, the greater the absolute benefit for a given relative risk reduction. Likewise, if your baseline risk is very low (because of the absence of risk factors, for example), even a large relative risk reduction with treatment will have little effect on your risk, since most likely you would not have had the outcome anyway.

continued on page 5

Overworked Doctors Walk Off the Job

Kai Ryssdal, anchor:

Hundreds of Texas-based doctors and other medical professionals walked off the job on Monday, protesting malpractice suits they say lead to sky-high insurance premiums. One doctor even complained of emotional stress caused by frivolous lawsuits. Commentator and Colorado-based Dr. Marc Ringel argues that doctors' emotional stress is caused not just by lawsuits and insurance companies, but by the traditions of the medical system itself.

Dr. Marc Ringel:

It's time to speak out for one of the most depressed groups I know, doctors in training. Inhuman treatment of medical apprentices speaks volumes about why American health care is so dysfunctional. And I use the word dysfunctional deliberately, with all its connotations of psychological abuse.

For starters, doctors in training routinely work over 100 hours a week. Many doctors have worked at these very extreme levels for up to seven years of graduate training and for at least some of four years of medical school. Does such a routine sound abusive to you? How about nuts? What do you think such a grueling schedule does to a person?

Sleep deprivation is a crucial technique for brainwashing at prison camps. And would you want a sleep-deprived doctor whose judgment may be flagging to take care of you or your loved one? You can bet it's already happened to you. The habit of working when they need to be sleeping persists through many physician's careers. Overtired doctors are as common as underpaid teachers.

At least Congress is trying to address the plight of doctors in training. The House of Representatives is considering the Patient and Physician Safety Act of 2001. This legislation would limit how much doctors who are residents can work to a maximum of 80 hours per week, no more than 24 hours in a row, one full day off per week, and one full weekend off per month. It's pathetic that for any group it's necessary to legislate an 80-hour work week, but this act is still better than nothing, a step toward recognizing the human needs that we doctors have been trained to deny.

High rates of divorce, suicide, drug and alcohol abuse, depression and whining in the physicians lounge attest to the price doctors pay for their self-denial. As scientifically competent as rigorous training makes physicians, it's just as likely to leave us emotionally incompetent.

Still, passage of the Physician and Patient Safety Act is far from a slam dunk. For decades, hospital interests have balanced their books on the backs of resident physicians by paying fixed wages for unlimited hours of work. They will lobby against the act. Some physician organizations will also resist it. As products of a dysfunctional professional upbringing, many doctors believe that abuse is the best tool for molding a physician. Don't listen. Support the act, because ultimately patients' safety and doctors' sanity are inextricably linked.

Kai Ryssdal:

Marc Ringel is a family doctor who practices in Brush, Colorado. If you missed part of today's program, you can catch us again on the Web. It's marketplace.org. And in Los Angeles, I'm Kai Ryssdal. Thanks for being with us.

* * *

To support the Patient and Physician Safety Act and Public Citizen's companion petition to the Occupational Safety and Health Administration, go to *http://www.citizen.org/hrg* and click on "Take Action."

UNDERSTANDING RISK, *from page 4*

How much in absolute terms, will the treatment reduce my risk?

This will depend on your baseline risk. Relative risk reductions will make benefits seem greater than they actually are. A reduction of 1 percent, say from 4 percent to 3 percent, means that had you not been treated, there was a 96 percent chance that you would *not* have had a bad outcome during the period of treatment. With treatment, this probability is now 97 percent that you will not have the outcome, an absolute difference of 1 percent. This sounds considerably less impressive than does a reduction in risk of 25 percent, which is the relative reduction in risk from 4 to 3 percent.

What is my risk of having an adverse event on account of the treatment (and does it outweigh the benefit?)

If the risk of a serious adverse event (for example a bleeding ulcer) equals or comes close to equaling the benefits of the treatment, the treatment does not make much sense. As in the case for benefits, the greater one's baseline risk for an adverse event, the greater is the absolute risk from the treatment.

Decision aids (for example, booklets, videotapes) are now available that help patients and doctors discuss risk. Unfortunately, they are seldom used. Talk to your doctor!

