PUBLIC CITIZEN HEALTH RESEARCH GROUP

Health Letter

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Survey of Doctor Disciplinary Information on State Medical Board Web Sites

State medical boards are responsible for taking action against physician misconduct and making information about those disciplinary actions available to the public. Given the Internet's power to rapidly disseminate vast amounts of information to many people, it is logical that the boards provide disciplinary information on the web. If the data are sufficiently detailed, complete, and easily accessible, providing the information on the Internet would not only benefit patients, but also the boards, which would receive fewer time-consuming phone and mail queries from patients and might then be able to devote more time and resources to their vital enforcement duties.

Between August 27 and October 28, 1999, HRG surveyed the 51 boards that regulate medical doctors in the United States. The structured questionnaire sought to answer the following questions: What types of information are available on the Internet? In what format is it presented? How complete and current is it? How does it compare to the disciplinary information a consumer can get by calling the board? For those boards without disciplinary action information available on the Internet, we asked whether they planned to get on the web and, if so, when.

We created a grading scale to assess the content of disciplinary information each web site provides. An adequate amount of information on a given action was defined as: 1) the doctor's name; 2) the disciplinary action taken by the board; 3) the offense committed by the doctor; 4) a concise summary narrative of the physician's misconduct; and 5) the full text of the actual board order. States that provided all five types of data earned a content grade of "A"; states that provided four of the five types of data earned a "B"; states that provided three of the five types of information received a "C"; states that reported two of the five types of information received a "D"; and states that named disciplined physicians but provided no details about the discipline received an "F." States that had no web sites or reported no doctor-specific disciplinary information on their web site earned an "X."

We also categorized the web sites as either user-friendly or not based on the format in which disciplinary data were presented. A user-friendly format was defined as either: a) a database from which physician information can be retrieved by entering a doctor's name in a search engine; or b) a single listing of all licensed physicians that includes dis-

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ciplinary information; or c) a single listing of all physicians disciplined by the board. Examples of formats that are not user-friendly include multiple reports, newsletters, or press releases. Each of these items must each be searched individually, a time-consuming, hit-or-miss process for patients.

Of the 51 boards regulating medical doctors, 41 have web sites providing doctor-specific disciplinary information (that is, the disciplined physicians are named). Although most of these boards have their own sites, a few states provide the data on the site of another regulatory body, such as the Department of Health. Of the 10 boards that do not provide doctor-specific disciplinary data on the web (Alaska, Arkansas, Delaware, Hawaii, Louisiana, Montana, New Mexico, North Dakota, South Dakota and Wyoming), seven have no site at all, while three (Alaska, Montana and South Dakota) have sites that provide no disciplinary data. These sites typically provide basic information like board addresses, phone and fax numbers, the names of board members, and the roles and duties of the boards. Of the 10, five (Arkansas, Delaware, Louisiana, New Mexico and North Dakota) said that they planned to have sites with disciplinary information in the near future, and four of those five said this would occur in the first half of 2000.

Seventeen boards began providing disciplinary data on the web in 1996 or 1997. Twenty-four boards began in 1998, 1999 or 2000.

Only one of the 50 states and the District of Columbia (2 percent) earned an "A" for content: Maryland. Twenty-four (47 percent) received "B's"; five (10 percent) received "C's"; eight (16 percent) earned "D's"; three (6 percent) earned "F's" and the 10 states (19 percent) that provided no doctor-specific disciplinary information on their web sites, or had no web sites, earned "X's" for content.

Although 80 percent of the state medical boards provide some doctor-specific disciplinary information on the Internet, 14 million patients live in the 10 states where no such data are available online. Clearly, these states need to act to expand their presence on the Internet. However, even among the state medical boards that do provide disciplinary action information on the Internet, the content, format, and timeliness of that information varies greatly and is often inadequate.

Unless a board web site provides adequate information about actions, patients will be unable to use the site to make an informed choice of a physician. For these patients, contacting the board by phone or mail will still be necessary, and this represents a lost opportunity for the board to enhance consumer access to doctor disciplinary data and reduce their own workload.

Disappointingly, only one state, Maryland (population 5.2 million), earned an "A" for the content of information featured on its web site. Although 260 million patients live in the 41 states that provide some disciplinary information on the Internet, 114 million of them (44 percent) are in states that provide three or fewer of the five minimum data types and therefore earned content grades of "C" or less.

Some boards report other important information on their licensees that might be of interest to patients. The California, Florida, Idaho, Massachusetts, and Tennessee boards provide data on malpractice claims. The California, Florida, Idaho, and Massachusetts sites also report disciplinary actions taken by hospitals against physicians. We believe that all states should include such data.

