PUBLIC CITIZEN HEALTH RESEARCH GROUP

Health Letter

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Public Citizen Petitions OSHA to Limit Residents' Working Hours

Picture this: It's 6 a.m. and you are in the obstetrics ward of a hospital, expecting to give birth to your first child at any moment. It has been a busy night, and there are several other expectant mothers also needing care. The resident (a young doctor just out of medical school and undergoing further training) who has been taking care of you rushes by. She looks exhausted, as if she had been in the hospital since early yesterday morning—which, in fact, she had. On closer look you notice that she's got an IV stuck in her arm.

It turns out that your resident is 26 weeks pregnant herself, and—just like you—is expecting her first child. It turns out that tonight she is the only doctor caring for the group of patients on your ward. In fact, she's started having contractions herself, but rather than seeking treatment, as any expectant mother would do, she has hooked herself up to an IV so that she can keep working. When she calls her senior physician to tell him what has happened, his response is "Will you be back...tomorrow?"

Seem impossible? Not according to a colleague of that resident, Sonya Rasminsky. Dr. Rasminsky is a second-year resident at Cambridge Hospital, and co-chair of the residents' union known as the Committee of Interns and Residents (CIR).

This story raises at least two questions: First, would you trust your care or the care of your unborn infant to a resident who had been working for 23 (or often as many as 36) hours straight, and who had most likely gotten little or no sleep during that time? Second, would you want your physician to be possibly harming herself in order to be helping you?

In recent years, many studies have supported the common sense notion that it is unsafe to subject patients to sleep-deprived and exhausted residents. Sleep-deprived residents have been shown to perform worse than rested colleagues on tests of memory, concentration, and problem-solving skills. Also, their ability to carry out certain medical procedures is diminished. A recent study demonstrated that staying up for 24 hours straight has an effect on cognitive performance equal to having a 0.1 percent blood alcohol level, a value above many U.S. driving limits. In one study, residents reported that 41 percent of their mistakes were due to fatigue and 31 percent of residents reporting mistakes said that their errors had resulted in the death of a patient.

During their residency training after medical school, residents can regularly work 100-hour weeks–2-1/2 times the normal work week in the U.S. In New York, the only state so far to have attempted regulating resident work hours (a limit of 80 hours per week), the state health department found that in New York City 94 percent of residents were working more than 85 hours per week, and 77 percent of surgical residents were working more than 95. One resident worked a man-killing *136 hours* in a single week.

This archaic system of training comes from a time at the turn of the previous

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century when physicians literally lived in the hospital and hence were literally "residents." But medicine has changed dramatically in the last 100-odd years. Patients are now more acutely ill, and their turnover rate in hospitals is higher. Yet long, exhausting hours for the doctors-in-training still remain as a vestige of the old system.

The medical profession has made some feeble attempts to regulate itself. The Accreditation Council on Graduate Medical Education (ACGME), the organization representing residency programs, has some work-hour guidelines for residents in place. These guidelines, however, are weak, voluntary, and differ for each medical specialty. Many programs have no limit on the length of a shift, and residency directors in general surgery, for example, decide how many hours per week are "appropriate" for their residents. Talk about letting the fox watch the henhouse!

Inspections by the ACGME have found that—just as in New York State—hospitals across the country are in poor compliance with even these weak standards. Although hospitals potentially face the penalty of having their accreditation withdrawn by the ACGME for violating the guidelines, none so far has ever lost accreditation solely for this reason. Furthermore, residents are unlikely to report work-hour violations to the ACGME, as withdrawal of accreditation is hardly an outcome desired by residents who depend on those hospitals for their training.

Most other industrialized nations have already taken active steps to limit residents' work hours, either through national legislation, ministerial directives, or other agreements. Provinces in Australia limit their residents to 75 hours of work per week. The European Union recently voted to phase in a 48-hour work week for residents by the year 2003. The United Kingdom limits its residents to 56 hours per week, and Denmark limits its residents to 45 hours per week.

And yet our own federal government has remained completely silent on this issue—puzzling when you consider that since the early 1900s it has regulated work hours in the transportation industries; ironic when you consider that residents work hours much longer than workers in the transportation industries—but understandable, perhaps, when you consider the power of the medical lobby in Washington. Airline pilots are allowed to fly no longer than 30 hours per week, and truck drivers are limited to 60 hours per week.

On April 30, Public Citizen jumped into the fray. Along with CIR and the American Medical Student Association, we filed a petition with the Occupational Safety and Health Administration (OSHA), the government body responsible for ensuring workplace safety, to put forth regulations limiting the number of hours that medical residents work (http://www.citizen.org/hrg/publications/1570.htm). Together with our cosigners, we asked for the following limits on residents' work hours: (1) a limit of 80 hours of work per week; (2) a limit of 24 consecutive hours per shift; (3) scheduling of on-call shifts only once every three days; (4) 10 hours of rest away from the hospital for residents between shifts; and (5) at least one day off in seven from the hospital.

Whereas previous attempts at resident work-hour reform have focused on harm to patients, we examined effects on the health of residents themselves as a result of their long work hours. From the medical literature, we found that residents experience harm in three areas: automobile accident risk; mental health; and complications during pregnancy.