Product Recalls

April 11—May 7, 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 & 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 reasonable 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*
PC SPES, Prostate Formula, herbal dietary supplement, 60 capsules, 320 mg each, OTC sales, indicated for "prostate health" claim. An herbal dietary supplement containing Chinese herbs (Reishi, Baikal Skullcap, Rabdosia, Dyer's Woad, Mum, Saw Palmetto, San Qi Ginseng, Licorice); The product contains the undeclared prescription drug warfarin	All lots and all codes; Unknown quantity distributed nationwide and internationally; International Medical Research, doing business as Botanic Labs Inc., Brea, California

Name of Drug or Supplement; Class of Recall; Problem	*Lot #; Quantity and Distribution; Manufacturer*
Cromolyn Sodium Nasal Solution; Class II; Good Manufacturing Practice Deviations: product was manufactured under the same conditions that yielded contaminated (microbial) product	Manufactured by Alpharma USPD under many labels, numerous lots; 1,423,008 units distributed nationwide; Alpharma USPD, Baltimore, Maryland
HAND MEDIC Antiseptic Skin Treatment, OTC, packaged in 500 ml cartridges, and 2 oz, 4 oz, and 8 oz bottles. Active ingredient: Benzalkonium Chloride 0.1%; Class III; Superpotency of the active ingredient (benzalkonium chloride)	Lot Numbers: 165461, 166095, 166581, 166826, 167503, 168453, and 168912; 9,703 cases distributed nationwide; GOJO Industries, Inc., Cuyahoga Falls, Ohio
Levothyroxine Sodium, tablets, 25 mcg (0.025 mg) and 50 mcg (0.05 mg) Rx only, 100 and 1,000 count bottles, sold under Vintage, Qualitest and URL labels; Class II; Stability—Inability to maintain potency throughout the labeled expiration date	Numerous lots; 28,838 bottles distributed in Alabama; Vintage Pharmaceuticals, Inc., Charlotte, North Carolina
Lovastatin Tablets, 20mg, bottle of 60 tablets; Rx only; Class III; Product failed stability requirement for impurity level	Lots 220F11 and 221F11, EXP 6/03; 1,674,900 tablets distributed nationwide; Purepac Pharmaceuticals, Elizabeth, New Jersey
PROVON Medicated Lotion Soap with Triclosan, OTC, packaged in 12 fl. oz. white plastic bottles, packaged under GOJO label; Class III; Misbranding: Back bottle label declares incorrect active ingredient	Lots #169738 and #168862; 37 cases distributed in Wisconsin, Illinois, Washington, Missouri, Nebraska, Louisiana, Massachusetts and California; GOJO Industries, Inc., Cuyahoga Falls, Ohio

continued on page 7

DRUGS & DIETARY SUPPLEMENTS *cont.*

Name of Drug or Supplement; Class of Recall; Problem	*Lot #; Quantity and Distribution; Manufacturer*
Ranitidine Tablets, 150 mg, Rx only, Unit Dose Tablets; Class III; Product name is misspelled on the outer carton label	Lot #4513-2002, EXP 7/31/02; 1,056 cartons distributed nationwide; NCS HealthCare of KY doing business as Vangard Labs, Inc., Glasgow, Kentucky
Urimax Tablets in 100 count bottles and 2 tablet patient sample package, Rx; Class III; Subpotent for one ingredient (hyoscyamine) at stabilty testing	Lots 01101, 10202, 10309, 10406, 10502, 108012, 109001 and 110083; 55,800 bottles distributed nationwide; Integrity Pharmaceutical Corp., Indianapolis, Indiana

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*.

Class I Recall

Name of Device; Class of Recall; Problem	*Lot #; Quantity and Distribution; Manufacturer*
Defibrillators; Defibrillator may fail to detect ventricular fibrillation and fail to deliver shock; Zoll M Series Advisory Defibrillator and Zoll M Series AED Defibrillator (semi automatic defibrillator)	Serial Numbers T98F00046-T01K27762 with System Software Version below 30.00 and Serial Numbers T98F0092-T01J27533 with System Software Version below 30.0; 13,667 distributed nationwide and worldwide; Zoll Medical Corp., Burlington, Massachusetts