The ease with which disciplinary data can be reviewed is determined largely by the format in which is it presented. A database from which physician information can be retrieved by entering a physician's name in a search engine is the most user-friendly format. A single listing of either all licensed physicians, which includes disciplinary information, or a single listing of all disciplined physicians, is not as elegant as a searchable database, but can be reviewed with relative ease. An archive of periodically posted documents, such as newsletters or press releases, is inconvenient because patients must review a number of separate documents individually to check

Table 1: Content Grades by State

Content Grade	*Number of States*	*Percentage of States*	*States*
A	1	2%	Maryland
B	24	47%	Arizona, District of Columbia, Florida, Idaho, Illinois, Indiana, Iowa, Maine, Massachusetts, Minnesota, Missouri, Nevada, New Hampshire, New York, North Carolina, Ohio, Pennsylvania, South Carolina, Utah, Vermont, Virginia, Washington, West Virginia and Wisconsin
C	5	10%	Connecticut, Michigan, New Jersey, Tennessee, Texas
D	8	16%	California, Colorado, Kansas, Kentucky, Mississippi, Nebraska, Oklahoma, Rhode Island
F	3	6%	Alabama, Georgia, Oregon
X	10	19%	Alaska, Arkansas, Delaware, Hawaii, Louisiana, Montana, New Mexico, North Dakota, South Dakota, Wyoming

for information on a physician.

Finally, it is clear that there is no relationship between the content of medical boards' web sites and their rates of serious disciplinary actions. A relatively high rate of discipline hardly excuses a state from getting this important information out in a complete and user-friendly manner. Conversely, having a complete, user-friendly web site is no substitute for a higher rate of discipline. Both are needed.

Recommendations

Public Citizen's Health Research Group recommends that all state medical boards adopt minimum uniform standards for providing disciplinary information on the Internet.

1) Each board should have a web site that links to a database of physician information. For each physician disciplined by the board, the information should include the action taken by the board, the offense committed by the physician, and a summary narrative of the physician's misconduct. The database should also feature links to the full text of board orders and other public documents related to the action.

2) This information should be provided for all disciplinary actions taken in the last 10 years.

3) Public access to disciplinary data should be preserved even when a physician's license is suspended, revoked, or expired.

4) Patients should be able to retrieve data by entering a physician's name and/or license number in a search engine.

5) Disciplinary action information should be updated as frequently as the boards meet to consider actions (usually once a month).

6) If a court overrules or vacates a board action and exonerates the physician and the court decision is final, then information on that action should be removed from the database. While an appeal is pending, or while a remanded action is being considered, information on the action and the court's decision should be reported in the database.

7) Any changes in a physician's record resulting from a court decision should be made within two weeks of the court ruling.

Table 2

State	*Web site address*
Alabama	http://bmedixon.home.mindspring.com/
Alaska	http://www.dced.state.ak.us/occ/pmed.htm
Arizona	http://www.docboard.org/bomex/index.htm
Arkansas	None
California	http://www.medbd.ca.gov
Colorado	http://www.dora.state.co.us/medical
Connecticut	http://www.state.ct.us/dph
Delaware	None
District of Columbia	www.dchealth.com/lra/news.stm
Florida	http://www.doh.state.fl.us/mqa
Georgia	http://www.sos.state.ga.us/ebd-medical/
Hawaii	None
Idaho	http://wwwidacare.org
Illinois	http://www.state.il.us/dpr
Indiana	https://www.ai.org/serv/hpb_lookup_ia
Iowa	hhp://www.docboard.org/ia/ia_home.htm
Kansas	http://www.ink.org/public/boha/
Kentucky	http://www.state.ky.us/agencies/kbml
Louisiana	None
Maine	http://www.docboard.org/me/me_home.htm
Maryland	http://www.docboard.org/md/default.htm
Massachusetts	http://www.massmedboard.org/
Michigan	http://www.commerce.state.mi.us/bhser/home.htm
Minnesota	http://bmp.state.mn.us/
Mississippi	http://www.msbml.state.ms.us
Missouri	http://www.ecodev.state.mo.us/pr/healarts/
Montana	http:// www.com.state.mt.us/license/pol/ pol_boards/med_board/board_page.htm
Nebraska	http:// www.hhs.state.ne.us/
Nevada	http:www.state.nv.us/medical/
New Hampshire	http://www.state.nh.us/medicine
New Jersey	http://www.state.nj.us/lps/ca/medical.htm
New Mexico	None
New York	http://www.health.state.ny.us/nysdoh/opmc/main.htm
North Carolina	http:www.docboard.org/nc
North Dakota	None
Ohio	http://www.state.oh.us/med/
Oklahoma	http://www.osbmls.state.ok.us/
Oregon	http://www.bme.state.or.us/
Pennsylvania	http://www.dos.state.pa.us/bpoa/medbd.htm
Rhode Island	http://www.docbord.org/ri/main.htm
South Carolina	http://ww.llr.state.sc.us/me.htm
South Dakota	http://www.state.sd.us/dcr/medical/med_hom.htm
Tennessee	http://www.state.tn.us/health
Texas	http://www.tsbme.state.tx.us/
Utah	http://www.commerce.state.ut.us/dopl/disc.htm
Vermont	http://www.docboard.org/vt/vermont.htm
Virginia	http://www.dhp.state.va.us/
Washington	http://www.doh.wa.gov/publicat/Publications.htm
West Virginia	http://www.wvdhhr.org/wvbom
Wisconsion	http://badger.state.wi.us/agencies/drl/
Wyoming	None

Untested Herbs and Food Supplements for Pregnant Women Making the FDA Retract its Dangerous Regulation

On January 6th of this year, the Food and Drug Administration (FDA), yielding to pressure from the herbal/dietary supplements industry, published a final regulation which, were it to have gone into effect, would have endangered hundreds of thousands of pregnant women. The following are excerpts from a letter written to the FDA on February 3rd by Dr. Sidney Wolfe and Dr. Godfrey Oakley, for 15 years the director of the division on birth defect and developmental disabilities in the federal Centers for Disease Control and Prevention.