A study comparing motor vehicle crash rates in residents before and during residency found that residents had almost seven times the likelihood of having an accident due to falling asleep at the wheel compared to the period before their residencies. Three out of five residents had a near-miss accident due to falling asleep. A second study found that 90 percent of the occasions when a resident fell asleep while driving were after an on-call shift lasting at least 24 continuous hours. One doctor commented, "Falling asleep at the wheel post-call is virtually *universal*. I have not found anyone who has not had this problem."

High rates of clinical depression have also been found in medical residents. Thirty-two percent of residents in one hospital reported depressed scores while working in the intensive care unit, a hospital rotation requiring over 100 hours of work per week. Residents working on rotations with fewer hours had lower rates of depressed scores.

Lastly, female residents were found to experience twice the rate of preterm labor requiring serious hospitalization, and twice the rate of preeclampsia or eclampsia (types of pregnancy-induced hypertension which can be fatal if not controlled), compared to the wives of male residents. Moreover, female residents working greater than 100 hours per week during their third trimester of pregnancy were twice as likely to have premature babies as residents working fewer than 100 hours per week.

Anandev Gurjala, a second-year medical student from Northwestern University working with Public Citizen, commented, "The medical profession has proved unable to police itself. Instead, residents are taught to subjugate their own health to their work requirements. No physician would offer such advice to his or her own patients."

Congress has charged OSHA with the responsibility "to send every worker home whole and healthy every day." Based on the latest scientific literature, resident work-hour reform is needed now, for both the safety of patients and the safety of the residents who are treating them.

What You Can Do

Send a letter to OSHA supporting Public Citizen's petition for regulation of resident work hours (send a copy of your letter to us too). If you have been the victim of a fatigue-caused medical error, or know of a resident who has experienced any of the harms described above, please tell OSHA your story. OSHA can be reached at: Acting Assistant Secretary for Occupational Safety and Health, U.S. Department of Labor, Occupational Safety and Health Administration—Room S2315, 200 Constitution Avenue, N.W., Washington, D.C. 20210, Phone: (202) 693-2000, Fax: (202) 693-2107.

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

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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)	Generic (BRAND NAME)	Generic (BRAND NAME)
Heart Drugs	Methyclothiazide (ENDURON)	Chlorpropamide (DIABINESE)
Acebutolol (SECTRAL)	Metolazone (DIULO, ZAROXOLYN)	Glimepiride (AMARYL)
Atenolol (TENORMIN)	Metoprolol (LOPRESSOR)	Glipizide (GLUCOTROL)
Benazepril (LOTENSIN)	Moexipril (UNIVASC)	Glyburide (DIABETA, MICRONASE)
Betaxolol (KERLONE)	Nadolol (CORGARD)	Tolazamide (TOLINASE)
Bisoprolol (ZEBETA)	Nitroglycerin (DEPONIT, MINITRAN, NITRO-BID, NITRODISC, NITRO-DUR, NITROSTAT, TRANSDERM-NITRO)	Tolbutamide (ORINASE)
Bumetanide (BUMEX)		
Captopril (CAPOTEN)		***Antidepressant/Antipsychotics***
Carteolol (CARTROL)		Drugs containing Amitriptyline (ELAVIL, LIMBITROL, TRIAVIL)
Carvedilol (COREG)		
Chlorothiazide (DIURIL)	Penbutolol (LEVATOL)	Amoxapine (ASENDIN)
Disopyramide (NORPACE)	Pindolol (VISKEN)	Bupropion (WELLBUTRIN)
Doxazosin (CARDURA)	Prazosin (MINIPRESS)	Chlorpromazine (THORAZINE)
Enalapril (VASOTEC)	Propranolol (INDERAL)	Desipramine (NORPRAMIN)
Fosinopril (MONOPRIL)	Quinapril (ACCUPRIL)	Doxepin (SINEQUAN)
Furosemide (LASIX)	Ramipril (ALTACE)	Fluphenazine (PROLIXIN)
Hydrochlorothiazide (ESIDRIX, HYDRODIURIL)**	Spironolactone (ALDACTONE)	Haloperidol (HALDOL)
	Terazosin (HYTRIN)	Imipramine (TOFRANIL)
Indapamide (LOZOL)	Timolol (BLOCADREN)	Lithium (ESKALITH, LITHOBID, LITHONATE)
Isosorbide-5-mononitrate (ISMO)	Trandolapril (MAVIK)	
Isosorbide Dinitrate (ISORDIL, SORBITRATE)	Trichlormethiazide (METAHYDRIN, NAQUA)	Maprotiline (LUDIOMIL)
		Nortriptyline (AVENTYL, PAMELOR)
Labetalol (TRANDATE)	***Oral Hypoglycemics***	Olanzapine (ZYPREXA)
Lisinopril (PRINIVIL, ZESTRIL)	Acetohexamide (DYMELOR)	