Name of Device; Class of Recall; Problem	*Lot #; Quantity and Distribution; Manufacturer*
Contact Lenses; Class III; Improper sterilization cycle	SoftPerm Daily Wear Soft (Hydrophilic), Lot Number 40114586200611, EXP 11/06; Eight individual lenses distributed in California, Massachusetts, Mississippi, New York, Ohio, Oregon, West Virginia and Nova Scotia; Ciba Vision Corp., Duluth, Georgia
First Aid Only All Purpose First Aid Kit; Class II; Kits were made using a recalled antiseptic spray that may be subpotent	Numerous lot numbers; 89,213 kits distributed nationwide; First Aid Only, Vancouver, Washington

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*
Air Powered Rockets; Foam tips can break off exposing sharp edges that can cause lacerations or eye injuries. Systems also have weak pump handles that can break during use, posing a risk of hand lacerations	GL-X200 Estes Air; 140,000 sold nationwide from February 2001 through February 2002; Estes Industries, Penrose, Colorado (800) 576-5811 www.estesrockets.com
Bicycles; Rear seatstays, the tube behind the seat that connects the rear axle to the rear shock, can break, possibly causing the rider to lose control and crash	2002 Enduro-brand; 2,200 sold nationwide from September 2001 through February 2002; Specialized Bicycle Components Inc., Morgan Hill, California (800) 214-1468

continued on page 8

Name of Product; Problem	*Lot #; Quantity and Distribution; Manufacturer*
Cribs; Slats on the cribs can loosen and detach from the drop side rail, creating a large opening between the slats where a child's head or neck could become entrapped, resulting in serious injury or death	Models 7010 Alpine, 7020 Caspian, 7030 Coventry, 7040 Dunmore and 7070 Haystack; 990 sold nationwide from January 2000 through March 2002; Vermont Precision Woodworks, Morrisville, Vermont (866) 869-7974
Duckie Ring Rattle/Teethers; Rattle may break, causing small beads to fall out, which presents a potential choking hazard to young children	Prestige, models 4576, 44576 and 84576; 4,600 sold nationwide from March through April 2002; Prestige Toy Corp., New York, New York (888) 268-8999
Gas Boilers, Recall to Repair; Burners could produce excess carbon monoxide (CO) in the flue, due to improper combustion, posing a risk of CO poisoning to consumers	Numerous brands and models; 8,000 sold nationwide from August 2001 through March 2002; ECR International, Utica, New York (800) 241-5501 www.boilerrecall.com
Extra Outlet Scented Oil Air Fresheners; May have been misassembled during manufacture, which could pose a risk of fire	Glade PlugIns with rotating outlets; 2.5 million sold nationwide from January through April 2002; SC Johnson, Racine, Wisconsin (800) 571-0920
Harry Potter Key Chains; Key chains can leak petroleum distillates, which can pose an ingestion hazard to children	Magic Potion Bottle filled with purple-colored oil and red water; 7,000 sold nationwide from October through November 2001; Hallmark Cards Inc., Kansas City, Missouri (800) 425-5627 www.hallmark.com
Mountain Bicycles; Forks can break apart, causing riders to lose control	Mongoose and Roadmaster mountain bicycles with Ballistic 105 front suspension forks; 103,000 sold nationwide from June 1998 through December 2000; Brunswick Corp., Lake Forest, Illinois (800) 508-2762 www.ballisticforkrecall.com
Power Saving Devices; Devices have reversed polarity, posing a shock hazard to consumers	White plastic, about 5-inches in height, with the words "Energy Smart" printed across the front in green writing; 45,000 sold nationwide from September 2000 through April 2002; Coast Energy Management Inc., Chandler, Arizona (800) 808-8897
SCUBA Regulators; Second stage orifices on these regulators can be cracked, bent or broken, which can result in a loss of breathing air underwater	Maximus model; 14,000 sold nationwide from January 1998 through November 2000; Sherwood SCUBA LLC, Irvine, California (800) 469-9929 www.sherwoodscuba.com
Trailer Bikes; Universal joint system can fail, causing a rider to lose control	Hitchhiker III NH300 Trailer Bikes; 4,300 sold nationwide from February through May 2001; InSTEP LLC, Mendota Heights, Minnesota (800) 242-6110 www.instep.net
Treadmills; Component of the electronic control panel can malfunction, causing the motor and walking belt to rapidly accelerate and the user can lose balance and fall	Model year 2000/2001 Paragon, Quantum and Omega; 5,900 sold nationwide from November 2000 through June 2001; Horizon Fitness, DeForest, Wisconsin (866) 864-3840
Wheelbarrows; Plastic wheel assemblies can break when being inflated with high pressure air hoses. This can result in plastic pieces exploding from the rims of the wheels, possibly hitting nearby consumers and causing injuries	Steel or plastic tubs with plastic rims and 14-inch wheel; 647,000 sold nationwide from January 1993 through December 2000; Ames True Temper Inc., Camp Hill, Pennsylvania (866) 239-2281

