

Health Letter

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FDA Fails to Get the Point on Safe Needles for Health Care Workers

Almost two decades into the AIDS epidemic, the Food and Drug Administration (FDA) is still permitting nurses, doctors and others on the front lines of health care delivery to be exposed unnecessarily to needlestick injuries and the risk of contracting HIV, hepatitis B and hepatitis C. Each year, about 590,000 U.S. health care workers sustain needlesticks and hundreds are stricken with these infections. Since the beginning of the AIDS epidemic, there have been 49 confirmed cases of occupational HIV infection, with many more unconfirmed.

Although medical devices that could protect health care workers from needlestick injuries have long been approved by the FDA, the agency has permitted conventional, unsafe equipment to remain on the market. Since the unsafe versions are usually less expensive, many hospitals and clinics opt for the cheaper ones, thus placing health care workers at unnecessary risk. The sad irony is that the new, safer needles are likely to more than pay for themselves by preventing needlesticks that result in large expenses for testing, counseling and treating health care workers. And of course, no financial value can be assigned to the enormous psychological toll exacted by every needlestick as the affected health care worker has to endure agonizing periods of waiting until blood tests finally come back.

Typically, the safer devices have

either a sliding sheath that can be activated to cover the hazardous point or a spring-loaded needle that can be retracted safely into the barrel of the device immediately after use. Others have recessed needles so that fingers and other body parts cannot be punctured accidentally.

In 1991, the Services Employees International Union (SEIU) petitioned the FDA, which regulates medical devices, to issue performance standards for syringes and similar equipment. The agency turned down the petition and opted for a voluntary approach, an all-too-common response from a Clinton administration inaccurately depicted by Republicans as pro-big government. In the interim, health care

worker deaths have continued to accumulate while more and better devices have been developed. Meanwhile, many of these devices gather dust in company warehouses or are not used by health care workers in facilities that also carry the unsafe devices.

Consequently, in November, Public Citizen and the SEIU petitioned the FDA for a ban on five specific unsafe medical devices: intravenous catheters, blood collection devices, "butterfly syringes," glass capillary tubes and intravenous infusion sets that use needles. For most of these devices, ECRI, a kind of *Consumer Reports* for the medical device industry, has rated the safer devices highly and clinical

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Sex Education Information on the Internet: Caveat Emptor!

Ten years ago, most people (except, perhaps, Al Gore) had never heard of the Internet or imagined the speed at which they would be able to communicate with friends or family across the world. Most had no idea that it would so rapidly become a repository of information, both good and bad, on almost every imaginable topic.

The question has now become: What does this invasion of computer-accessible information mean for the field of public health? We set out to answer this question in one area: sex education information. In some respects, sex education is the ideal subject for the Internet: many young adults feel uncomfortable discussing sexual issues with their parents or other adults and prefer exploring these issues in private. However, the Internet has also gained well-deserved notoriety for its explicit descriptions and depictions of sexual matters.

To shed some light on the issue, Public Citizen worked with three undergraduates at the University of Michigan on a research project published in the December issue of *Health Education & Behavior*. In the first part of the study, we conducted a detailed review of the content of web sites identified by specific key words related to sex education. This yielded more than 6 million web sites, of which slightly more than 1,500 had "compatibility" scores of over 70 percent; only 41 of these 1,500 actually met our criteria for

sexual health information. A surprising (or maybe not surprising) 63 percent of the 1,500 web sites were pornographic. Even the 41 sex education sites were lacking critical information; the sites received average content scores of 6.1 on a 10-point scale in which each potential subject (e.g., sexual decision-making, sexually transmitted diseases) addressed by the sites resulted in one point.

In the second part of the study, we asked University of Michigan undergraduates to locate specific pieces of information (the symptoms of sexually transmitted diseases, how to use a condom) and recorded the time and number of mouse-clicks it took to find the information. The subjects were able to locate correct information easily, with an average time of less than four minutes and fewer than six clicks. We concluded that it is difficult to locate comprehensive web sites with sex education material and that even those are often lacking in essential elements. However, accurate information on specific topics can sometimes be found quite easily.

