PUBLIC CITIZEN HEALTH RESEARCH GROUP

Health Letter

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Epilepsy

More than two million Americans—half of them children—have it. Yet some are being treated for it who in fact don't have it; others have it, but don't realize it and still others who have it are getting inappropriate treatment.

What we are talking about here is epilepsy, a family of disorders that have in common recurrent electrical disturbances in the brain. Contrary to popular opinion, those disturbances may or may not be accompanied by convulsions. Convulsions are, to be sure, a feature of grand mal epilepsy—which many doctors now call generalized tonic clonic epilepsy. But petit mal seizures—also called absence seizures—are characterized by brief periods of staring and being "out of it," rather than convulsions. And there are also other types of epilepsy in which convulsions do not occur.

Indeed, convulsions are not necessarily an indication of epilepsy. For example, it is not unusual for an infant or young child to have a convulsion in connection with a high fever. Yet doctors sometimes assume that once a youngster has a convulsion, he or she will develop epilepsy, and so is likely to have more. The fact is that most children who have a febrile seizure do not develop epilepsy and that when, as often happens, anticonvulsant medications are given to them on an ongoing basis, it does them no good and instead only exposes them to the adverse effects of the drugs.

In addition, there are medical conditions other than a high fever that can cause convulsions. Among them are heat exhaustion and some forms of poisoning.

The other side of the coin is that some cases of epilepsy go unrecognized. Children who frequently day dream in school, for instance, may simply be daydreaming. But frequent daydreaming in school age children also can be a hidden sign of absence seizures as can apparent confusion in such a child and sudden falls. Similarly, undiagnosed absence seizures in teenagers can be mistaken for drug or alcohol abuse. And while most epilepsy begins before age 18, the disorder can strike at any time of life. In fact, though fewer people are now having strokes—a major cause of brain damage and seizures—there is evidence to suggest that as more people are living into their 70s and beyond, there is an increase of epilepsy among the elderly.

For instance, a study of elderly nursing home patients by Dr. W. Alan Hauser, Professor of Neurology at Columbia University's College of Physicians and Surgeons found that almost 4 percent had recurrent seizures, a rate four times greater than that of the public at large.

Also at high risk of epilepsy are people of all ages who travel in cars and trucks without fastening their seat belts or ride motorcycles without wearing protective helmets. The head injuries sustained in traffic accidents are a major cause of epilepsy, particularly in young and middle-aged adults.

As for the inappropriate treatment of epilepsy, consider the story of Richard Smith, now 36, who had his first grand mal seizure when he was 14. At the time of the diagnosis, Smith's doctor prescribed Dilantin and phenobarbital. But because these drugs failed to control his seizures, more and more were added so that by 1962 he was taking as many as five drugs at a time.

For the next 19 years, Smith not only continued to have seizures, but was so incapacitated mentally and physically that he had to be led to the table and

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spent virtually all of his time sitting around the house. Had, in fact, his neurologist not become concerned about his white blood cell count and sent him to be evaluated at the Bowman-Gray Medical School in Winston-Salem, N.C., chances are that he would still be living the life of an invalid.

That was in September 1981. Bowman-Gray is one of about a dozen medical centers in the nation that has a comprehensive epilepsy program. There, sophisticated monitoring of the electrical activity in Smith's brain disclosed that, besides the grand mal seizures he had been prone to, he was having as many as 75 staring spells—i.e., petit mal seizures—a day.

He was immediately taken off all his previous medications and after more tests were performed was given a drug—valproic acid—he had not taken before. He has not had a seizure—either grand mal or petit mal—since.

More importantly, Smith's I.Q. has improved by 30 points and he is off the welfare rolls. In fact, he has been promoted at the landscaping firm where he works, has a second job on Saturdays, and plans to be married.

Smith's story is recounted here because it is a classic case of what the Epilepsy Foundation of America and its medical advisors—one of whom is Dr. J. Kiffin Penry, director of the epilepsy center at Bowman-Gray—believe is a common situation that deprives thousands of epilepsy patients and their family of better health.

For one thing, they say, periodic reevaluation of all epilepsy patients by modern diagnostic methods is vital both for people who, like Smith, have been struggling with epilepsy for years and still are having seizures and for those diagnosed more recently.

Difficult cases, for example, may benefit from closed circuit television monitoring in which half of the screen shows and records a close-up of the patient's face and body movements while the other half continuously displays and records the electrical activity in the patient's brain. Performed over several hours or even overnight, the monitoring enables a neurologist to see exactly what happens to the body as brain wave patterns change. This, in turn, betters an understanding of the nature of a patient's seizures and suggests what drugs—or in some instances surgery—are most likely to bring them under control.

As important as an accurate diagnosis, according to the Foundation, is a long term treatment plan for every patient that includes possible alternatives for therapy if the original therapy fails and also provides for regular review of the quality of the patient's life. Thus, for example, a physician should make an effort to find out if a child with epilepsy is doing poorly at school or is being so overprotected at home that the youngster is immature and has few friends. Because epilepsy is a chronic illness which the patient must learn to cope with, prompt remedial measures for such problems are essential if the boy or girl is to grow up to be an independently functioning adult.