Dear Commissioner Henney:

We are writing to urge that you immediately make important changes concerning uses during pregnancy, in the final rule concerning dietary supplements, published on January 6, 2000. The rule is scheduled to go into effect on February 7, 2000.

The rule categorizes "ordinary morning sickness" and "leg edema associated with pregnancy" as common conditions that are not "diseases." Under the Dietary Supplement Health Education Act (DSHEA), that categorization allows dietary supplement manufacturers to promote products as treatments of those conditions without first proving that the products are safe and effective. We strongly disagree with that categorization. Both morning sickness and edema of pregnancy, when uncomfortable enough to cause a woman to use a substance for relief of symptoms, are severe enough to be considered diseases. We urge you to immediately amend the rule explicitly to include morning sickness and edema of pregnancy as diseases.

The condition could very well be one that could cause "significant or permanent harm." For example, edema of pregnancy could well be an early symptom of pre-eclampsia or other types of toxemia of pregnancy which, if undiagnosed and not properly treated, can jeopardize the health of both the mother and infant.

As you are well aware, substances or viruses of little consequence to the mother can have profoundly harmful effects on the developing embryo and fetus. Thalidomide, although effective as a sleeping pill for the expectant mother, can cause very substantial birth defects when taken in the first trimester of pregnancy. Another example, the congenital rubella syndrome that can cause blindness, birth defects and mental retardation, is caused by a rather mild rubella infection of the mother during the first trimester. Thus, products that are safe for an adult woman herself may have profoundly adverse affects on a developing embryo and fetus.

The cause of most birth defects remains unknown. The best evidence suggests that many birth defects are caused by agents that humans have consumed for hundreds of years. For example, in the early 1970s, we learned that alcohol can cause severe physical and mental birth defects. Although we do not have the evidence to identify which dietary supplements have been and continue to cause birth defects, it is reasonable to assume that humans are now consuming such agents. A government regulation that facilitates consumption by pregnant women of such agents, which have not been tested for their adverse effects on the fetus, will unfortunately put embryos and fetuses at risk.

In sharp contrast, chemicals that are classified as drugs must undergo rigorous scrutiny, before marketing approval, for any adverse effects on reproduction, including fetal toxicity. As a result, data are available to allow such drugs to be categorized into one of several categories concerning risk of use during pregnancy. Currently, 81 drugs are listed in FDA Pregnancy Category X, defined as drugs in which: "Studies in animals or humans demonstrate fetal abnormalities or adverse reaction reports indicate evidence of fetal risk. The risk of use in a pregnant woman clearly outweighs any possible benefit." Included on this list are such chemicals as Vitamin A, ephedrine, and caffeine—all of which are found, not infrequently, in herbal preparations or dietary supplements. When sold as herbals or food supplements, these three chemicals sometimes, but not always have a pregnancy warning. Because DSHEA does not allow the FDA to require the kinds of studies that would produce evidence to categorize other food supplements or herbals into safe or unsafe categories for use in pregnancy, claims for morning sickness or edema of pregnancy will be unaccompanied by any assurance that the products will not cause birth defects or other kinds of fetal toxicity.

Ironically, almost 40 years ago the FDA won worldwide acclaim by keeping thalidomide, a drug used to treat morning sickness in pregnant women, off the U.S. market. By this action, the FDA saved hundreds if not thousands of American children from being born with severe birth defects. Now, the same agency seems to have thrown caution to the wind and appears willing to endanger unborn babies by pretending that medical conditions such as morning sickness and edema of pregnancy are not diseases, thereby allowing the marketing of dietary supplements/herbals that have not been tested for safety. We simply cannot believe that the agency has really considered the consequences of this aspect of the final rule. We therefore urge you to immediately revoke those parts of the rule that reclassify as non-diseases morning sickness and edema of pregnancy. We appreciate your prompt reply to this urgent request.

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Dr. Allen Mitchell, a physician and epidemiologist who has spent most of his career studying the causes of birth defects, wrote to Commissioner Henney several days later as follows:

I take strong exception to classifying these conditions as non-diseases, since they can lead to complications (such as dehydration) that can adversely affect

the pregnant woman and her fetus. More urgently, however, to allow such claims to be made in the absence of evidence of fetal safety is to ignore the very history that made the FDA the world's most highly regarded regulatory agency....The notion that vitamins and products derived from plants are safe may be debated with respect to the risks to the pregnant woman herself, but assumptions of safety are simply without foundation when it comes to the fetus. Indeed, we worry greatly about the fetal risks of high-dose vitamin A, and the vitamin A congener isotretinoin (Accutane) is a classic and potent human teratogen. Further, we and others have now demonstrated that pseudoephedrine is likely responsible for an increased risk of the rare but potentially devastating birth defect gastroschisis. It should not go unnoticed that pseudoephedrine, derived from ephedra, is a plant product that is commonly found in herbal supplements currently promoted for cough and colds—indeed, only last week I heard an advertisement for a Tom's of Maine cold product that contained pseudoephedrine but was safer than other products because it did not contain alcohol!....