Preventing Heat Induced Death and Illness

During hot summers, there have been as many as 1,000 excess deaths in the United States caused by heat stress. Many of these deaths are preventable if people drink much more fluid than needed to simply quench their thirst (the cooling caused by the evaporation of sweat is the only way people who do not have the luxury of air-conditioning can survive in very hot weather) and engage in other heat-coping behaviors.

Much of the information in this article was published in 1980 in the federal Centers for Disease Control bulletin, *Morbidity and Mortality Weekly Report* following a complaint by Public Citizen's Health Research Group that the government had given out dangerously incomplete information about how to survive the heat. Special precautions should be taken for certain higher-risk groups. These safeguards may include increased efforts to keep cool or closer observation by others for early signs of heat illness. The high-risk groups are: a) infants

continued on page 10

Ways to Avoid Heat Induced Death and Illness

1. *Keep as cool as possible:*
   - Avoid direct sunlight.
   - Stay in the coolest available location (it will usually be indoors).
   - Use air-conditioning, if available.
   - Use electric fans to promote cooling.
   - Place wet towels or ice bags on the body or dampen clothing.
   - Take cool baths or showers.
2. *Wear lightweight, loose-fitting clothing.*
3. *Avoid strenuous physical activity,* particularly in the sun and during the hottest part of the day.
4. *Increase intake of fluids,* such as water and fruit or vegetable juices. Thirst is not always a good indicator of adequacy of fluid intake. Some studies indicate that fluid intake in hot weather should be 1.5 times the amount that quenches thirst. Persons for whom salt or fluid is restricted should consult their physicians for instructions on appropriate fluid and salt intake; otherwise, drink at least a gallon of liquid a day when the outside temperature is above 90° and you cannot be in air-conditioned surroundings.
5. *Do not take salt tablets* unless so instructed by a physician.
6. *Avoid alcohol* (beer, wine, and liquor).
7. *Stay in at least daily contact with other people.*

Drugs Which Can Impair Your Response to Heat*

Generic (BRAND NAME)

Heart Drugs

Acebutolol (SECTRAL)
Atenolol (TENORMIN)
Benazepril (LOTENSIN)
Betaxolol (KERLONE)
Bisoprolol (ZEBETA)
Bumetanide (BUMEX)
Captopril (CAPOTEN)
Carteolol (CARTROL)
Carvedilol (COREG)
Chlorothiazide (DIURIL)
Disopyramide (NORPACE)
Doxazosin (CARDURA)
Enalapril (VASOTEC)
Fosinopril (MONOPRIL)
Furosemide (LASIX)
Hydrochlorothiazide (ESIDRIX, HYDRODIURIL)**
Indapamide (LOZOL)
Isosorbide-5-mononitrate (ISMO)

Generic (BRAND NAME)

Isosorbide Dinitrate (ISORDIL, SORBITRATE)
Labetalol (TRANDATE)
Lisinopril (PRINIVIL, ZESTRIL)
Methyclothiazide (ENDURON)
Metolazone (DIULO, ZAROXOLYN)
Metoprolol (LOPRESSOR)
Moexipril (UNIVASC)
Nadolol (CORGARD)
Nitroglycerin (DEPONIT, MINITRAN, NITRO-BID, NITRODISC, NITRO-DUR, NITROSTAT, TRANSDERM-NITRO)
Penbutolol (LEVATOL)
Pindolol (VISKEN)
Prazosin (MINIPRESS)
Propranolol (INDERAL)
Quinapril (ACCUPRIL)
Ramipril (ALTACE)
Spironolactone (ALDACTONE)

Generic (BRAND NAME)