Beyond that, says the Foundation, there are now more than a dozen antiepilepsy drugs that have been approved by the Food and Drug Administration. Yet some doctors continue either to rely almost exclusively on phenobarbital and Dilantin (generic name phenytoin)—which have been around since 1912 and 1938, respectively—or to use one or both of them in combination with other drugs.

Such practices, according to Dr. Penny, reflect the failure of as many as half of the nation's neurologists to take advantage of recent knowledge which has more precisely defined different types of seizures and made it possible, in most cases, to begin the patient's treatment with the drug that is most likely to help.

Moreover, although some patients do require treatment with more than one drug, the majority of them are better off on the single medication that is best for them because they then are exposed to fewer drug-induced adverse effects.

Dr. Eileen Vining is a pediatric neurologist at the Johns Hopkins School of Medicine and also a medical advisor to the Epilepsy Foundation. While she says there are epilepsy patients who need phenobarbital and/or Dilantin, because of their adverse effects, she always considers alternatives.

More precisely, phenobarbital has the disadvantage of dulling the senses, interfering with a patient's ability to learn and to be alert. Indeed, some patients on phenobarbital are in a perpetual daze. "I've seen people in such a fog on phenobarbital that it takes a while for them to tell their right hand from their left," says Vining. "I'd rather have them have an occasional seizure than be totally wiped out."

As for ongoing use of Dilantin, the Epilepsy Foundation warns that it can have undesirable cosmetic adverse effects such as the growth of unwanted body hair, coarsening of the facial features and swelling of the gums which increases the chances of gum infections which may lead to the loss of teeth. Good oral hygiene helps to minimize the gum problem, but it is not sure-fire. Besides, it is often difficult to get patients, particularly teenagers, to conscientiously thoroughly brush and floss.

"Since we (physicians) now have other choices," says Vining, "we ought to consider them. And if they are still the drugs of choice for a given patient, the very least a doctor can do is to continue to look very closely at whether they are having any of these adverse effects. With Dilantin, for example, the coarsening of the facial features and the swollen gums may reverse if the patient is taken off the drug. But the extent of the reversal varies and in some patients is slight or does not occur at all."

Also important to remember, say Vining and the Foundation, is that though some patients do need several drugs to control their epilepsy, the fewer the better. Thus the physician should keep trying to work toward the goal of prescribing only one.

One of Vining's patients, a Baltimore college student, is a case in point. Because she continues to have both grand mal and petit mal seizures, she is now on two drugs. But in the belief that it may be possible to further reduce the number of her seizures with either a different drug or a different combination of drugs, Vining is continuing to

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Epilepsy: Recognition and First Aid

SEIZURE TYPE	WHAT IT LOOKS LIKE	OFTEN MISTAKEN FOR	WHAT TO DO	WHAT NOT TO DO
CONVULSIVE GENERALIZED TONIC-CLONIC (Also called Grand Mal)	Sudden cry, fall, rigidity, followed by muscle jerks, frothy saliva on lips, shallow breathing or temporarily suspended breathing, bluish skin, possible loss of bladder or bowel control, usually lasts 2-5 minutes. Normal breathing then starts again. There may be some confusion and/or fatigue, followed by return to full consciousness.	Heart attack. Stroke. Unknown but life threatening emergency.	Look for medical identification; protect from nearby hazards; loosen ties or shirt collars; place folded jacket under head. Turn on side to keep airway clear. Reassure when consciousness returns. If single seizure lasted less than 10 minutes, ask if hospital evaluation wanted. If multiple seizures, or if one seizure lasts longer than 10 minutes, take to emergency room.	Don't put any hard implement in the mouth; Don't try to hold tongue. It can't be swallowed; Don't try to give liquids during or just after seizure. Don't use oxygen unless there are symptoms of heart attack. Don't use artificial respiration unless breathing is absent after muscle jerks subside, or unless water has been inhaled; Don't restrain.
NON-CONVULSIVE ABSENCE (Also called Petit Mal)	A blank stare, lasting only a few seconds, most common in children. May be accompanied by rapid blinking, some chewing movements of the mouth. Child having the seizure is unaware of what's going on during the seizure, but quickly returns to full awareness once it has stopped. May result in learning difficulties if not recognized and treated.	Daydreaming. Lack of attention. Deliberate ignoring of adult instructions.	No first aid necessary, but medical evaluation should be recommended.	
SIMPLE PARTIAL (Also called Jacksonian)	Jerking begins in fingers or toes, can't be stopped by patient, but patient stays awake and aware. Jerking may proceed to involve hand, then arm, and sometimes spreads to whole body and becomes a convulsive seizure.	Acting out bizarre behavior.	No first aid necessary unless seizure becomes convulsive, then first aid as above.	
SIMPLE PARTIAL (Also called Sensory)	May not be obvious to onlooker, other than patient's preoccupied or blank expression. Patient experiences a distorted environment. May see or hear things that aren't there, may feel unexplained fear, sadness, anger, or joy. May have nausea, experience odd smells, and have a generally "funny" feeling in the stomach.	Hysteria. Mental illness. Psychosomatic illness. Parapsychological or mystical experience.	No action needed other than reassurance and emotional support.	
COMPLEX PARTIAL (Also called Psychomotor or Temporal Lobe)	Usually starts with blank stare, followed by chewing, followed by random activity. Person appears unaware of surroundings, may seem dazed and mumble. Unresponsive. Actions clumsy, not directed. May pick at clothing, pick up objects, try to take clothes off. May run, appear afraid. May struggle or flail at restraint. Once pattern established, same set of actions usually occur with each seizure. Lasts a few minutes, but post-seizure confusion can last substantially longer. No memory of what happened during seizure period.	Drunkenness. Intoxication on drugs. Mental illness. Indecent exposure. Disorderly conduct. Shoplifting.	Speak calmly and reassuringly to patient and others. Guide gently away from obvious hazards. Stay with person until completely aware of environment. Offer to help getting home.	Don't grab hold unless sudden danger (such as a cliff edge or an approaching car) threatens. Don't try to restrain. Don't shout. Don't expect verbal instructions to be obeyed.
ATONIC SEIZURES (Also called Drop Attacks)	The legs of a child between 2-5 years of age suddenly collapse under him and he falls. After 10 seconds to a minute he recovers, regains consciousness, and can stand and walk again.	Clumsiness. Lack of good walking skills. Normal childhood "stage".	No first aid needed (unless he hurt himself as he fell), but the child should be given a thorough medical evaluation.	
MYOCLONIC SEIZURES	Sudden brief, massive muscle jerks that may involve the whole body or parts of the body. May cause person to spill what they were holding or fall off a chair.	Clumsiness. Poor coordination.	No first aid needed, but should be given a thorough medical evaluation.	
INFANTILE SPASMS	Starts between 3 months and two years. If a child is sitting up, the head will fall forward, and the arms will flex forward. If lying down, the knees will be drawn up, with arms and head flexed forward as if the baby is reaching for support.	Normal movements of the baby, especially if they happen when the baby is lying down.	No first aid, but prompt medical evaluation is needed.	