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

Generic (BRAND NAME)	Generic (BRAND NAME)	Generic (BRAND NAME)
Prochlorperazine (COMPAZINE)	Drugs containing Azatadine (TRINALIN)	Drugs containing Terfenadine (SELDANE, SELDANE-D)
Promethazine (PHENERGAN)	Drugs containing Brompheniramine (DIMETAPP)	Drugs containing Triprolidine (ACTIFED)
Risperidone (RISPERDAL)	Drugs containing Chlorpheniramine (ALERMINE, CHLOR-TRIMETON, NALDECON, DECONAMINE, ORNADE)	***Antiparkinsonians***
Thioridazine (MELLARIL)	Drugs containing Clemastine (TAVIST, TAVIST-1, TAVIST-D)	Benztropine (COGENTIN)
Thiothixene (NAVANE)	Cyproheptadine (PERIACTIN)	Bromocriptine (PARLODEL)
Trazodone (DESYREL)	Diphenhydramine (BENADRYL, SOMINEX FORMULA)	Levodopa (LARODOPA)
Trifluoperazine (STELAZINE)	Fexofenadine (ALLEGRA)	Levodopa and Carbidopa (SINEMET)
Ziprasidone (GEODON)	Hydroxyzine (ATARAX, HY-PAM, VISTARIL)	Trihexyphenidyl (ARTANE)
Anticholinergics/Belladonna Alkaloids	Ipratropium (ATROVENT)	**Other Drugs**
Drugs containing Atropine (DONNATAL, LOMOTIL)	Loratadine (CLARITIN)	Orphenadrine (NORFLEX, NORGESIC FORTE)
Drugs containing Clidinium (LIBRAX)	Meclizine (ANTIVERT)	Oxybutynin (DITROPAN)
Dicyclomine (BENTYL)	Drugs containing Phenyltoloxamine (NALDECON, TUSSIONEX)	Tropicamide (MYDRIACYL)
Drugs containing Hyoscyamine (URISED)		
Loperamide (IMODIUM)		
Trimethobenzamide (TIGAN)		
Antihistamines		
Astemizole (HISMANAL)		

* 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 3*

observation by others for early signs of heat illness. The high-risk groups are: a) infants 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 on pg. 3 and 4 that 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 below. 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.

Product Recalls

April 11—May 11, 2001

DRUGS & DIETARY SUPPLEMENTS

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

Class I Recalls

Class I recalls of Chinese Herbs that contain aristolochic acid which is a potent carcinogen and nephrotoxin (kidney toxin):

Mayway Corp., Oakland, California has recalled 48 1 lb. bags and 15 3.5 oz. bottles of all codes of these products (distributed nationwide)

- Temple of Heaven Brand Chinese Herbs, Top Grade, Radix Aristolochiae, Net Wt. 16 oz. (manufactured by Sam Luen Co., Hong Kong)
- Plum Flower Brand, Sulphur Free—Chlorine Free—Aluminum Phosphate Free, Ma Dou Ling, Aristolochia, MW# 5344, Net Wt. 250g (8.83 oz.) (manufactured by Anguo MeiWei Medicinal Herbs, Anguo, China)
- Chinese Herb Frucutu Aristolochiae Net Wt. 16 oz. (manufactured by Lam Hoi Trading Co., Hong Kong)
- Plum Flower, Fructus Aristolochiae, Herbal Extract Powder, Net Wt. 3.5 oz. (100g). (manufactured by Shanghai Institute of Herbal Products, Shanghai, China)
- Plum Flower Brand Single Herb Extract Full Spectrum 5:1 Herb Extract Powder, Ma Dou Ling, Aristolochia Debilis Fruit, MW# 5344C, Net Wt 3.5 oz. (100 g) (manufactured by Shanghai Institute of Herbal Products, Shanghai, China)

Lotus Herbs, Inc., La Puente, California has recalled 240 bottles of these products (distributed nationwide) manufactured by Lotus Herb Products, Sung-shan District, ROC

- Lotus Herb Fang Ji (Stephania tetranda radix) Premium Herbal Product, 3.5 oz. plastic bottle, code SW12261, EXP 12/04
- Lotus Herb Mu Tong (Clematis armandi) Premium Herbal Product, 3.5 oz. plastic bottle, code SL04461, EXP 09/04

Sheng Chang Qualiherb, a Division of Finemost Corporation, Cerritos, California has recalled an undetermined quantity of all codes of the products noted below (distributed nationwide) that were manufactured by Sheng Chang Pharmaceutocal Co., Ltd., Chung Ho City, Taipei, Taiwan

- Qualiherb Dianthus Formula, Ba Zheng San, item #20209
- Qualiherb Stephania & Astragalus Combination, Fang Ji Huang Qi Tang, item # 20711
- Qualiherb Clematidis Armandii Caulis, Chuan Mu Tong, item # 10424A
- Qualiherb Clematidis Radix, Wei Ling Xian, item # 12401
- Qualiherb Stephaniae Tetrandrae Radix, Han Fang Ji, item # 10731
- Qualiherb Aristolochiae Fructus, Ma Dou Ling, item # 11052

Metabolife International of San Diego, California announced a recall of 1.5 million Metabolife Diet & Energy Bars sold nationwide from December 25, 2000 to May 4, 2001. They contain about 32,500 International Units of vitamin A. Levels above 25,000 can cause severe liver damage, bone and cartilage abnormalities, increased pressure in the brain and birth defects. The bars have a red label in the flavors Outrageous Oatmeal Raisin, Perfectly Peanut, Downright Chocolate and Lemony Lemon. For more information, call 800-540-7099 www.metabolife.com/news/050701.htm.