This research suggests both the potential and limitations for sex education on the Internet. If one could skip the pornography and efficiently locate accurate information, the Net could prove to be a vital resource, particularly for sensitive subjects like sexuality. Certainly, the four minutes to find the specific information in our study is far less than it would

take to visit the local library.

Much will depend on the nature of the Internet itself. Many people, particularly poorer people, are still not connected to the Internet. The quality and diversity of sites can change rapidly. Public health educators need to become more comfortable creating and maintaining high quality sites, and designing them to be most attractive to young people (music, graphics, etc.). Parents will need to accept the fact that their computer-savvy children may use the Internet in this way and should discuss the appropriate and inappropriate uses of the new technology.

Three sites received a content score of 10. These sites were sponsored by Healthwise (an educational division of Columbia University; <http://www.columbia.edu/cu/healthwise/Cat6.html>), the Minnesota Organization on Adolescent Pregnancy Prevention and Parenting (MOAPPP; <http://www.cyfc.umn.edu/youth/MOAPPP/html/teens.htm>) and M-Web (now Peer Partners, Inc.; www.regsex.com). The MOAPPP site, in particular, was focused on teen sexuality.

Like most new technologies, the Internet offers both opportunity and hazard. The challenge is to maximize the accessibility of high quality information, while steering young people away from poor quality sites and pornography.

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studies have documented their effectiveness in reducing needlestick rates. The petition can be viewed at <http://www.citizen.org/brg/PUBLICATIONS/1548.htm>.

At a press conference in Washington, D.C. where the petition was made public, nurse Noreen Prill described how she was stuck with a needle in 1978, resulting in hepatitis C infection. "It is sad and ironic that the same kind of needle that infected me more than

20 years ago is still on the market today," Prill said.

The petition is the most recent initiative in a slew of efforts to force the adoption of safer devices. Seventeen states have enacted legislation to address the needlestick problem, although in many cases the legislation is restricted to the public sector or does not go beyond federal Occupational Safety and Health Administration (OSHA) standards which merely require institutions to "evaluate" safer services. And

in November, the President signed a bill that will shore up OSHA's enforcement activities so that more attention is paid to medical devices.

But in the final analysis the most effective way to protect health care workers will be to rid hospitals and doctors' offices of these hazardous devices. Only the FDA has the authority to do this. Now the country is watching to see if the FDA will finally get the point.

Product Recalls

November 10—December 6, 2000

DRUGS & DIETARY SUPPLEMENTS

This chart includes recalls from the Food and Drug Administration (FDA) Enforcement Report for drugs and dietary supplements, and Medical Devices, and Consumer Product Safety Commission (CPSC) recalls of consumer products.

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

Class I Recalls

Name of Drug or Supplement; Class of Recall; Problem

Rich's MSM Eye and Ear Drops (Methylsulfonylmethane), in 1-ounce bottles; Class I; Microbial contamination (*Pseudomonas fluorescens*)

Tia-Cutz Capsules, Thyroid Stimulator, (1000 mcg Tiratricol), in 90-count containers, OTC indicated for use in weight loss and in conditions of obesity; Class I; Product is an unapproved new drug

Eyewash, Emergency Eye/Face Body Wash, Eyewash Concentrate and Normal Saline: Lavoptik Brand: Emergency Eye/Face/Body Wash in 16 oz. and 32 oz., Eye Wash in 6 oz., Eye Wash Concentrate For use in Portable Eye Wash Stations in 70 oz. and 180 oz. Bottles. Rapid-Clear Brand: Rapid-Clear Eye Wash 16 oz., and 32 oz. and 128 oz Rapid-Clear Eye Wash Concentrate For Use in Portable Eye Wash Stations 180 oz. Bottle. Zee Brand: Zee Protector II Refill Sterile Eye Wash Solution for use in Eye Wash Station, 5 Qt. **Normal Saline Solution** 16 oz.; Class I; Microbial contamination (*Burkholderia cepacia*)

Lot #: Quantity and Distribution; Manufacturer

All products (Product not coded); Undetermined quantity distributed nationwide and internationally; Rich Distributing, Portland, Oregon

Lot 990426 EXP 12/01; 1,569 bottles distributed nationwide; Ultra Health Products, Phoenix, Arizona. Recalled by Gentech LLC, doing business as Gaspari Nutrition, Edison, New Jersey