How You Can Report Adverse Reactions To the Food and Drug Administration

Consumers can play an important public health role by reporting to the Food and Drug Administration (FDA) any adverse experience with drugs and medical devices, including dietary and herbal supplements. This can be done through MedWatch, the FDA's medical products reporting program.

The MedWatch program played major roles in recent decisions to remove the painkilling drug bromfenac (DURACT) from the market following reports of deaths and liver injuries. The FDA also moved to withdraw the blood pressure treatment mibefradil (POSICOR) after learning of drug interactions that led to serious adverse reactions.

The FDA encourages patients or their family members to ask their doctor to make the report because he or she can provide clinical information based on your medical record that can help the FDA to evaluate the report. There may be a variety of reasons that you do not wish to have the form filled out by your doctor or your doctor may choose not to complete the form. Doctors are not required to report adverse events to the FDA.

The FDA emphasizes that it is not necessary to prove that a medical product caused an adverse reaction—a suspected association is sufficient reason to make a report to the agency.

The FDA is particularly interested in suspected adverse events that led to the following outcomes:

- *Death*—If an adverse reaction to a medical product is a suspected cause of a patient's death.

- *Life-threatening hazard*—If the patient was at risk of dying at the time of the adverse reaction or if it is suspected that continued use of a product would cause death. A pacemaker breakdown or the failure of an intravenous (IV) pump that could cause excessive drug dosing are examples.

- *Hospitalization*—If a patient is admitted or has a prolonged hospital stay because of a serious adverse reaction. For example, a serious allergic reaction to a product such as latex.

- *Disability*—If the adverse reaction caused a significant or permanent change in a patient's body function, physical activities, or quality of life. Examples of this type of outcome would be strokes or nervous system disorders brought on by drug treatment.

- *Birth defects, miscarriage, stillbirth, or birth with disease*—If exposure to a medical product before conception or during pregnancy is suspected of causing an adverse outcome in the child such as a malformation in the child caused by the acne drug isotretinoin (ACCUTANE).

- *Needs intervention to avoid permanent damage*—If use of a medical product required medical or surgical treatment to prevent impairment (examples: burns from radiation equipment or breakage of a screw supporting a bone fracture).

The FDA offers several ways for health professionals or consumers to submit MedWatch reports:

- *Online*—Go to the MedWatch Website *at www.fda.gov/medwatch/* and follow the instructions for submitting a report electronically.

- *By mail*—Use the MedWatch form accompanying this article which includes the address.

- *By phone*—The toll free number for reporting to the FDA is 1-800-FDA-1088.

- *By fax*—You can submit a completed form to MedWatch's fax number at 1-800-332-0178.

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change her medication.

"You have to keep very careful records of where you have been, so that you don't end up reinventing the wheel," she says. "And since all medications can have adverse effects, you have to test for and keep track of such things as the patient's white blood cell count and liver function. The point is that all patients who are having drug-induced adverse effects or whose seizures are not well-controlled by their current medication should be reevaluated frequently."