Name of Drug or Supplement; Class of Recall; Problem	*Lot #; Quantity and Distribution; Manufacturer*
Acetaminophen Caplets, Extra Strength, 500 mg, 24, 50, 100, 120, 175, and 500 count; Class III; Labeling incorrectly declared an extended expiration date	Numerous lot numbers; 362,953 units distributed nationwide; Leiner Health Products, Inc., Wilson, North Carolina
Amoxycillin 250 mg and 500 mg capsules; Class III; Unapproved drug—distributed prior to approval of manufacturing changes	Lot numbers and EXP dates: 107283, 107284, 107285 EXP 05/02; 107297 EXP 06/02; 108375, 108376, 108377, 108378, 108379 EXP 09/02; 108868 EXP 10/02; 108865, 108866, 108867, 109430 EXP 11/02; 22,355,500 capsules distributed in Colorado, Florida, New York, Oklahoma and Virginia; Biochemie GmbH, Tyrol, Austria. Recalled by Geneva Pharmaceuticals, Broomfield, Colorado
Fluocinolone Acetonide Solution, 0.01%, 20 and 60 mL units; Class III; Subpotency (12th month stability)	Lot No. N133, EXP 12/01; 10,457 bottles distributed nationwide and in Puerto Rico; Thames Pharmacal Co., Inc., Ronkonkoma, New York
Garamycin Ophthalmic Solution, Gentamicin Sulfate Ophthalmic Solution, 3 GM/ML, 5 ML bottles; Gentak Sterile Solution, DC 17478-283-0, private label for AKORN, INC., Buffalo Grove, Illinois; Class III; Chemical contamination-Dicyclohexyl Phthalate (DCHP) product label adhesive migration	Numerous lot numbers; 389,089 units distributed nationwide; Schering Laboratories, Kenilworth, New Jersey
Inderide LA 160 mg/50 mg caps (Propranolol HCL 160 mg/ Hydrochlorothiazide 50 mg), bottles of 100 caps; Class III; Dissolution failure for hydrochlorothiazide component	Lot # 999041 EXP 7/01; 5,576 bottles distributed nationwide; Wyeth Pharmaceuticals Company, Guayama, Puerto Rico
Isoxsuprine HCl Tablets, 20 mg, 1,000 count; Class II; Metal particles in tablets	Lots 00504, 00602, and 00603; 11,818 bottles distributed nationwide; Integrity Pharmaceutical Corp., Fishers, Indiana
Keftab (Cephalexin Hydrochloride) 500mg in bottles of 100 and 60 count blisters; Class II; Problems with dissolution properties	Numerous lots; 45,189,243 units distributed nationwide; Lilly del Caribe, Carolina, Puerto Rico. Recalled by Eli Lilly and Co., Indianapolis, Indiana
MGP Multi-Vita Drops with Fluoride 0.25 mg and 0.5 mg; Class III; Subpotency of vitamin C prior to expiration date	Product Code 8659, lots 22647A, 22431A, 22657A, 22534A, 22534C, 22534E, 22884-A, 22998A, 23077A, 23184A, 23232A, 23351A; Product Code 8496, lots 22308A, 22460A, 22602A, 22602C, 22769A, 23000A, 23000C, 23032A; 487,701 bottles distributed nationwide; Morton Grove Pharmaceuticals, Inc., Morton Grove, Illinois
Premarin® Tablets (conjugated estrogens tablets), 0.625 mg, 100 & 1,000 count bottles and 2.5mg, 100 count bottles; Class III; Dissolution failure by manufacturer	Leiner Lot # 8K01061, 8H03878, 9D00864, 9D00862, 8H02890, 9F01554 and Wyeth-Ayerst Lot # 9980299, 9980299, 9990298, 9990298, 9980299, 9990283; 38,985 bottles distributed in New York, California and Illinois; Ayerst Laboratories Inc., Philadelphia, Pennsylvania
Tetrahydrozine HCl Nasal Spray 0.1% and **Pediatric Nasal Drops** 0.05%. Brand name-Tyzine, 15 ml (1/2 fl oz); Class II; High counts of microbiological contamination	Lots: 6234 EXP 8/02, 6235 EXP 8/04; 36,992 units distributed nationwide; Denison Pharmaceuticals, Inc., Pawtucket, Rhode Island
True Care Decongestant Nasal Spray, 1/2 fl. oz., Ozymetazoline Hydrochoride 0.05%; Class III; Mislabeling—failure to declare warning against use if heart disease exists	Lot N416; 920 mislabeled bottles distributed in Kansas City, Missouri; Thames Pharmaceutical Co. Inc., Ronkonkoma, New York. Recalled by Apothecary Products, Inc., South Burnsville, Minnesota