Terazosin (HYTRIN)
Timolol (BLOCADREN)
Trandolapril (MAVIK)
Trichlormethiazide (METAHYDRIN, NAQUA)

Oral Hypoglycemics

Acetohexamide (DYMELOR)
Chlorpropamide (DIABINESE)
Glimepiride (AMARYL)
Glipizide (GLUCOTROL)
Glyburide (DIABETA, MICRONASE)
Tolazamide (TOLINASE)
Tolbutamide (ORINASE)

Antidepressant/Antipsychotics

Drugs containing Amitriptyline (ELAVIL, LIMBITROL, TRIAVIL)
Amoxapine (ASENDIN)
Bupropion (WELLBUTRIN)

continued on page 10

Drugs Which Can Impair Your Response to Heat* *continued*

Generic (BRAND NAME)

Chlorpromazine (THORAZINE)
Desipramine (NORPRAMIN)
Doxepin (SINEQUAN)
Fluphenazine (PROLIXIN)
Haloperidol (HALDOL)
Imipramine (TOFRANIL)
Lithium (ESKALITH, LITHOBID, LITHONATE)
Maprotiline (LUDIOMIL)
Nortriptyline (AVENTYL, PAMELOR)
Olanzapine (ZYPREXA)
Prochlorperazine (COMPAZINE)
Promethazine (PHENERGAN)
Quetiapine (SEROQUEL)
Risperidone (RISPERDAL)
Thioridazine (MELLARIL)
Thiothixene (NAVANE)
Trazodone (DESYREL)
Trifluoperazine (STELAZINE)
Ziprasidone (GEODON)

Anticholinergics/Belladonna Alkaloids

Drugs containing Atropine (DONNATAL, LOMOTIL)

Generic (BRAND NAME)

Drugs containing Clidinium (LIBRAX)
Dicyclomine (BENTYL)
Drugs containing Hyoscyamine (URISED)
Loperamide (IMODIUM)
Trimethobenzamide (TIGAN)

Antihistamines

Drugs containing Azatadine (TRINALIN)
Drugs containing Brompheniramine (DIMETAPP)
Drugs containing Chlorpheniramine (ALERMINE, CHLOR-TRIMETON, NALDECON, DECONAMINE, ORNADE)
Drugs containing Clemastine (TAVIST, TAVIST-1, TAVIST-D)
Cetirizine (ZYRTEC)
Cyproheptadine (PERIACTIN)
Desloratadine (CLARINEX)
Diphenhydramine (BENADRYL, SOMINEX FORMULA)
Fexofenadine (ALLEGRA)

Generic (BRAND NAME)

Hydroxyzine (ATARAX, HY-PAM, VISTARIL)
Ipratropium (ATROVENT)
Loratadine (CLARITIN)
Meclizine (ANTIVERT)
Drugs containing Phenyltoloxamine (NALDECON, TUSSIONEX)
Drugs containing Triprolidine (ACTIFED)

Antiparkinsonians

Benztropine (COGENTIN)
Bromocriptine (PARLODEL)
Levodopa (LARODOPA)
Levodopa and Carbidopa (SINEMET)
Trihexyphenidyl (ARTANE)

Other Drugs

Orphenadrine (NORFLEX, NORGESIC FORTE)
Oxybutynin (DITROPAN)
Tropicamide (MYDRIACYL)

* Many of the drugs mentioned here are also in combination products or in other dosage forms not listed. Check with your doctor or pharmacist to ascertain if any of the drugs you are taking contains any of these drugs.

** Note that many heart drugs contain hydrochlorothiazide. Check with your doctor to see if yours does.

HEAT ILLNESS, *from page 9*
less than one year old; b) persons over 65 years old; c) persons who are less able to care for themselves because of chronic mental illness or dementia of any cause; d) persons with chronic diseases, especially cardiovascular or kidney disease; and e) persons taking any of the drugs listed in the box above reduce the ability to sweat or regulate temperature. If you are taking any of these drugs, it is even more important that you follow the guidelines on pg. 9. These persons at higher risk are more likely to build up body heat, which may lead to one of the following three heat-related conditions.