All lots; 40,000-50,000 units distributed nationwide; H.L. Bouton Company, Inc., Buzzards Bay, Massachusetts

Name of Drug or Supplement; Class of Recall; Problem

Allegra Tablets (fexofenadine HCL), 60 mg, physician sample units, Rx for relief of symptoms of seasonal allergic rhinitis, and for treatment of chronic idiopathic urticaria; Class III; Mislabeling—label bears unapproved dosage instructions for patients other than adults

ALLERx(tm) Tablets, (Pseudoephedrine HCL 120 mg, Methscopolamine Nitrate 2.5 mg, Chlorpheniramine Maleate 8 mg), 10 day trade pack, Rx; Class III; Tablets in reverse order for AM and PM dispensing

Lot #: Quantity and Distribution; Manufacturer

Lot #1021570 EXP 03/02, Lot #1022502 EXP 10/21/02, Lot #1021572 EXP 10/18/02, Lot #1023169 EXP 11/06/02, Lot #1021573 EXP 10/20/02, Lot #1022714 EXP 03/20/02, Lot #1022501 EXP 10/21/02; 207,878/30 2-tablet card boxes distributed nationwide; Aventis Pharmaceuticals, Inc., Kansas City, Missouri

Lot #0606701; 7,678 individual units distributed nationwide and Puerto Rico; Adams Laboratories, Inc., Fort Worth, Texas

Name of Drug or Supplement; Class of Recall; Problem

Conjugated Estrogen Tablets, Rx, Premarin, 0.625 mg, 0.9 mg, 1.25 mg, 2.5 mg in 100, 1000 and 5000-tablet bottles; Premphase 0.625 mg/5 mg tablets (conjugated estrogens/ Medroxyprogesterone acetate) in EZ-dial dispensers; Class III; Dissolution failure

Conjugated Estrogen Tablets, Rx, repackaged in bottles as follows: Premarin(r) Tablets (conjugated estrogens tablets), 0.625 mg, 0.9mg, 1.25mg, and 2.5mg 90, 100, and 1,000-count bottles; Class III; Dissolution failure

Cough and Cold Touro Brand, Rx, in unit dose packages of physician samples as follows: a) TOURO ALLERGY Capsule, (Brompheniramine Maleate 5.75 mg and Pseudoephedrine 60 mg), Physician sample, b) TOURO CC Caplets, (Dextromethorphan hydrobromide 30 mg, Pseudoephedrine 60 mg and Guaifenesin 575 mg), Physician sample, c) TOURO DM Caplets, (Dextromethorphan hydrobromide 30 mg and Guaifenesin 575 mg), Physician sample, d) TOURO EX Caplets, (Guaifenesin 575 mg), Physician sample, e) TOURO LA Caplets, (Pseudoephedrine HCL 120 mg and Guaifenesin 575 mg), Physician sample; Class III; Lack of data to support labeled expiration date

Desoximetasone Ointment, 0.25%, in 15 and 60-gram tubes, Rx topical corticosteroid ointment; Class III; Degradation failure at 12 month stability testing

Estratab Tablets (Esterified Estrogens Tablets), 2.5 mg, in 100-count bottles; Class III; Firm withdrawal of application (stability data)

Glyburide Tablets, 6 mg and 1.5 mg in 100-count bottles, Rx, adjunct to diet to lower blood glucose in patients with non-insulin-dependant diabetes mellitus (Type II); Class II; Blend uniformity non-conformance with RSD specification and subpotency

Isopropyl Alcohol (Pueblo Xtra brand), 70% Rubbing Alcohol, in 16-fluid ounce bottles; Class III; Mislabeling—Product bears both the correct label strength of 70% and an incorrect label declaration of 50%

Nortriptyline Hydrochloride Capsules, 25 mg, in 500-count bottles, Rx; Class III; Dissolution failure (stability)

Lot #: Quantity and Distribution; Manufacturer

Numerous lot numbers and expiration dates; 2,556,717 100-tablet bottles, 33,607 1000-tablet bottles, and 18,726 5000-tablet bottles and 41,220 dial dispensers distributed nationwide and Malta; Ayerst Laboratories, Division of Wyeth-Ayerst Pharmaceuticals, Inc., Rouses Point, New York, and Wyeth Pharmaceuticals Company, Guayma, Puerto Rico. Recalled by Wyeth-Ayerst Laboratories, Richmond, Virginia