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*
Backpack Blowers; Engine exhaust can emit flames, posing fire and burn hazards	Models ASTRON KB-541 and TMC KTBL-5600XA; 3000 sold nationwide from October 2000 through February 2001; Kawasaki Motors Corp. USA, Irvine, California, in cooperation with Star Garden Supply Inc., Pico Rivera, California, and TMC Power Equipment Inc., Monterey Park, California. Call Kawasaki (800) 433-5640
Basketball Sets (Child's); Some of the nets have enlarged openings creating a strangulation hazard	Grow-to-Pro model 72408; 55,000 sold nationwide from January through May 2001; Fisher- Price, East Aurora, New York (800) 247-9395 www.fisher-price.com
Bean Bears; Yellow pom-pom can detach, posing a choking hazard to young children	Snuggle Teeny Bean Bear included with fabric softener products; 150,000 distributed nationwide from March through April 2001; Unilever Home and Personal Care USA, Greenwich, Connecticut (800) 598-5005 www.snuggletime.com
Car Seats/Carriers (Recall to Repair); When used as an infant carrier, the handle can unexpectedly release, causing the seat to flip forward	Joyride®; 3.4 million sold nationwide from January 1988 through December 1998; Evenflo Co. Inc., Vandalia, Ohio (800) 557-3178 http://www.joyridecarseat.com/
Children's Costumes; Fabric used can ignite readily and presents a serious risk of burn injuries in violation of the Federal Flammable Fabrics Act	Princess Ariel (The Little Mermaid) sold in youth sizes 2-4, 4-6X and 8-10; 54,000 sold nationwide from July 2000 through January 2001 by DisneyStore.com and The Disney Store catalog; Return to any Disney Store or call Disney Store, Glendale, California (800) 328-5902 disneystore.costume@disneyonline.com
Cigarette Lighters; Lighters do not have child-resistant mechanisms, as required by federal law	Hotery Pocke Torch, shaped like fire extinguisher and Pocket Torch, shaped like fire hydrant; 5,300 sold nationwide from January 1999 through December 2000; Tools Exchange Inc., Lynwood, California (310) 604-4444
Cigarette Lighters (refillable); Lighters do not have child-resistant mechanisms, as required by federal law	Electronic ignition lighters that bear location names such as "Hawaii," "Guam," "Saipan," "Las Vegas," "USA" etc. packaged in souvenir sets with ashtrays, pencils or pens; 65,000 sold at DFS stores in Hawaii, Guam, Saipan, San Francisco, Las Vegas, and Portland from January 1996 through April 2001; DFS Group Ltd., San Francisco, California (800) 225-2777
Dehumidifiers (Recall to Repair); Internal electrical connection can overheat, presenting a potential fire hazard	Goldstar DH2510, DH4010 and DH5010; General Electric AHG25LAG1, AHG40LAG1 and AHG50LAG1; Sears Kenmore 580.59600; 100,000 sold nationwide from January through December 1999; LG Electronics Inc., Seoul, South Korea (800) 651-1602 www.easyrecalldehumidifier.com
Disposable Lighters; Child-resistant mechanisms are frequently ineffective, posing a fire hazard	Brand name, "BODA-BING," "GIL," "HAPPY," or "WAX"; 13 million sold nationwide from January 1998 through February 2001; Gladstrong Investments USA, Hacienda Heights, California (877) 666-0664

Name of Product; Problem	*Lot #; Quantity and Distribution; Manufacturer*
Easter Egg Garlands; String can break and release the eggs, posing a choking hazard to young children	6-feet long, with plastic, colored, egg-shaped beads; 200,000 sold nationwide from February through April 2001; Tony USA Inc., Encinitas, California. Return to store where purchased.
Electric Drills; Switches can stick causing the drills to operate after the trigger is released	Models 1610-1, 1630-1, 1670-1, 1675-1 (Milwaukee Electric Tool) and models DW124 and DW124K (Dewalt Industrial Tool Co.); 58,000 sold nationwide from May 2000 through April 2001; Milwaukee Electric Tool Corp., Brookfield, Wisconsin (866) 473-2288 and Dewalt Industrial Tool Co., Baltimore, Maryland (800) 433-9258
Electric Ranges; Liquid can enter the indicator light and can cause sparking and flaming in the light, presenting a fire hazard	30-inch free-standing units with control panel in the front between the door panel and main top. Crosley brand have model numbers CE35000AAW or CE35000AAT, Magic Chef brand have model numbers CER1110AAT or CER1110AAH; 13,000 sold nationwide from January 2000 through March 2001; Maytag Corp., Newton, Iowa (800) 462-9267 www.maytag.com
Fax Machines; A component failure can cause the Faxphone to catch on fire	Faxphones with model number B640. "FAXPHONE B640"serial numbers UKK52923 to UKK55442, UKK60513 to UKK99999, and YKK02001 to YKK20000; 60,000 sold nationwide from October 1999 through May 2001; Canon USA Inc. Lake Success, New York (888) 280-7858 www.cusa.canon.com/consumer
Home Soda Machines; Components inside the soda machine can break apart, posing a serious risk of lacerations to consumers who can be struck by shrapnel	Model name "Drink Master," "Drink Maker," "The Drink Machine," or "The Carbonator" shaped like coffee makers; 4,000 sold at state and county fairs and conventions from 1990 through 1996; Drinkmaker of Sweden AB. Call The Soft Drink Company, Seattle, Washington (877) 438-7632
Kid's Meal Toys; Clear plastic lens covers on these compass toys can come off and pose a choking hazard to young children	"Whatagear" compass toys; 330,000 distributed with kids' meals in Whataburger Restaurants in Alabama, Arizona, Florida, Louisiana, New Mexico, Oklahoma and Texas from March 2001 through April 2001; Return toy to any Whataburger Restaurant or call Creative Consumer Concepts Inc. Overland Park, Kansas (866)327-2216 www.c3.to
Locks (Padlocks and Cable Gun); Padlocks can be opened with keys other than those provided. Cable locks can be opened if struck with force potentially allowing unauthorized access to firearm	Boxes using these padlocks were shipped by Ruger with its pistols and revolvers from 1987 until 1995. Red cable locks were shipped with Ruger rifles and shotguns from 1998 until March 2001; 1.2 million padlocks and 800,000 cable gun locks distributed nationwide; Sturm, Ruger & Co. Inc., Southport, Connecticut (888) 317-6887 www.Ruger-Firearms.com
Mountain Bicycles; Front-suspension forks can break during use, resulting in serious injury	Boys' "NEXT SHOCKZONE" orange bicycles model number 8536-33; 38,000 sold at Wal-Mart stores nationwide from September 1999 through March 2001; Dynacraft Industries Inc., San Rafael, California (800) 551-0032 www.dynacraftbikes.com
Mountain Bicycles; Pedals can loosen and fall off while riding	Magna Equator 18-speed men's (red) 8547-19 and women's (green) 8546-84; 54,000 sold at Toys R Us stores nationwide from January 2000 through April 2001; Dynacraft Industries Inc., San Rafael, California (800) 551-0032 www.dynacraftbikes.com/about_us.html