The fact that the agency retains the ability to remove a product if it finds it to be unsafe (i.e., teratogenic) is little comfort. Unlike most drug risks, evidence of human teratogenesis comes almost entirely from human exposures and tragedies. I have spent my career investigating how to identify drugs that cause birth defects in humans, and I am painfully aware of our limited abilities to rapidly identify new teratogens. This is particularly problematic for supplements whose efficacy is unproven and whose constituents might not be accurately known.

Based on existing teratogenic concerns surrounding certain vitamins (e.g., vitamin A) and plant-derived agents in dietary supplements (e.g., pseudoephedrine), there is little doubt that some dietary supplements carry the strong potential to be human teratogens. Allowing their promotion for treatment of a disease directly associated with the early stages of pregnancy serves to encourage their use, particularly since pregnant women will be led to believe that dietary supplements represent a "safe" alternative to prescribed or OTC medications....

We as a society and FDA as a regulatory agency must not forget the lessons of the thalidomide tragedy. To maintain the above-cited rule is to invite a medical, moral, and public health disaster that could, with simple revision of that rule, be averted.

Edema of pregnancy could well be an early symptom of pre-eclampsia or other types of toxemia of pregnancy

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Dr. Phillip Landrigan, a pediatrician, epidemiologist and Chairman of a National Academy of Sciences' Committee on Pesticides in the Diets of Infants and Children, also wrote to Commissioner Henney, stating that: "on the basis of our [the panel's] recognition of fetus', infants' and children's unique patterns of exposure and unique susceptibility to chemical pesticides...we recommended that legislative and regulatory procedures...for pesticides...be substantially revamped so as to take cognizance of the special risks and vulnerabilities of children." He also pointed out that as a result of this panel's work, a Presidential Executive Order issued in 1997 required "all agencies of the federal government to take into account the unique vulnerabilities of infants and children in setting standards and issuing regulations." Dr. Landrigan went on to say that "Your final rule fails to recognize that if a pregnant woman ingests an inadequately labeled [because of a failure to require testing] patent medicine that contains a fetotoxic chemical, then the result can be structural malformation or functional deficit in her developing child."

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Congressman Henry Waxman of California, met with Commissioner Henney on Friday, January 6th, and discussed, among other issues, his serious concern about the consequences of this FDA final regulation.

In a remarkably quick about-face, the FDA announced, on February 9th, two days after the final rule went into effect, that it was backing down. The following excerpts from an article in the *Washington Post* the following day capture some of what happened:

FDA Cancels Labeling Rule: Firms Told Not to Market Diet Products to Pregnant Women

The Food and Drug Administration backed away from its new diet supplement labeling rule yesterday, warning companies not to promote their products as treatments for morning sickness, leg swelling or any other condition affecting pregnant women.

The FDA issued the statement after consumer advocates and health care providers complained that the labeling rule allowed diet supplements to be marketed to pregnant women when most of the substances had never been tested to see if they were safe for developing fetuses.

"Scientifically, everyone knows that the unborn fetus is extremely susceptible, and they [the FDA] should have known this," said Sidney M. Wolfe, director of Public Citizen's Health Research Group in Washington. "It's a stupid move to have [issued the rule]. At least, they caught it before too much damage was done."

Representatives of the diet supplement industry were not available for comment. Margaret Dotzel, acting FDA commissioner for policy, said the agency intends to hold a public meeting sometime in the near future to discuss "the safety concerns that have been raised." The statement said the agency would then "issue further guidance."

Woodcock [Director of the drug center at the FDA] said the agency did not

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Product Recalls

January 6—February 9, 2000

This chart includes recalls from the Food and Drug Administration (FDA) Enforcement Report for drugs and medical devices and Consumer Product Safety Commission (CPSC) recalls of consumer products.

DRUGS & DIETARY SUPPLEMENTS

The recalls noted here reflect actions taken by a firm to remove a product from the market. Recalls may be conducted on a firm's own initiative, by FDA request, or by FDA order under statutory authority. A Class I recall is a situation in which there is a reasonable probability that the use of or exposure to the product will cause serious adverse health consequences or death. Class II recalls may cause temporary or medically reversible adverse health consequences. A Class III situation is not likely to cause adverse health effects. If you have any of the drugs noted here, label them *Do Not Use* and put them in a secure place until you can return them to the place of purchase for a full refund. You can also contact the manufacturer. If you want to report an adverse drug reaction to the FDA, call (800) FDA-1088. The FDA website is http://www.fda.gov.