As a matter of fact, says Vining and the Foundation, the same goes for patients—particularly children—whose seizures are well controlled by drugs, even if they do not experience incapacitating adverse effects.

The reason is that medications can sometimes be safely discontinued. Several studies have reported that 70-75 percent of children who remain seizure-free for four years while on medication will then remain seizure-free if it is withdrawn. Indeed, a study published in the *New England Journal of Medicine* found the same to be true for 66 of 88 young patients who, after just two years of drug treatment with no seizures, stopped taking their medications.

Patients with epilepsy and their families often are dissatisfied with the patient's progress, but don't know where to turn for help. The Epilepsy Foundation's advice is to start by frankly discussing the situation with the patient's doctor. Should that be unproductive, it may be time to turn to a support group—many people with epilepsy are enormously lonely and so benefit from sharing experiences from others in the same boat—to a new doctor, or both.

For more information, ask your neurologist about local patient groups.

MEDWATCH

THE FDA MEDICAL PRODUCTS REPORTING PROGRAM

For VOLUNTARY reporting by health professionals of adverse events and product problems

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Form Approved: OMB No. 0910-0291 Expires:12/31/94
See OMB statement on reverse

FDA Use Only

Triage unit sequence #

A. Patient information

1. Patient identifier — In confidence
2. Age at time of event: or Date of birth:
3. Sex — ☐ female ☐ male
4. Weight — ___ lbs or ___ kgs

B. Adverse event or product problem

1. ☐ Adverse event and/or ☐ Product problem (e.g., defects/malfunctions)
2. Outcomes attributed to adverse event (check all that apply)
   - ☐ death ___ (mo/day/yr)
   - ☐ life-threatening
   - ☐ hospitalization – initial or prolonged
   - ☐ disability
   - ☐ congenital anomaly
   - ☐ required intervention to prevent permanent impairment/damage
   - ☐ other:
3. Date of event (mo/day/yr)
4. Date of this report (mo/day/yr)
5. Describe event or problem
6. Relevant tests/laboratory data, including dates
7. Other relevant history, including preexisting medical conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)

C. Suspect medication(s)

1. Name (give labeled strength & mfr/labeler, if known)
   #1
   #2
2. Dose, frequency & route used
   #1
   #2
3. Therapy dates (if unknown, give duration) from/to (or best estimate)
   #1
   #2
4. Diagnosis for use (indication)
   #1
   #2
5. Event abated after use stopped or dose reduced
   #1 ☐ yes ☐ no ☐ doesn't apply
   #2 ☐ yes ☐ no ☐ doesn't apply
6. Lot # (if known)
   #1
   #2
7. Exp. date (if known)
   #1
   #2
8. Event reappeared after reintroduction
   #1 ☐ yes ☐ no ☐ doesn't apply
   #2 ☐ yes ☐ no ☐ doesn't apply
9. NDC # (for product problems only)
   – –
10. Concomitant medical products and therapy dates (exclude treatment of event)

D. Suspect medical device

1. Brand name
2. Type of device
3. Manufacturer name & address
4. Operator of device
   - ☐ health professional
   - ☐ lay user/patient
   - ☐ other:
5. Expiration date (mo/day/yr)
6. model # ___
   catalog # ___
   serial # ___
   lot # ___
   other #
7. If implanted, give date (mo/day/yr)
8. If explanted, give date (mo/day/yr)
9. Device available for evaluation? (Do not send to FDA)
   ☐ yes ☐ no ☐ returned to manufacturer on ___ (mo/day/yr)
10. Concomitant medical products and therapy dates (exclude treatment of event)

E. Reporter (see confidentiality section on back)

1. Name, address & phone #
2. Health professional?
   ☐ yes ☐ no
3. Occupation
4. Also reported to
   - ☐ manufacturer
   - ☐ user facility
   - ☐ distributor
5. If you do NOT want your identity disclosed to the manufacturer, place an " X " in this box. ☐

FDA

Mail to: MEDWATCH
5600 Fishers Lane
Rockville, MD 20852-9787

or FAX to:
1-800-FDA-0178

FDA Form 3500 (6/93)

Submission of a report does not constitute an admission that medical personnel or the product caused or contributed to the event.

ADVICE ABOUT VOLUNTARY REPORTING

Report experiences with:

- medications (drugs or biologics)
- medical devices (including in-vitro diagnostics)
- special nutritional products (dietary supplements, medical foods, infant formulas)
- other products regulated by FDA

Report SERIOUS adverse events. An event is serious when the patient outcome is:

- death
- life-threatening (real risk of dying)
- hospitalization (initial or prolonged)
- disability (significant, persistent or permanent)
- congenital anomaly
- required intervention to prevent permanent impairment or damage

Report even if:

- you're not certain the product caused the event
- you don't have all the details

Report product problems – quality, performance or safety concerns such as:

- suspected contamination
- questionable stability
- defective components
- poor packaging or labeling

How to report:

- just fill in the sections that apply to your report
- use section C for all products except medical devices
- attach additional blank pages if needed
- use a separate form for each patient
- report either to FDA or the manufacturer (or both)

Important numbers:

- 1-800-FDA-0178 to FAX report
- 1-800-FDA-7737 to report by modem
- 1-800-FDA-1088 for more information or to report quality problems
- 1-800-822-7967 for a VAERS form for vaccines

If your report involves a serious adverse event with a device and it occurred in a facility outside a doctor's office, that facility may be legally required to report to FDA and/or the manufacturer. Please notify the person in that facility who would handle such reporting.