Name of Product; Problem	*Lot #; Quantity and Distribution; Manufacturer*
Notebook Computer Batteries; Batteries can overcharge, causing them to become very hot, release smoke, and possibly catch fire	Dell Inspiron 5000 and 5000e; 284,000 sold nationwide through catalogs and the internet from January 2000 through March 2001; Dell Computer Corp., Austin, Texas (877) 237-3355 www.dell.com
On/Off Switches for Rope and Cable Lights; Switch on power cord could allow lights to remain energized, posing a potential electric shock hazard	270,000 packages of Westek rope lights sold nationwide from April 1997 through October 2000 and 350,000 Light Tech switches included in cable lights packages sold nationwide from September 1997 through October 2000; American Tack & Hardware Co. Inc., Monsey, New York (800) 777-0801 and Light Tech, Grand Rapids, Michigan (800) 485-3080
Propane Torches; Hose that comes with the propane torch can crack or burst, presenting a fire and explosion hazard	22.5 inches long, comes as a kit with a wand, flow valve, turbo blast trigger, hard rubber grip and a hose that attaches to propane tanks; 500 sold nationwide from May through September 2000; Harbor Freight Tools, Camarillo, California (800) 444-3353
Scuba Buoyancy Compensator Devices; Overpressure valve can stick in the open position, presenting a drowning hazard	Sherwood brand Silhouette, Magnum, Avid, Luna, Outback and Freedom models, Genesis brand Cayman, Cobra, Athena, Phantom, Talon and ReCon models, Aeris brand Atmos model; 10,000 sold at dive stores and mail-order catalogues nationwide from September 2000 through March 2001; Sheico PKS Inc., Carlsbad, California (800) 808-3306 www.sherwoodscuba.com/opv, www.genesisscuba.com/opv, or www.diveaeris.com
Scuba Regulators; First stage spring can break causing restricted airflow, posing a drowning hazard	Titanium Model number T1, T1x, B1 and Z1; 3,000 sold from May 1999 through February 2000; Atomic Aquatics Inc., Huntington Beach, California (888) 270-8595
Space Heaters; Overheating inside the heaters can cause the exterior to become extremely hot, posing fire and burn hazards	White with a silver grill cover. The vent-less heaters have the name "Vermont Castings" on the label directly below the grill. The heater model numbers start with the letters VBVH or VPVH; 3,900 sold in the southeastern U.S. from August 2000 through January 2001; Vermont Castings, Majestic Products (VCMP), of Ontario, Canada (866)757-6649
Tea Kettles; Boiling water can be expelled from the kettle's spout, presenting a burn hazard	Martha Stewart Everyday® Brand; 24,000 sold nationwide at Kmart from October 2000 through March 2001; Kmart Corp., Troy, Michigan. Return to Kmart or call Wilton Industries Inc. (800) 273-9398
Wrestling Ear Guards; Plastic protective shell can break when hit against a hard surface, resulting in impact injuries to the head	White, red, purple, black, blue, green or gold ASIC Gel Wrestling Ear Guard with Neoprene. Recalled guards have date codes (found underneath the outer rim) beginning with 98 or 99; 60,000 sold nationwide from June 1998 through March 2001; ASICS TIGER Corp., Irvine, California (888) 380-8222 www.asicstiger.com

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such cases "resolved over several days to weeks without sequelae or complications."