Name of Drug or Supplement; Class of Recall; Problem	*Lot #; Quantity and Distribution; Manufacturer*
Cyndal HD Cough Syrup (Hydrocodone Bitartrate 1.57mg/ Phenylephrine Hydrochloride 5mg/Chlorpheniramine Maleate 2mg), in 16 fluid ounce and 1 gallon containers; Class III; Subpotency of the phenylephrine (50%) due to incorrect weight addition in batch production	Lot #91949; 118 gallon bottles and 7,032 pint bottles distributed in southeastern United States; Great Southern Laboratories (GSL), Houston, Texas
Diltiazem Hydrochloride Extended Release Capsules, 120 mg, 100-capsule bottles, Rx for angina pectoris due to coronary artery spasms; Class III; Dissolution failure at 3 months stability	Lot 11829 EXP 2/01; 9,597 bottles distributed nationwide; Teva Pharmaceuticals USA, Sellersville, Pennsylvania
Esgic-Plus Tablets (butalbital 50mg, acetaminophen 500mg, caffeine 40mg), in 100-tablet bottles; Class III; Mislabeling—Bottles contain capsule form of the same ingredient product; not the labeled tablet form of product	Lot #90248A 1 EXP 8/01; 999 bottles distributed in New York; Med-Pro, Inc., Lexington, Nebraska
Mega Min Dietary Supplement, in 100-tablet bottles, OTC dietary supplement; Class III; Some bottles labeled as "Mega Min" actually contain a different supplement—"Formula 7"	Lot 019-3061; 48-72 bottles distributed in southeastern United States; Vitalabs, Inc., Jonesboro, Georgia
Naproxen Tablets, 500 mg, in 100, 500 and 1,000 tablet bottles; Class II; Metal wire/particle contamination	Lots 105921, 106119, 106583, 106584 04/02, 106585, 106585 05/02; 8,209,100 bottles distributed nationwide; Geneva Pharmaceuticals, Inc., Broomfield, Colorado
Neomycin and Polymyxin B Sulfates and Hydrocortisone OTIC Solution, Rx, 3.5mg/10,000 units/10mg (1%), 10 mL with sterile dropper; Class III; One unit was found to contain Hydrocortisone Otic Suspension not Hydrocortisone Solution as labeled	Lot #205101 EXP 4/01; 45,808 units distributed nationwide; Bausch and Lomb Pharmaceuticals Inc., Tampa, Florida
Potassium Chloride (Klor-Con) Packets, 20mEq/4-ounce packets, Rx; Class III; Mislabeling—Exterior plastic holding packet incorrectly labels the product as 20 mEq granules not 10 mEq tablets	Lots 18264 1 EXP 2/01, 18308 1 EXP 4/01; 50 100-packet boxes distributed in Colorado; Med-Pro, Inc., Lexington, Nebraska
Quinidine Gluconate Extended Release Tablets, 324 mg, in 100-tablet bottles, Rx for atrial fibrillation/flutter and suppression of ventricular arrhythmias; Class III; Dissolution failure (12 month stability 8 hours time point)	Lot 39239 EXP 8/01; 5,836 bottles distributed nationwide; Mutual Pharmaceutical Company, Philadelphia, Pennsylvania

DRUGS & DIETARY SUPPLEMENTS, *cont.*

Name of Drug or Supplement; Class of Recall; Problem	*Lot #; Quantity and Distribution; Manufacturer*
Quinidine Gluconate Extended Release Tablets, 324 mg, in 100, 250, and 500-tablet bottles, Rx antimalaria and antiarrhythmic; Class III; Product may not meet dissolution specification over labeled expiration period	Lots C8D0669, C8D0670, C8B0265, C8B0266, C8D0671, C8D0672, C8D0673, C8B0263, C8B0264 EXP 04/00, C8E1066, C8E1068, C8E1070, C8E1071, C8E1067 EXP 06/00, C8F1173, C8F1174 C8F1170, C8F1171 EXP 07/00, C8F1234, C8F1235 EXP 08/00; 30,050 bottles distributed nationwide; Danbury Pharmacal, Inc., Carmel, New York. Recalled by Schein Pharmaceuticals, Inc., Brewster, New York
Radic Electrolyte Formula, liquid, in 8-ounce clear plastic bottles, OTC dietary supplement to help the body heal itself naturally; Class II; Product contains catechol (carcinogen)	All 8-ounce products; Approximately 20 bottles distributed in California and Nevada; Medical Research Products, also known as Consolidated Marketing Ltd., Miami, Florida. Recalled by Hope For Life Foundation of Southern California, Mission Viejo, California
Vanceril(r) Double Strength Inhalation Aerosol, (Beclomethasone Dipropionate), 84 mcg, in 5.4 g inhalers, 3 per holding carton, Rx indicated for maintenance treatment of asthma; Class II; Some units may not contain any active drug substance	Lots 9-DMT-157, 9-DMT-158, 9-DMT-160, 9-DMT-161, 9-DMT- 163 EXP 7/00; 82,029 units distributed nationwide; Schering Laboratories, Inc., Kenilworth, New Jersey

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 details. You can also call the FDA's Device Recall and Notification Office at (301) 443-4190. To report a problem with a device, call 1-800-FDA-1088. The FDA website is http://www.fda.gov.

Name of Device; Class of Recall; Problem	*Lot #; Quantity and Distribution; Manufacturer*
Mini-Med MMT-508 Insulin Pump, indicated for the continuous delivery of insulin at set and variable rates for the management of diabetes mellitus in persons requiring insulin; Class II; Pump's software has an error in displaying current basal rate profile	Serial numbers with suffix numbers -20A2, -20A3, -20A4, -20A5; 2,909 units distributed nationwide; Mini-Med, Inc., Sylmar, 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 (CPSC), call their hotline at 1-800-638-2772. The CPSC website is http://www.cpsc.gov.