Confidentiality: The patient's identity is held in strict confidence by FDA and protected to the fullest extent of the law. The reporter's identity may be shared with the manufacturer unless requested otherwise. However, FDA will not disclose the reporter's identity in response to a request from the public, pursuant to the Freedom of Information Act.

FDA Form 3500-back **Please Use Address Provided Below – Just Fold In Thirds, Tape and Mail**

Department of Health and Human Services
Public Health Service
Food and Drug Administration
Rockville, MD 20857

Official Business
Penalty for Private Use $300

NO POSTAGE NECESSARY IF MAILED IN THE UNITED STATES OR APO/FPO

BUSINESS REPLY MAIL
FIRST CLASS MAIL PERMIT NO. 946 ROCKVILLE, MD

POSTAGE WILL BE PAID BY FOOD AND DRUG ADMINISTRATION

MEDWATCH
The FDA Medical Products Reporting Program
Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20852-9787

Product Recalls

August 10—September 6, 2000

DRUGS & DIETARY SUPPLEMENTS

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.

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.*

Name of Drug or Supplement; Class of Recall; Problem	*Lot #; Quantity and Distribution; Manufacturer*
Cortef(r) Oral Suspension (hydrocortisone cypionate) 10 mg/5mL, in 4 fluid ounce units; Class II; Product may not always be effective for the treatment of congenital adrenal hyperplasia	Lot numbers: 62CAT, 63CAT, 64CAT, 23CRW, 24CRW, 04CJX, 05CJX, 19DAJ, 98DXA and 91DTM; 144,357 bottles distributed nationwide and internationally; Pharmacia Corporation, Kalamazoo, Michigan
Marquee Brand Menthol Sore Throat Spray (Phenol 1.4%), OTC, in 6-fluid ounce bottles; Class III; Product is missing the tamper resistant protection	Lot #9JV0178 EXP 8/01; 10,452 bottles distributed nationwide; Perrigo Company, Allegan, Michigan
New Life Colostrum(tm) Cream (unscented moisturizing/repair skin cream), in 2-ounce jars; Class II; Microbial contamination—Pseudomonas putida and Tsukamurella paurometabolum	Lot #A2106990 EXP 1/01; Undetermined quantity distributed nationwide, Puerto Rico and Canada; Vege-Kurl, Glendale, California. Recalled by Symbiotics, Inc., Sedona, Arizona
Orasone(tm) 5 Tablets (Prednisone Tablets), 5 mg, in bottles of 1,000, Rx anti-inflammatory agent; Class III; Dissolution failure (18 month stability)	Lot #89335; 3,765 bottles distributed nationwide; Solvay Pharmaceuticals, Inc., Baudette, Minnesota. Recalled by Solvay Pharmaceuticals, Inc., Marietta, Georgia

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 Drug or Supplement; Class of Recall; Problem	*Lot #; Quantity and Distribution; Manufacturer*
Diode-pumped Solid State Micro Lasers, for various uses including academia and industry applications; Class II; The laser product failed to comply with the Federal laser product performance standard in that products lack: beam attenuators, key controls, emission indicators, remote interlock connectors and labeling	Model numbers 43XX, 45XX, 46XX; 40 units were distributed nationwide; JDS Uniphase, Manteca, California
Laser Pointers, wide range in academic, industry and consumer use; Class II; Noncompliance with performance with the Federal laser product performance standard in that products lack beam attenuators, emission indicators, remote interlock connectors, and required labeling	Polaris Model DPGL Series 1000, 2000, 3000, 3000F and Model DPIR Series 1000 and 2000;1,280 units distributed nationwide; Casix, Inc., Chatsworth, California

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 *http://www.cpsc.gov*.