Glossy six-page advertisements in specialist medical journals claimed that Lotronex had "a favorable safety profile and [was] generally well-tolerated." The advertisements did, however, mention the problem of ischemic colitis, although the warning emphasized that a causal connection between the drug and this adverse event was uncertain. By July 2000, concerns about the balance of risk and benefit were being voiced. Between February and June that year, seven patients had developed serious complications of constipation, three of whom required surgery. Eight further cases of ischemic colitis were reported. The FDA had an opportunity then to take stock of its earlier decision. The clinical data confirmed the substantial and potentially life-threatening risks hinted at during pre-approval review. But instead of withdrawing Lotronex and calling for more evidence, the FDA issued a medication guide designed to warn patients of escalating risks, while keeping the drug on the market.

This decision was to prove fatal. On November 28, GlaxoWellcome withdrew Lotronex from the market after the deaths of five patients. There had been 49 cases of ischemic colitis and 21 of severe constipation, including instances of obstructed and ruptured bowel. In addition to the deaths, 34 patients had required admission to the hospital and 10 needed surgery. A letter from Janet Woodcock, director of CDER, declared that the "FDA is committed to working with pharmaceutical sponsors to facilitate the development and availability of treatment options for patients with IBS." There was no word of sorrow or regret for the families of those who had died.

The course of these events can be followed through documents posted on the FDA's website (*www.fda.gov*). But what these press releases, talk papers, and letters do not reveal is the internal struggle and suppression of dissenting opinion that took place within the FDA once reports of serious complications and deaths began to come in. An evaluation of Lotronex's risk profile in the summer of 2000 found that the warning in the proposed medication guide was impracticable. The new guidance would be that women should stop taking Lotronex if they experienced "increasing abdominal discomfort." But since abdominal pain is a cardinal symptom of an irritable bowel, FDA scientists argued that it was unreasonable to expect either patients or their physicians to judge pain as an early warning of possibly fatal ischemic colitis. This view was dismissed by FDA officials. The scientists who raised these issues felt intimidated by senior colleagues and were excluded from further discussions about Lotronex's future. Instead, the FDA preferred to support a series of epidemiological studies into ischemic colitis and constipation. An independent review of these research protocols revealed profound flaws in their design. A more rigorous research proposal from one FDA scientist was ignored.

A memorandum dated November 16, 2000, and disclosed through the Freedom of Information Act by Public Citizen's Health Research Group, shows the extent of FDA scientists' concern. The company believed that the risk of Lotronex could be managed safely by looking for warning symptoms. But the note from FDA scientists to Lilia Talarico, director of the Division of Gastrointestinal and Coagulation Drug Products, explains that "Early warning of the dire side effects of this drug is clearly not feasible." The scientists state that "the sponsor [GlaxoWellcome] has not identified a subset of women who will respond to Lotronex therapy safely." Moreover, and crucially, given recent maneuvers to reintroduce Lotronex, the report states that "a risk management plan cannot be successful that will eliminate deaths, colectomies, ischemic colitis, and complications of treatment that were never seen previously in the management of IBS."

This unambiguous conclusion was blurred by the time of the key November 28 meeting between GlaxoWellcome and FDA officials. Rather than reject the company's risk-management proposal and withdraw Lotronex, the FDA offered several conciliatory options—e.g., voluntary withdrawal of Lotronex, temporary suspension of marketing pending further discussion, and restricted marketing to specialists. Pleased and quite likely surprised by the FDA's desire to bargain over the terms of public access to Lotronex, the company pressed for a new advisory committee hearing and affirmed its view that risk management

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was feasible. The FDA's options were heavily criticized, the process was deemed unfair, and FDA scientists were accused of not taking irritable bowel syndrome seriously. There was stalemate, and the company blinked first.

Once GlaxoWellcome had withdrawn Lotronex, recriminations within the FDA began in earnest. In addition, Woodcock was swamped by e-mails from patients asking for the drug to be brought back. The company gave money to support groups for patients with irritable bowel syndrome to assist their research and educational programs, according to Ramona DuBose, a GlaxoSmithKline spokeswoman. The FDA was brought under further pressure when the new Bush administration removed its Commissioner, Jane Henney, probably because of her support for the abortion-inducing mifepristone.

As arguments about Lotronex intensified, FDA officials took an increasingly hard line towards their own scientists. Yet new data acquired since the November withdrawal only strengthen the view that Lotronex should not be made widely available again. A further internal review of the incidence of ischemic colitis among women taking Lotronex suggests that the company may have seriously underestimated the hazards of the drug. And additional adverse reports obtained by Public Citizen show rising numbers of cases of ischemic colitis and severe constipation in women who continued to take Lotronex.

While the FDA held further internal discussions about how to respond to patients' groups and congressional pressure, private communications opened up between Woodcock and senior executives at the newly merged GlaxoSmithKline. The company was now worried that the open meeting it had proposed could produce a media circus, that committee members might disagree with a settlement made via these private communications, and that the entire process might be unduly prolonged. When I rang the FDA for a comment, I was told that the agency was "working with GlaxoSmithKline to discuss issues surrounding Lotronex and we are making progress." It is expected that the company will reluctantly agree to a few conditions for the reapproval of Lotronex—i.e., there may be restrictions on which physicians can prescribe the drug and a requirement for signed patient-physician agreements. To ensure that the advisory committee does not overturn this privately determined decision, a senior representative of the company has asked the FDA about the composition of the committee. And the FDA has undertaken to work with the company to set limits to the meeting's agenda and questions.