Name of Product; Problem	*Lot #; Quantity and Distribution; Manufacturer*
Baby Garments; Rose-shaped buttons can detach, posing a choking hazard to young children	One-piece coveralls, and two-piece, babydoll-style top and legging sets. 100 percent cotton garments in sizes 0-3M to 24M. Writing on collar labels includes, "MADE IN CHINA" and "Peek-A-Babe"; 9,800 sold at Shopko stores nationwide from June through October 1999; Shopko Stores, Green Bay, Wisconsin (800) 791-7333 www.shopko.com
Children's Overalls; Snaps can detach from garments, posing a choking hazard to young children	Blue denim size 6 months—4T and red, navy and green overalls lined with red check flannel size 6 months—3T; 7,700 sold nationwide through their stores, web site, and catalog from January through December 1999; L.L. Bean Inc., Freeport, Maine (800) 555-9717 www.llbean.com

Name of Product; Problem	*Lot #; Quantity and Distribution; Manufacturer*
Computer Armoires; Upper doors or upper door components can fall off, causing injury to nearby consumers	Monarch style models 2549 (washed pine), 2649 (woodland oak), 2749 (classic cherry), 8449 (fruitwood) and 9649 (amber oak); 212,400 sold nationwide from July 1997 through December 1999; Sauder Woodworking Co., Archbold, Ohio (888) 800-6315
Engines and Fuel Filters; Fuel filters on these engines can leak gasoline, posing a fire hazard to consumers	Identification tags on side of red or black engines with model numbers 294442, 294447, 303442, 303447, 350442 or 350447. Only engines with 9-quart fuel tanks manufactured by Briggs & Stratton are part of this recall. Also involved in recall are replacement filters that were sold separately; 2,600 engines and 4,600 filters sold nationwide from March through November 1999; Briggs & Stratton, Milwaukee, Wisconsin (800) 999-9444
Fire and Smoke Suppressants; Product does not suppress fires and could intensify fires	16-ounce aerosol cans are red, orange, yellow, black and white with a red plastic cap and aerosol button. Wording on front of can reads in part, FIRE CAP...FIRE and SMOKE SUPPRESSANT. FOR USE ON SMALL SPOT FIRES...; 136,000 sold at Snap-On Tools dealers, Home Shopping Network Inc., and direct market distributors, including Mid-State Fire Systems, and Contract Filling Inc. nationwide from February 1996 through September 1999; The Colbra Group (now out of business). Return it to the place where purchased for a full refund. Consumers should call CPSC's toll-free hotline at (800) 638-2772 for instructions on returning the product to the place of purchase.
Fleece Robes (Ladies); Robes fail to meet federal flammability standards for clothing and can ignite readily, presenting a serious risk of burn injuries	Five different styles of white, blue, ivory, beige and gray recalled robes (sizes XS through L) made of 90 percent cotton and 10 percent polyester fleece. Robes contain sewn-in label HANRO of Switzerland; 2,100 sold nationwide from October 1999 through January 2000; HANRO USA Inc., New York, New York (800) 889-7443
Furniture Refinisher; Product and vapors can seep from nozzle base, posing risk of fire and chemical injuries	Formby's Conditioning Refinisher, 32-ounce metal can with lot numbers A961600, A961610, A961620, A961630, A967270 and A969330 in black ink on bottom of can; 3,000 cans sold nationwide from October 1999 through January 2000. Sherwin-Williams Co., Cleveland, Ohio and Brockway Standard Inc., Atlanta, Georgia (800) 523-9299
In-line Skates; Plastic brake mount could crack and fail, causing skater to fall and suffer serious injury	FLIGHT ALX brand model S00161 or S00162; 12,000 sold nationwide from August through November 1999; K2 Corporation, Vashon, Washington (800) 426-1617 www.K2skates.com/flight_recall.htm
Keychains sold with teddy bears; Skateboards' wheels can come off, posing choking hazard to young children	Miniature skateboard attached to Zany Brainy Z.Z. Jamboarder teddy bears; 15,500 sold nationwide through their stores, web site and catalog from November through December 1999; The Vermont Teddy Bear Co., Shelburne, Vermont (877) 293-2327 and Zany Brainy, Inc., King of Prussia, Pennsylvania www.zanybrainy.com
Novelty Lighters; Lighters do not have any child-resistant mechanisms, presenting a fire hazard	Intruder and Jupiter models with brand name Prometheus; 4,000 sold at tobacco stores nationwide from March 1997 through February 1999. Lighters were advertised on their web site www.prometheuskkp.com; Prometheus International Inc., Bell, California (800) 229-5233
Oven Cleaner; Contents can spew out because of improperly attached valve assembly that can separate from can. Direct contact with contents poses risk of chemical burns to skin and eyes	EASY-OFF Heavy Duty 16 oz. lot B9305-NJ2; 50,000 cans sold nationwide from November 1999 through January 2000; Reckitt & Colman Inc., Wayne, New Jersey (888) 993-3389 *continued on page 9*

Supplement Regulations, from page 5

want to discuss possible outcomes yet, but in the meantime, the statement said, the "FDA urges all pregnant women to consult their health care provider before taking any dietary supplements or medication."

Yesterday's statement marked the latest flare-up in the FDA's prolonged, confusing and often acrimonious efforts to regulate the booming diet supplement industry, which under current law can make and sell new products without prior FDA approval as long as manufacturers do not claim to prevent, treat or cure a disease.

On January 6, the FDA issued a rule narrowing its definition of "disease" and giving diet supplement companies much greater freedom in making claims that relate to the "structure" or "function" of the human body. For example, the new rule said that "for the relief of occasional sleeplessness" is an acceptable "structure/function" claim, while "helps to reduce difficulty falling asleep" is not because it implies insomnia, "a disease."