Heat stroke or collapse is a medical emergency requiring immediate attention by a doctor. The symptoms of heat stroke include: faintness, dizziness, staggering, headache, nausea, loss of consciousness, high body temperature (104°F/40°C or higher), strong rapid pulse, and flushed skin. In severe cases, blood pressure drops as circulation fails.

Because body heat can continue to build up for days after a heat wave ends, doctors and others who care for the elderly or the ill should monitor body temperatures closely during and after periods of extreme heat.

Heat syncope is marked by dizziness, fatigue, and sudden faintness after exercising in the heat. In contrast to heat stroke, the victim of heat syncope recovers when removed from direct exposure to the heat.

The symptoms of heat syncope are: cool, sweaty, pale skin; weak pulse; falling blood pressure; and faintness. Heat syncope results from sudden exercise or a lack of acclimatization to the hot weather. Treatment involves resting (it is best to lie or sit down with the head lowered), cooling off, and drinking extra liquids.

The most common form of illness due to hot weather is *heat exhaustion*. This condition takes longer to develop and results from a loss of body fluids and salt. The symptoms of heat exhaustion are: thirst; fatigue; giddiness; elevated body temperature; and in severe instances, delirium. When both body water and salt are depleted, muscle cramps may also be present.

Heat exhaustion is treated by resting in bed away from the heat and restoring body water by drinking cool fluids, taking alcohol sponge baths (on the advice of a physician), or applying wet towels to the body.

OUTRAGE, *from page 12*
ous enough to require one of these interventions. One-half of the withdrawals occurred within two years following the drug's approval and one-half of the black box warnings and withdrawals happened within seven years after a drug's introduction.

The most common reasons for black box warnings were cardiovascular toxicity 17 times, liver toxicity 15 times, blood (bone marrow) toxicity 13 times, and risk in pregnancy 9 times. Other adverse reactions accounted for the other 36 percent of black box actions.

An editorial in the same issue of *JAMA*, written by physician officials from the FDA's Center for Drug Evaluation and Research (CDER), accompanied the study. CDER is the part of the agency responsible for reviewing new drug applications. The editorial attempted to assure readers that the safety of new drugs is getting better: "Recent changes in drug development should help protect against some of the most important past causes of drug withdrawal," the editorial said, adding that "...there is reason to believe that some of the more common causes of significant toxicity will be less likely in the future."

A look at the most recent history of black box warnings and drug withdrawals tells a story much different than the FDA's editorial message, however. Since the cut-off date for drugs included in the *JAMA* study an additional three new drugs have come off the market for safety reasons. These are the cholesterol-lowering drug cerivastatin (BAYCOL), rapacuronium (RAPLON) a muscle relaxant used in surgery, and alosetron (LOTRONEX) a drug that was used for treating the symptoms of irritable bowel syndrome in women. In the cases of rapacuronium and alosetron the life-threatening adverse reactions that led to their removal were seen in clinical trials conducted before these drugs were approved. Cerivastatin's professional product label warning about a life-threatening muscle damage was strengthened four months before it was withdrawn from the market for this reason. It should have come off the market at the first sign of a problem because five other cholesterol lowering drugs in the same family already existed and are safer.

The FDA editorial specifically addressed two of the most common types of toxicity that can result in black box warnings or drug withdrawals: QT prolongation (a change in the heart's electrical conduction that can lead to fatal heart rhythm disturbances, and liver toxicity.

Unfortunately, drugs that were known to cause QT prolongation are continuing to be approved without black box warnings. The new antipsychotic drug ziprasidone (GEODON) was approved in February 2001. This drug was known to cause QT prolongation and was less effective than a much older antipsychotic drug. We listed ziprasidone as a *Do Not Use* drug in the June 2001 issue of *Worst Pills, Best Pills News*. In February 2002, the drug's existing warning about QT prolongation was strengthened, but a black box was not required.

The three newer fluoroquinolone antibiotics—gatifloxacin (TEQUIN), moxifloxacin (AVELOX), and sparfloxacin (ZAGAM)—were all known to cause QT prolongation before approval. All have warnings about this condition, but none have a black box.

We listed moxifloxacin and sparfloxacin as *Do Not Use* drugs in the February 2000 *Worst Pills, Best Pills News*. There are safer, equally or more effective antibiotics available for the same uses as these three fluoroquinolones.