Name of Product; Problem	*Lot #; Quantity and Distribution; Manufacturer*
All-Terrain Vehicles; Throttles on these ATVs can stick, preventing the ATV from slowing down when released. This can cause the vehicle to lose control and crash, resulting in severe injury or death	Some 1999 and 2000 Scrambler, Sport, and Xplorer 400 models. Polaris dealers will help consumers determine if their ATV is part of this recall; 13,600 sold nationwide from December 1998 through July 2000; Polaris Industries Inc., Minneapolis, Minnesota (800) POLARIS www.polarisindustries.com
Bassinets. Recall to Repair; Infants can become entrapped in an opening between the bassinet's side and mattress platform and suffocate. Additionally, fabric can separate from the metal frame. Infants can be injured when they scrape against or become caught in the frame	"Le Cradle Bassinette;" 46,000 sold nationwide from January 1989 through May 2000; Kids Line Inc., Los Angeles, California (866) LECRADL (532-7235)
Bicycle Indoor Training Stands; Flywheels, which are red or blue can fracture in use. Metal pieces of broken flywheels can hit riders or bystanders, causing cuts and bruises	Minoura, Schwinn, Performance or Univega brand stands with painted red or blue exposed flywheels; 29,500 sold nationwide from January 1989 through December 1994; Minoura Company Ltd., Japan, and Minoura North America, Fremont, California (800) 601-9592 http://www.minoura.co.jp/voluntary_recall.htm
Busy Poppin' Pals Toys; Small springs inside the toy can break loose, posing a choking and laceration hazard to young children; Busy Poppin' Pals 13 inch long white plastic toy with blue, yellow and red buttons, levers and knobs of various shapes that, when activated, make animal characters pop up from under the toy's base	Model # 5415; 420,000 sold nationwide from January 1996 through August 2000; Playskool, Pawtucket, Rhode Island (877) 518-9743 www.hasbro.com/consumer/safety.html
Children's Riding Vehicles; Vehicles' battery charger or wires can overheat, presenting fire and injury hazards to children	Model names: Prowler, Dodge Ram, Corvette, SPX Motorcycle and Honda, powered by one 6-volt battery and manufactured before April 2000; 294,000 sold nationwide from July 1998 through April 2000 Tek Nek Toys, Mokena, Illinois (877) 446-7719
Children's Riding Vehicles. Recall to Repair; Vehicles' battery chargers can overheat, presenting fire and injury hazards to children	Model names: Go-Kart, Beach Splash, Sun Dream, Trail Tracker, Rescue Patrol, and Chevy Z-71 Pick-Up Truck powered by two 6-volt batteries, and were manufactured from July 1995 to December 1996; 113,000 sold nationwide from July 1995 through December 1997; Empire Industries, Tarboro, North Carolina (800) 872-1869
Children's Riding Vehicles. Recall to Repair; Foot pedals, which activate the ride-ons, can stick in the "on" position	Power Wheels Harley-Davidson model numbers 74290, 74293 (with a red body) and 74298 (with a black body); 218,000 sold nationwide from September 1999 through August 2000; Fisher-Price, East Aurora, New York (888) 289-9292 http://www.fisher-price.com/us/help/harley.asp
Gas Grills; Grills can be difficult or impossible to turn off and the temperature control can malfunction. This poses fire, burn, and explosion hazards to consumers	Suitcase Grill Model #15-3597291; 950 sold nationwide from March through July 2000; Williams-Sonoma Inc., San Francisco, California (888) 779-5173
Gel Pens; Because these pens contain an extra spring, the end caps can shoot off with great force, posing a risk of eye and facial injuries	Included with Icee Black notebooks and Icee Black notepads; 7,400 sold nationwide from June through July 2000; Colorbök, Dexter, Michigan (800) 366-4660

CONSUMER PRODUCTS *cont.*

Name of Product; Problem	*Lot #; Quantity and Distribution; Manufacturer*
Go-Karts. Recall to Repair; Karts have guards designed to help prevent entanglements, but riders' long hair or loose clothing still can become entangled in partially exposed rotating components behind the drivers' seats, causing death or serious injury	First group have serial numbers lower than 1757022. Second group have serial numbers within ranges: 1757022 through 1855821, and 3000010 through 3050632; 91,000 sold under Manco, Phoenix, Fox, Rattler and Coyote labels nationwide from January 1983 through July 2000; Manco Products Inc., Fort Wayne, Indiana (800) 293-0795 http://www.mancoprod.com/recall.htm
Inflatable Playrings for Babies; Soft surface covers the baby's nose and mouth, restricting airflow, and posing the risk of suffocation	Used as an activity center and looks like a pool float; 18,000 sold nationwide at Walmart stores, and One Step Ahead mail-order company from July 1998 though April 2000; Kinderkids™ Lawrence, Kansas (888) 433-6251
Nightshirts (Girl's); Fail to meet federal children's sleepwear flammability standards, could ignite easily and present a serious risk of burn injuries; Long sleeved with a pattern of brown bears wearing pink pajamas and the words "p.j. bear" printed on a white background	Identification code "GPU CF79761" and "Carter's" are printed on a label sewn into the collar; 1,000 sold nationwide from May through August 2000; The William Carter Co. (Carter's), Morrow, Georgia (888) 339-2129 www.carters.com/recall.html
Propane Cylinders; Cylinders can have missing or damaged internal seals in the cylinder valves	Sleeve over the tank has writing "Blue Rhino" and a drawing of a blue rhinoceros. Cylinders have either three stars arranged in a triangular shape under the top knob of the valve or the writing "B-75-3" on the side of the valve; 4,700 sold in Pennsylvania, New Jersey, Maryland, Delaware, Virginia, West Virginia, Florida and Mississippi from May through July 2000; R4 Technical Center—North Carolina LLC, of Hamptonville, North Carolina (866) 802-4492 or Blue Rhino (800) 258-7466
Shirts and Rompers; Buttons can come off, posing a small parts choking hazard to young children	Boys baseball shirts and one-piece rompers sizes 3 to 36 months; 120,000 sold nationwide from January through July 2000; The Children's Place, Secaucus, New Jersey (800) 839-3144
Starting Fluid (lubricant to aid starting gas and diesel engines); Cans can leak as a result of internal to external corrosion. Fluid is extremely flammable, posing a fire hazard	113,000 cans sold nationwide from November 1999 through August 2000 under Penray, Super-X and Service Pro brand names in 10.1 ounce cans. Number printed on the dome of the can ranges from 9305 through 9365; Penray Companies Inc., Wheeling, Illinois (800) 323-6329
Swings; Children can maneuver out of the restraints and fall out of the swings, resulting in serious injuries	Lift 'n Lock outdoor swing with plastic "T"-shaped restraint shield to hold children (ages 9 months to 3 years) model numbers 2092, 75960, 75970, 75973 or 75980; 2.5 million sold nationwide from January 1991 through August 2000; Fisher-Price, East Aurora, New York (800) 343-1502 www.fisher-price.com
Swivel Rocker; The base of the chair can crack, causing the person seated in the chair to fall.	Echo swivel rocker chairs model # 189930 and model # 199930; 1,440 sold nationwide from January through May 2000; Tropitone Furniture Co., Irvine, California (800) 654-7000
Tangled Treeples Toys Included in Kids Meal; Bottom of container can fit over a child's nose and mouth, which could pose a suffocation hazard to children under 3 years of age	The toy is a green plastic container with small, blue plastic animal figures inside; 425,000 included with Kids Meals at KFC restaurants nationwide from June through July 2000; KFC Corporation, Louisville, Kentucky (800) CALL-KFC http://www.kfc.com/SAFETY.htm