Many consumer advocacy groups were incensed because they had hoped the new rule would tighten labeling regulations rather than loosen them up. Of particular concern were the examples that characterized "ordinary morning sickness" and "leg edema associated with pregnancy" as legitimate structure/function claims.

Dotzel acknowledged that "a series of letters" like Wolfe's "raised concerns about safety issues about the use of diet supplements during pregnancy," and caused the agency to issue the statement and advertise the hearing.

Many consumer advocates and health care experts have charged that the lack of regulation in the supplement industry has caused a dangerous free-for-all among companies competing for business in a growing market worth $12 billion per year.

Wolfe noted that a web site for "Snowbound Herbals" described the herb "black cohosh" as "useful in pregnancy" because it "tones uterus" and "regulates contractions at birth," although it should be taken "only in the third trimester." The company did not return telephone calls seeking comment.

By contrast, the Natural Medicines Comprehensive Database, compiled by pharmacists and physicians as a reference guide for health care providers to sort out conflicting claims, describes black cohosh as "unsafe" for pregnant women because it has "menstrual and uterine stimulant effects."

Using multiple vitamins, including folic acid (which actually prevents birth defects) and iron is very important for pregnant women to do in consultation with their physician, nurse-midwife, or nurse practitioner.

What You Can Do

The larger issue, because there are still dangers lurking about because of the remaining aspects of the 1994 Dietary Supplements Law, is how many further disasters will have to occur before this law is significantly amended or, better yet, repealed. Write to your senator or representative urging introduction and support of such legislation.

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CONSUMER PRODUCTS, *cont.*

Name of Product; Problem	*Lot #; Quantity and Distribution; Manufacturer*
Pull Toys; Wooden wheels and pegs could come off, presenting choking hazard to young children	Enchanted Garden Inchworm, item number EG150; Merry Meadows Cow, item number FS150; and Sunny Safari Blue Elephant, item number SS150; 3,400 sold nationwide from July through December 1999; Manhattan Group LLC, Minneapolis, Minnesota (800) 541-1345
Race Car Collectibles; Fluorescent light base of unit becomes extremely hot and can melt, presenting a fire hazard	Illuminated race car panels include Tony Stewart Home Depot Car, Jeff Gordon Dupont Car, Dale Earnhardt GM Goodwrench Car and Dale Earnhardt Jr. Budweiser Car; 1,600 sold nationwide during December 1999; Action Performance Companies Inc., Phoenix, Arizona (888) 810-4057
Snowblowers; Fuel can leak from the fuel-line connection, posing a fire hazard	Ariens orange models 938010, 938011, 938012, 938015 and 938016 and Lesco green model LSS522; 27,000 sold nationwide from July 1997 through January 2000; Ariens Co., Brillion, Wisconsin (888) 927-4367
Sweatshirts (Men's); Sweatshirts, which fail to meet federal mandatory standards for fabric flammability, could ignite readily and present a serious risk of burn injuries	Long-sleeved gray with phrase Made in USA on neckline label; 2,000 sold at Eddie Bauer stores nationwide from March through May 1999; Eddie Bauer, Richmond, Virginia (800) 426-6253
Toy Chests; The lids on these toy chests could fall onto a child's head or neck	Oak Models 841LQ and 1814LQ; 400 sold at furniture stores nationwide from January through November 1999; Thornwood Furniture Manufacturing, Phoenix, Arizona (877) 351-0067 www.thornwood.com

New Concerns About Menopausal Hormones and Breast Cancer

For years, Public Citizen's Health Research Group has warned of evidence that hormones given to women after menopause cause breast cancer. It was always plausible that such hormones did this; it has been known for decades that women with the greatest exposure to their own natural hormones (early onset of puberty, late menopause, late childbearing or none at all) have increased breast cancer rates. Although there were studies both confirming and excluding the risk, research reported by the U.S. Centers for Disease Control and Prevention in 1991 showed that the best-conducted studies tended to confirm the risk.

Deciding whether to take hormones after menopause is a complicated balancing act. On the one hand, estrogens (estrogens and progestins are the two categories of female hormones) can reduce the rate of bone loss (osteoporosis), although exercise and a calcium-rich diet beginning early in adult life will suffice for most women. On the other hand, estrogens clearly cause uterine and breast cancer. The claimed benefit of estrogens in preventing heart disease remains unproven (see below).

In the November 11, 1997 issue, the British journal *The Lancet* published an analysis of the risks of menopausal hormone use from 51 studies in 21 countries—90 percent of the world's data on whether menopausal hormones cause breast cancer. The study found that risk was significantly increased among those who were currently using hormones (mostly estrogens) or had only relatively recently stopped doing so. For those with an average of 11 years of hormone use, the risk of breast cancer was increased by 35 percent.

Meanwhile, the claimed benefits of hormone replacement therapy were also being questioned. In a study in which women with preexisting heart disease randomly either received hormone replacement with both estrogen and progestin (the progestin was added because it reduces the risk of uterine cancer due to the estrogen component) or an inactive placebo, combination hormone replacement actually increased the risk of heart disease in the first year. By the end of the study (an average of 4.1 years), there was no difference in heart disease or total mortality between the two groups. Gall bladder disease and blood clots, known complications of hormone therapy, were increased in the group who received hormones.