Lot Numbers: 8086 EXP 8/6/00, 8482 EXP 9/25/00, 8898 EXP 11/10/00, 8923, EXP 11/13/00, 11210A, EXP 6/28/01, 11210B EXP 7/9/01, 11210C EXP 7/20/01, 11492A EXP 8/10/01, 11492B EXP 8/30/01, 11935 EXP 9/29/01, 12336 EXP 11/16/01, 12878 EXP 2/25/02, 13496 EXP 1/17/02; 14,785 bottles distributed nationwide; Wyeth-Ayerst Laboratories, Rouses, New York. Recalled by AmeriSource Health Services Corporation, doing business as American Health Packaging (AHP) (relabeler/repacker/ distributor)

Lot Numbers: a) 419, b) 772, c) 471, d) 394C01, e) 699; 4074 boxes of 30 UDPs distributed in Connecticut, Massachusetts, Rhode Island; PharmaFab, Grand Prairie, Texas. Recalled by Dartmouth Pharmaceuticals, Inc., Wareham, Massachusetts (repacker)

Lot #D756 EXP 11/00; 4,265 tubes distributed nationwide; Atlanta, Inc., Hicksville, New York

All lots; 16,418 units distributed nationwide; Solvay Pharmaceuticals, Baudette, Minnesota

Lot Numbers ST 43001A EXP 3/01, TT 2411A EXP 11/00; 10,615 bottles distributed nationwide; M OVA Pharmaceuticals Corporation, Caguas, Puerto Rico

Lot Numbers: B125 and B143; 7,200 units distributed nationwide; Omega, Inc., Carolina, Puerto Rico

Lot #P9E0175 EXP 5/01; 6,756 bottles distributed nationwide; Danbury Pharmacal of Puerto Rico, Inc., subsidiary of Schein Pharmaceutical, Inc., Humacao, Puerto Rico

DRUGS & DIETARY SUPPLEMENTS *cont.*

Name of Drug or Supplement: Class of Recall: Problem

Prednisone 5 mg Tablets, in 100 and 1000-count bottles, 12 bottles per innerpack, and 12 innerpacks per carton, sold under Mutual label in 1000-count bottles and the URL label in 100-count bottles, intended for endocrine, hematological and rheumatic disorders, collagen, dermatological, ophthalmic, respiratory, neoplastic and gastrointestinal diseases, allergic and edematous states; Class III; Blend uniformity failure

Prednisone Tablets, 5 mg, in 1-tablet blister packages, Rx oral glucocorticoid adrenocortical steroid used in treatment of adrenocortical insufficiency; Class III; Blend uniformity failure

Zagam Tablets (Sparfloxacin), 200 mg, in 55-count bottles, Rx broad spectrum antimicrobial agent; Class II; Dissolution failure (six months stability station testing)

Lot #: Quantity and Distribution: Manufacturer

Lot Numbers: 42129 EXP 12/02 and 42130 EXP 12/02; 3,857 100-tablet bottles and 6,391 1000-tablet bottles distributed nationwide; Mutual Pharmaceutical Company, Inc., Philadelphia, Pennsylvania

Lot #0H568 EXP 5/02; 4,076 unit cartons of 25 tablets each distributed nationwide; Mutual Pharmaceutical Company, Inc., Philadelphia, Pennsylvania. Recalled by UDL Laboratories, Inc., Rockford, Illinois (repacker)

Lot #MN4062 EXP 11/01; 105 bottles distributed nationwide; Aventis Pharma Ltd., Republic of Ireland. Recalled by Bertek Pharmaceuticals, Inc., Sugar Land, Texas

M E D I C A L D E V I C E S

Device recalls are classified in a manner similar to drugs, Class I, II or III, depending on the seriousness of the risk presented by leaving the device on the market. Contact the company for more information. You can also call the FDA's Device Recall and Notification Office at (301) 443-4190. To report a problem with a medical device, call 1-800-FDA-1088. The FDA web site is <http://www.fda.gov>.