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unsubstantiated advice.

Clerks in 36 of the 40 stores recommended 38 different products for breast cancer. The most popular single product was shark cartilage and oil, recommended by 17 stores. The frequent recommendation of shark cartilage speaks volumes about the quackery that continues to take place in health food stores.

Shark cartilage producers Lane Labs-USA, Inc. and Cartilage Consultants, Inc. agreed on June 29, 2000, to settle Federal Trade Commission (FTC) charges that they made unsubstantiated claims about the efficacy of two products—Benefin and Skinanswer—in the prevention, treatment and cure of cancer. The FTC asserted that in addition to the unsubstantiated efficacy claims, the companies falsely represented that clinical studies have shown that Benefin and Skinanswer are effective in preventing, treating, and curing cancer, and falsely represented that the Food and Drug Administration (FDA) has evaluated the effectiveness of Benefin. In separate settlements, both companies are prohibited from making unsubstantiated health-related claims about any food, drug or dietary supplement. In addition, the proposed settlement with Lane Labs and its president Andrew J. Lane included a $1,000,000 judgment. This penalty is excessively soft. It is too bad that the FTC cannot jail Mr. Lane.

Other frequent recommendations by clerks dealt with plant products, particularly those that could be taken in tea form, such as essiac and wheatgrass. Dietary supplements were also suggested by a number of stores, with coenzyme Q10 and vitamin C being the most frequent recommendations.

A very small fraction of health food store clerks were reluctant to provide any information to the University of Hawaii researcher. Clerks in four stores did not make any product recommendations, whereas in 36 stores, one or more products were suggested.

Clerks in eight stores suggested to the researcher that her mother participate in a planned program (usually provided by the store), such as consultation with a store specialist, a personalized program of products, or diagnostic "tests." These tests included such preposterous practices as muscle testing. In this scam the subject holds a tube of supplements, with the expectation that their muscles will "give way" when holding the tube with the supplement that the individual is deficient in. Other outlandish tests are iridology, using a flashlight with a scope to examine the irises of the eyes for parasites in the glands and organs and blood analysis which involves testing the blood for "parasites and crystals."

Clerks in nine of the stores (23 percent) suggested complementary/alternative medicine practitioners, usually naturopaths and acupuncturists for treating breast cancer.

Clerks said that some products were "immune-boosters," for example, shark cartilage, maitake mushroom, coenzyme Q10, vitamins, Astragulus, chlorophyll, garlic, and una de gato. Others claimed that some products worked by being "cleansing," and others by bringing the body back into "balance." One store provided a pamphlet about the importance of the "cleansing principle," with a list of the "signs and symptoms of toxicity," such as "circulatory deficits," "high blood fats," and "fatigue." In one case, essiac herbal tea was recommended because it is "a gentle but deep cleanser." Similarly, one store manager explained that the red clover (*Trifolium pratense*) "cleansed the blood" and that cancer was "primarily a blood disease." A clerk stated that a chlorophyll product "cleanses" and "balances." One clerk asserted that fresh-water algae chlorophyll balances the "acidic bodies" typical of cancer patients by making the body alkaline. Chlorophyll also cleanses the body by "stimulating bowel movement, aiding in the discharge of toxins from the liver and kidneys," the researcher was told.