A clear association between hormone use and breast cancer was again apparent

In the January 26, 2000 issue of the *Journal of the American Medical Association* an article lends new weight to fears about hormone replacement. The researchers followed 46,355 postmenopausal women who had undergone mammography for an average of 10 years and determined whether or not they developed breast cancer. The study was unique in one regard: for the first time there were enough progestin users to measure the risk of breast cancer from these hormones.

In women who had not used hormones for at least four years, there was no increase in breast cancer, consistent with the earlier *Lancet* study. However, for those with more recent use, a clear association between hormone use and breast cancer was again apparent. Compared to those using no hormones, those using only estrogens were at a 20 percent increased risk of breast cancer over the study period. But here was the shocker: those using a combination of estrogen and progestin were 40 percent more likely to be diagnosed with breast cancer than nonusers. This means that for each year that a woman uses combined replacement therapy—now the most common way estrogens are used—her risk of breast cancer grows by another 8 percent compared to nonusers: 8 percent increased risk in year one, 16 percent increased risk in year two, 24 percent in year three, etc. There was one other surprising finding: lean women were at increased risk of hormone-induced breast cancer, but heavier women were not. One explanation for this is that heavier women already have higher estrogen levels and so the addition of more estrogen in pill form has little impact.

Where do these new data leave postmenopausal women? Given the benefits of estrogens in preventing osteoporosis, hormone replacement therapy may be advisable for those at high risk for osteoporosis, especially those who have had a hysterectomy and are therefore not at risk for uterine cancer. But for the great majority of women, these recent studies further undermine the already shaky case for routine postmenopausal hormone therapy.

OUTRAGE, *from page 12*

flatus incontinence at three months were also considerably higher in the episiotomy group compared to the other two groups (34 percent vs. 19 percent and 21 percent), and these differences persisted at six months.

A potential criticism of this study is that the women who received episiotomies were different from those who did not. In particular, the women who underwent episiotomies might have undergone more difficult labors, making the procedure necessary for the speedy delivery of the child. The higher rates of incontinence in the episiotomy group might also have resulted from the use of instruments such as forceps and vacuum cups during delivery. To address this issue, the authors conducted separate analyses in women who had uncomplicated, non-instrumental births. These analyses showed that, even after taking these factors into account, there was still an increased risk of incontinence conferred by episiotomy.

Defenders of episiotomy have long argued that it is better to have a controlled, surgical tear than a spontaneous one, because the smooth edges produced by the surgical tear will lead to better healing after the tear is repaired. The authors addressed this by comparing women with so-called second-degree tears (a moderate complication of delivery; the most severe tear is fourth-degree) due to either episiotomy or spontaneous tearing. The rates of fecal and flatus incontinence at three and six months were two to three times higher in the episiotomy group than in the spontaneous-tear group. A nurse, writing to the *British Medical Journal* in response to this article, put the issue in common sense terms: "Any tailor knows that the easiest way to tear a piece of fabric is to put a tiny cut at its edge....How can it be any surprise that women who are [surgically] cut experience more extensive damage?"

You should express your strong preference to avoid an episiotomy unless it is absolutely necessary.

There are situations in which episiotomy can be justified. These include many breech (feet-first) deliveries, if the baby's shoulders become stuck or other conditions arise that endanger the life of mother or baby. But these situations are quite uncommon. More typically, this study suggests, episiotomy can and should be avoided.

What You Can Do

Clinical practices in obstetrics are often unaffected by emerging data. Although extensive evidence exists that the cesarean section rate in this country is much higher than it should be and that routine electronic fetal monitoring does not protect the infant and does increase the risk of cesarean section, these practices continue. It remains to be seen whether this important study will have a significant impact upon clinical practice—43 percent of vaginal deliveries in the U.S. in 1996 involved episiotomy. In the meantime, if you are a pregnant woman (or her partner), you should express your strong preference to avoid an episiotomy unless it is absolutely necessary.

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The Unkindest Cut of All Unnecessary Episiotomies

For decades, many obstetricians have insisted that an episiotomy (an incision made during labor in the skin beginning at the woman's vagina and continuing in the direction of the rectum) would produce healthier babies and promote quicker healing for mothers. Slowly but surely, these claims have been debunked. The latest claim to run afoul of improved clinical investigation techniques is that episiotomies are less likely to lead to involuntary loss of stool (fecal incontinence) or gas (flatus incontinence) after delivery. A study in the January 8, 2000 issue of the *British Medical Journal* strongly suggests that the opposite is probably true: fecal and flatus incontinence are substantially more common in women who have undergone episiotomies.

In the study, the researchers contacted women six months after they gave birth and asked whether they had fecal or flatus incontinence then or three months after delivery. The women belonged to three groups: those who did not have an episiotomy and had only minor tears of the skin around the vagina during delivery; those who had no episiotomy but had more substantial tears; and those who underwent an episiotomy. The researchers then compared the rates of fecal and flatus incontinence among the three groups.

At three months after delivery, the rate of fecal incontinence among women in the episiotomy group greatly exceeded those in the other two groups (10 percent vs. 3 percent and 2 percent). At six months, the rates of fecal incontinence were lower than at three months, but were still higher in the episiotomy group than in the other two groups. Rates of

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