Name of Device: Class of Recall: Problem

Accu-Chek Volcemate System, designed for testing glucose in whole blood by visually impaired persons with diabetes; Class II; Meter placed in one system reports results in mmol/L instead of mg/DL, which may result in an 18-fold difference in numbers reported in voice readout to the patient

Belisle Brand Advanced Facial Muscular Therapy, an electrical muscle stimulator system; Class II; Device was marketed without a 510(k) or PMA

Lot #: Quantity and Distribution: Manufacturer

Catalog #2030802 Lot #119164, serial number on meter 7674342975; 200 units distributed nationwide; SCI Systems, Inc., Huntsville, Alabama. Recalled by Roche Diagnostics Corporation, Indianapolis, Indiana

All units; 30 units distributed in Texas, New York, California, Kansas, Oklahoma, Georgia, Virginia, Florida, North Dakota, Louisiana; Belisle Systems, Inc., Clearwater, Florida

C O N S U M E R P R O D U C T S

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

All-Terrain Vehicles; Improper welding on mounting bracket and incorrect assembly of brake pads

Bicycle Handlebar Stems; Stems can break during use

Lot #: Quantity and Distribution: Manufacturer

Honda Rancher TRX350 and Honda TRX400EX; 126,000 sold nationwide from July 1999 through September 2000; American Honda Motor Co., Inc., Torrance California (888) 289-8226 www.hondamotorcycle.com/press/index.html

Recalled stems have "Profile" and "Stiffy" written on them; 8,000 sold nationwide from March 1997 through April 2000; Profile Design LLC, Carson, California (888) 800-5999 www.profile-design.com

*Name of Product: Problem**Lot #: Quantity and Distribution: Manufacturer*

Bicycle Helmets; Helmets fail impact testing

Variflex X-Games Aggressive, TSG Metallic Gold, Gloss Black, Foundation Blue, Guardian Junior; 243,000 sold nationwide from October 1999 through October 2000; Variflex Inc., Moorpark, California (800) 248-5327; NHS Inc., Santa Cruz, California (877) 743-7820; First Team Sports Inc., Anoka, Minnesota (800) 528-5872

Bicycles; Brakes can stick and prevent the brake pads from returning to the proper position when the brake lever is released

Raleigh M600, M800, M8000. Diamondback Zetec Comp, X-2. Univega DS950, Alpina 700; 5,000 sold nationwide from November 1999 through June 2000; DiaTech USA, Kenmore, Washington and Derby USA, Kent, Washington (800) 222-5527

Circuit Testers; May fail to indicate if electric current is present, posing a risk of electric shock

Sterling-brand model ML-24; 4,000 sold nationwide from January through September 2000; Kole Imports, Carson, California (866) 251-0982 www.koleimports.com/Recall.htm

Desk Fans; Fans could overheat during use, and do not have sufficient guards to prevent possible finger entrapment, presenting electrocution, shock, fire, and finger amputation hazards

16-inch "PIONEER" brand; 4,500 sold in the metropolitan New York area from April 1999 through June 2000; The Morton Paper Co., Brooklyn, New York (718) 417-1717

Electric Fans; Fans could overheat during use and do not have sufficient guards to prevent fingers from contacting the blades

12 and 16 inch desk fans, 16 and 18 inch stand fans and 18 inch stand fan with base. Writing on all fans includes "AGIS" and "MADE IN TAIWAN"; 11,800 sold at discount stores in the metropolitan New York area from April 1998 through September 1999; Agis Enterprises Co. Inc., West Keansburg, New Jersey (732) 787-1191

Fondue Sets; Some sets have alcohol burners that can produce high flames beyond the intended cooking surface of the fondue pot. Another set, which uses chafing fuel, is being recalled because the chafing fuel holder could tip as it burns down. Both problems present potential fire and burn hazards to consumers

Farberware models 86600, 86700, 86702, 76743 and Roshco model 58903; 132,000 sold nationwide from June 1999 through October 2000; Lifetime Hoan Corp., Westbury, New York (877) 523-7190 www.lifetime.hoan.com/default.asp?page=fondue

Go-Kart Seat Belts (Recall to Repair); Seatbelts can unintentionally unlatch, posing a risk of serious injury