A list of the 38 untested, unproven, and possibly dangerous products recommended by the health food store clerks can be found on page 11.

Patients with a diagnosis of cancer

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CONSUMER PRODUCTS *cont.*

Name of Product; Problem	*Lot #; Quantity and Distribution; Manufacturer*
Toys Included with Kids Meals; Bottom of container can fit over a child's nose and mouth, which could pose a suffocation hazard to children under 3 years of age; Plastic, barrel-shaped container with small, plastic tomato and ravioli figures inside	310,000 offered with kids meals sold at Fazoli's restaurants nationwide from January through August 2000; Fazoli's Management Inc., Lexington, Kentucky (877) 401-7408 www.fazolis.com/recall.html
Walkers (three-sided push toy); Young children leaning forward on the front of the toys can tip them over and fall. Also, the windshield wipers on some of the toys, which stick out, can injure young children when they fall	Get Up & Go Walkers; 246,000 sold nationwide from July 1997 through August 2000; Fisher-Price, East Aurora, New York (800) 343-1502 www.fisher-price.com
Weather Radios; Radio can fail to decode certain signals broadcast by the National Weather Service or can provide incorrect warnings of severe weather that puts lives and property at risk	Model number WR-122 printed on the bottom. Writing on the radio reads "NOAA Weather Radio" and "OREGON SCIENTIFIC;" 10,000 sold nationwide from December 1999 through July 2000; Oregon Scientific Inc., Tualatin, Oregon (800) 869-7779 www.websitetoday.net/osi

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have a right to decide what level of risk they are willing to accept in the treatment of their disease. We feel strongly that fully informed cancer patients should have access to experimental treatments before these receive formal Food and Drug Administration (FDA) approval if they and their doctors decide there is a sound basis for thinking that an experimental treatment may slow the progress of the disease or improve quality of life. In fact, the FDA has had a long-standing policy of expediting access to experimental treatments for patients with serious and life-threatening illnesses.

The agency now operates the FDA Oncology Tools web site at: www.fda.gov/cder/cancer. The Oncology Tools page was developed by the FDA's Division of Oncology Drug Products. The new web site will make it easier for patients to obtain reliable information about different types of cancer and treatments, as well as clinical trials and patient support groups.

Cancer is a frightening disease, making some patients exceptionally vulnerable to swindlers selling cures. We can think of little that is lower than health food store charlatans selling false and usually expensive hope, in the form of dietary supplements and herbs, to cancer patients and their families.

What You Can Do

You should not, and cannot, rely on the advice of a health food store clerk for health information.

Untested And Unproven Products Recommended For Metastatic Breast Cancer By Health Food Store Clerks

	Number of Stores
Herbs	
Agaricus mushroom	1
Butterbur	1
Chinese herbal combination product	1
Chlorella	1
Chlorophyll	2
Essiac combination product	8
Flax seed oil	3
Garlic	2
Huang chi (*Astragalus*)	2
Kombucha mushroom	1
Maitake mushroom	7
Mistletoe	1
Mushroom essence	1
Pau d'arco	3
Pine bark extract	3
Red clover	2
Seaweed	1
Una de gato	2
Wheatgrass	3
Nutritional and Food Supplements	
Antioxidants	1
beta-carotene	1
Coenzyme Q10	5
DHEA	1
Germanium	4
IP-6 (vitamin B derivative)	4
Multivitamins	3
Selenium	2
Vitamins A, C, E	3, 5, 2
Biological Products	
Bee propolis	1
Fish oils (omega 3,6)	1
Natural progesterone	1
Pancreatic enzyme	2
Parasite-killing agent	2
Shark liver oil	2
Shark cartilage	17
Thymus extract	1

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Victimizing the Vulnerable

Health Food Store Recommendations For Breast Cancer Patients

Researchers from the Cancer Research Center of Hawaii, part of the University of Hawaii, surveyed the recommendations for breast cancer made by clerks working in health food stores on the island of Oahu. The results of the survey were published in the August 2000 issue of *Archives of Family Medicine*. The survey was conducted in 40 stores between April and August 1998.

One of the researchers represented herself as the daughter of an advanced breast cancer patient with bone metastases and told the health food store clerk that she was looking for cancer products for her mother. She said her mother had asked her to find out what was available because it was hard for the mother to talk about her disease in public. The "daughter" indicated that this was the first store she had visited and that she was there just to gather and record information, not to purchase anything at that time.

The most popular single product was shark cartilage and oil

The clerks' most common way of providing information was referral to information sources on cancer and alternative medicine. Twenty-one stores (53 percent) directed the researcher to books, articles, and brochures, including promotional material with ingredient lists, physician and patient testimonials about various products' effectiveness, and general advice such as information about blood analysis, and parasite treatment.

The most popular in-store reference or suggested book to purchase was *Prescription for Nutritional Healing*. Five stores kept this publication on hand to be used as a reference by clerks and customers. This book is most notable for its inclusion on the QuackWatch list of Nonrecommended Books because it promotes misinformation, espouses unscientific theories, and/or contains

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