This two-track process, one official and transparent, one unofficial and covert, is contrary to FDA's stated policy. According to Crystal Rice, an FDA spokeswoman, the correct procedure is for the company to write officially to the FDA replying to CDER's concerns and providing new data on safety. A full FDA review should then take place before an advisory committee meeting. In the case of Lotronex, private communications appear to have subverted official procedures, while suppressed scientific debate has superseded a full and open review process. GlaxoSmithKline commented that "A team of FDA and GSK scientists have met on several occasions in an attempt to work out a risk management plan that would allow appropriate patients to receive benefit from the medicine while risks can be clearly understood and appropriately managed." This "effort is ongoing and no final decision has been made." The company also denied that there had been a back-channel for private communication between CDER officials and the sponsor. This claim was "untrue and very misleading," according to DuBose. "All meetings between GSK and the FDA have occurred primarily at the operational level between scientific teams." The FDA would "not comment on or discuss any details with regards to internal discussions between FDA and sponsors."

A further insight into the FDA's favorable attitude to industry was provided by a 1998 survey of FDA medical officers. Many of these physicians reported that since the 1992 Prescription Drug User Fee Act (PDUFA), which enabled the FDA via direct industry funding ($329 million) to hire almost 700 more medical officers to review new products, standards for drug approval have declined. Many officers felt under greater pressure from FDA supervisors to approve new drugs; they received inappropriate calls from the sponsor about the drug under review; and they believed that the FDA too often interfered on the company's behalf in the drug-approval process. The Lotronex episode may show in microcosm a serious erosion of integrity within the FDA, and in particular CDER, whose operating budget now depends greatly on industry money.

Where next for Lotronex and the FDA? The clinical evidence indicates that, at most, Lotronex should be reclassified as an investigational new drug, with additional restrictions, thus limiting its use to experimental settings only. Meanwhile, on this evidence, the FDA urgently needs to re-establish the public's trust. First, all covert private communications between senior FDA officials and industry must be closed. Drug approvals and safety reviews should take place through accountable procedures. Second, greater weight should be placed on the epidemiological and statistical advice provided to advisory committees. Third, there should be an independent congressional audit of the FDA's drug-approval processes, including its priority reviews, since implementation of PDUFA. Fourth, pharmacovigilance should be removed from CDER's control. It is an impossible conflict for safety issues to be overseen by a center that receives funding from industry to review and approve new drugs. Fifth, the culture within the FDA should welcome, not censure, differences of opinion about the impact of science on policymaking.

Finally, the FDA's new Commissioner should be an epidemiologically trained physician with substantial experience of conducting clinical trials, a person with a strong track record of institutional leadership, and, most importantly of all, someone who is demonstrably independent of the pharmaceutical industry.

Lotronex and the FDA: A Fatal Erosion of Integrity

The following was reprinted from the May 19, 2001 issue of The Lancet.

In March last year, *The Lancet* published the results of a randomized trial reporting that alosetron (Lotronex, GlaxoWellcome) "was well tolerated and clinically effective in alleviating pain and bowel-related symptoms" in women with irritable bowel syndrome. Michael Camilleri and colleagues described their findings as "important." Indeed, irritable bowel syndrome, although not life threatening, can be severely disabling. Lotronex was an early example of a new class of drug for irritable bowel, the 5-HT antagonists. This apparent pharmacological breakthrough has generated an explosion of new research interest in functional bowel disease.

Camilleri and colleagues also found that 1 in 10 patients taking Lotronex withdrew from the trial because of constipation, but they argued that this symptom was not "perceived as a negative consequence" of treatment. They concluded that "No serious drug-related adverse events or deaths were reported during the study." A single case of ischemic colitis was, they wrote, misdiagnosed.

Lotronex was licensed by the Food and Drug Administration (FDA) in February, 2000. By November, GlaxoWellcome had voluntarily withdrawn Lotronex from the market. At least five people had died after taking the drug. Yet many within the FDA's leadership now want to bring Lotronex back. An advisory committee meeting set up to do so is being planned for June or July. This story reveals not only dangerous failings in a single drug's approval and review process but also the extent to which the FDA, its Center for Drug Evaluation and Research (CDER) in particular, has become the servant of industry.

New drug application 21-107 (alosetron hydrochloride) was submitted to CDER on June 29, 1999, and assigned priority review. Seven months later, Victor Raczkowski, deputy director for the FDA's Office of Drug Evaluation dealing with Lotronex, wrote to inform GlaxoWellcome that, in the FDA's view, Lotronex was "safe and effective for use as recommended." He also reminded the company of its commitment to "A large, long-term (1 year) population risk trial to assess the incidence of colitis in patients receiving alosetron." The FDA was clearly anxious about the drug's risk profile. The printed labeling accompanying Lotronex warned about the possibility of acute ischemic colitis but noted that

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