Murray Outrage Model GT60102x92A or GT60304A with manufacturing date codes from 00082 to 00147; 1,150 sold at Wal-Mart and Army Air Force Exchange Services (AAFES) stores nationwide from March through October 2000; AMSAFE Commercial Products Inc., Phoenix, Arizona (800) 251-8007

Gun Cabinets; Cabinets have push button locks that can be opened without the use of a key allowing unauthorized access to firearms

Brand name "Stack-On" model GCP-910 or GCP-914 and "Sentinel" model GPW-14; 3,300 sold nationwide from May through September 2000; Stack-On Products Co., Wauconda, Illinois (800) 323-9601 www.stack-on.com

High Chairs; In recline position, seats can separate from the frame. In upright position, seats can slip from set position to the lowest position or can fall to the ground. Some seats were also sold with metal restraint anchor that can slip through the back of the seat allowing child to fall

Cosco Options 5 Model number 03-286 manufactured from December 1, 1997 through August 11, 2000; 1,000,000 sold nationwide; Cosco Inc., Columbus, Indiana (800) 221-6736 www.coscoinc.com/services/servfram.html

Musical Pull Toys; Toy has two elastic cords that form a loop, posing a strangulation risk to young children

Stuffed musical "Curious George" toy; 4,600 sold nationwide at Kmart stores from June through September 1999; Prestige Toy Corp., New York, New York (866) 666-8266

Name of Product; Problem

Off-Road Motorcycles; Bolts that attach the handlebars can break. If handlebars separate from the motorcycle, the rider loses steering control and can crash

Off-Road Motorcycles; A frame "down tube" can crack below the steering head. Use of the motorcycle with a cracked down tube can result in failure of the frame

Pacifiers; The pacifiers failed CPSC testing standards, presenting a choking hazard to infants

Paper Shredders; Shredders do not have a protective shield to guard against exposure to cutting blades

Plush Rabbit Toys; Eyes on toys could detach, posing a choking hazard to young children

Power Strips and Extension Cords; Power strips have undersized wires, lack over-current protection and grounding, and plastic case is flammable

Radial Arm Saws (Recall for Repair); Sold without a guard that covers the entire blade

Recessed Lights; Glass ring exterior portion or trim can fall from the fixture, posing a risk of lacerations and impact injuries

Scooters; On one model, scooter handles can unexpectedly come out of the steering column if the clamp holding them in is not tight. On another model, the plastic "T" joint between the handlebars can break

Toddlers' Slippers; Drawcord around ankle can break and release the toggle used to tighten drawcord, presenting a choking hazard

Lot #: Quantity and Distribution; Manufacturer

2000 and 2001 Model number XR50R, red cycles; 22,000 sold nationwide from September 1999 through October 2000; American Honda Motor Co., Torrance California (888) 289-8226 www.hondamotorcycle.com/press/index.html

Lime green, Motocross Competition KX65 Model Year 2000; 4,000 sold nationwide from November 1999 through October 2000; Kawasaki Motors Corp. U.S.A., Irvine, California (866) 802-9381

"Pacee" aqua blue pacifiers have a soft, butterfly-shaped shield and semi-circle tab handle. "Pacee" and "Small Beginnings" are imprinted on the shield; 16,000 sold nationwide from October 1999 through April 2000; Small Beginnings Inc., Hesperia, California (800) 676-0462

GBC Shredmaster with serial numbers beginning with MS or MT; 3,000 sold nationwide from August through September 2000; General Binding Corp. (GBC), Northbrook, Illinois (888) 247-4135 www.quartetgbc.com/products/shredders/75x_recall.html

The Boyds Collection label Natalie Nibblenose and Nickie Nibblenose 6 inches tall with movable joints; 60,000 sold nationwide from December 1999 through September 2000; Small Small World, Englewood, New Jersey (800) 485-7211

2-prong plug with plastic base (not labeled). 6 ft long extension cords with 2-prong plug (not labeled); 17,500 power strips and 10,000 extension cords sold at discount stores in the eastern United States and Puerto Rico from September 1998 through September 2000; The Howard Berger Co. Inc., Brooklyn, New York (800) 221-6895