Arsenic trioxide (TRISENOX), an injectable drug used to treat a type of leukemia, was approved in September 2000 with a black box warning about QT prolongation.

The following drugs have received black box warnings about QT prolongation since the 1999 cut off date for the *JAMA* study: droperidol (INAPSINE); itraconazole (SPORANOX); levomethadyl (ORLAAM); mesoridazine (SERENTIL); thioridazine (MELLARIL)

If the FDA has a policy about QT prolongation warnings, it is dangerously inconsistent.

An example of a new drug with known liver toxicity before its approval is the arthritis drug leflunomide (ARAVA) that was approved in September 1998. The drug also appears to be less effective than other drugs for the treatment of rheumatoid arthritis.

Two liver toxic drugs that were removed from the market in other countries remain available in the U.S. These are the fluoroquinolone antibiotic trovafloxacin (TROVAN) and tolcapone (TASMAR) a drug used in Parkinson's disease. There was simply no reason to ever approve trovafloxacin, since this drug's liver toxicity was known before its approval. The current warning is buried in the labeling rather than being inside a highly visible black box.

Whatever the FDA's policy is on liver toxic drugs, it appears to be as muddled as its QT prolongation policy.

The FDA editorial appears incoherent and far from reassuring about improvements in the safety of newly approved drugs. It implies that "recent changes" in drug development coupled with black box and other warnings in the labeling will reduce the likelihood of significant toxicity. This is plainly not true, because research has shown that the addition of warnings, even the black box kind, usually does not reduce the unsafe prescribing of drugs. Some of this research has been published by physicians and pharmacists from the FDA. In the October 2001 issue of *Worst Pills, Best Pills News* we reviewed the ineffectiveness of labeling changes to alter prescribing habits.

What You Can Do

Follow the Health Research Group's new seven-year rule.

You should wait at least seven years from the date of release to take any new drug unless it is one of those rare "therapeutic advances" that offers you a documented therapeutic advantage over older, proven drugs. New drugs are tested in a relatively small number of people before being released, and serious adverse effects or life threatening drug interactions may not be detected until the new drug has been taken by hundreds of thousands of people. A number of new drugs have been withdrawn within their first seven years after release. Also, black box warnings about serious new adverse reaction have been added to the labeling of a number of drugs, or new drug interactions have been detected, often within the first seven years after a drug's release.

New Study: Wait Seven Years to Use New Drugs

A study published in the May 1, 2002 *Journal of the American Medical Association (JAMA)* has resulted in a major change in the Health Research Group's drug safety policy. The study, in association with physicians from the Harvard Medical School, examined the frequency and timing of the identification of new adverse drug reactions resulting in the addition of a black box warning in the drug's professional product labeling or its outright removal from the market.

Three of the authors have close identification with the Health Research Group—its director, Sidney M. Wolfe, and former HRG staffers Drs. Steffi Woolhandler and David Himmelstein. The other co-authors are affiliated with the Harvard Medical School.

As a result of this study, we have decided to modify our long-standing recommendation that you wait at least five years after a new drug is approved to use it, unless (and this is a rare exception) the new product is a drug that offers a documented therapeutic advantage over older drugs that are already available.

For safety's sake, we now recommend at least a seven year precautionary wait, since, by seven years after approval about half of the black box warnings or withdrawals will have occurred.

The study analyzed the appearance of new black box warnings in the *Physicians' Desk Reference* from 1975 through 1999. Also, the frequency and timing of drug withdrawals over this period was calculated.

A black box warning is the strongest type of warning that the Food and Drug Administration (FDA) can require. It is generally reserved for adverse reactions that may lead to death or serious injury. Black box warnings ordinarily are based on events occurring in humans but may be required when serious animal toxicity has been seen and no information is available in humans.

Between 1975 and 1999 the FDA approved 548 new drugs never before marketed in the U.S. A new black box warning was required for 56 (10.2 percent) of these drugs. Forty-five (8.2 percent) needed more than one such warning. And during this time 16 drugs (2.9 percent) were withdrawn from the market.

The estimated probability of a new drug requiring a new black box warning or being withdrawn from the market between 1975 and 1999 was calculated to be 20 percent. In other words, the chance was one in five that a newly approved drug during this period would turn out to have a safety problem seri-