Craftsman® Radial arm 8, 8-1/4, 9 and 10 inch saws with model number beginning with 113; 3.7 million sold through Sears stores and catalogs nationwide from 1958 through 1995; Emerson Tool Co., St. Louis, Missouri (800) 511-2628 www.radialarmsawrecall.com

Halo brand Metropolitan Ice Series #945 and #1945; 34,000 sold nationwide from September 1996 through October 2000; Cooper Lighting, Elk Grove Village, Illinois (800) 954-7145

Kickin' Mini-Scooters made of chrome-plated steel and Racer X20TM model; 90,000 Kickin' Mini scooters sold at Toys R Us stores nationwide from May through September 2000. 7,500 Racer X20TM scooters sold at Discovery and Mervyn's stores and Discovery web site from August through September 2000; Kent International Inc., Parsippany, New Jersey (800) 451-KENT (5368) and Kash 'N Gold Ltd., Ronkonkoma, New York (800) 354-8785

Red, blue or aqua fleece "Snuggle Up" slippers with suede soles; 2,000 sold nationwide through L.L. Bean stores, catalogs and their website; L.L. Bean Inc., Freeport, Maine (800) 555-9717

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Topics are listed alphabetically. Following each topic, the volume and issue number of the *Health Letter* containing the article is listed. For example, an article on the topic of Accutane can be found in volume 4 number 5 (V4#5) of the *Health Letter*. Volumes are chronological (volume 1 was issued in 1985). Back issues are \$3.00 each. Indicate issues wanted and send check made to Public Citizen, 1600 20th Street, NW, Washington, DC 20009.

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regulations that the FDA issued three Notices of Intent to Revoke (withdrawal of authorization to ship blood products in interstate commerce) for various ARC establishment licenses and actually revoked one license (the Albany Regional Blood Center). On September 10, 1990 FDA Acting Commissioner Benson wrote to the ARC citing "continuing release of unsuitable blood products and specified the corrective actions that ARC must take such as establishing control over regional operations..."

Since 1993, according to the FDA brief, "FDA has sent ten letters...advising ARC of significant areas of noncompliance.... At no time has ARC indicated that it disagreed with a letter."

In addition, an FDA inspection of ARC headquarters, completed in April 2000, found among 63 observations, "a deficient quarantine system that does not prevent release of unsuitable products; improper release by ARC of cytomegalovirus (CMV)-positive blood products; donors being associated with

An August 14, 2000 meeting involving Dr. Bernadine Healy, current ARC President, you and other FDA and ARC personnel yielded some shocking statements from Dr. Healy. She said that the findings of the April 2000 FDA inspection of ARC headquarters were "alarming" and that the "ARC headquarters was at fault regarding problems with its centralized computer system that had periodically "lost functionality". She also said that the "severity" of the issues held the potential for "grave impact" to patients. She stated, however, that ARC management had not been aware of the seriousness of these problems. In a July 10, 2000 phone call from Dr. Healy to Robert Bowers, Director of the Baltimore FDA District office, Dr. Healy said she was "stunned" by the conditions found by the FDA at ARC Headquarters and said she was totally unaware of the number of problems and the period of time over which some problems had existed. She assured Mr. Bowers that her predecessor, Elizabeth Dole, had said she too was unaware of the deviations.

Whether Dr. Healy or Elizabeth Dole personally knew of these serious ARC problems is not relevant. They, like all manufacturers of blood products, have a legal obligation to ensure that the necessary systems and controls are in

In summary, the ARC, including its regional blood centers, have for at least 15 years been consistently violating the laws and regulations governing the conduct of the blood industry. For the last eight years, there have been flagrant violations of the 1993 Consent Decree with never-ending promises that things will get better. It is time for the FDA to stop playing dangerous, cooperative, polite games with the ARC and ask that the organization be held in contempt of court for recklessly disregarding the 1993 Consent Decree. Otherwise, it will only be a matter of time before (if it has not happened already) patients receiving blood or blood products will become needlessly infected because of the sloppy procedures documented in many FDA inspections.

We look forward to hearing from you!

Public Citizen's Health Research Group ♦ *Health Letter* ♦ 15

FDA Accuses Red Cross of Jeopardizing the Safety of the Blood Supply

On December 1, Dr. Sidney Wolfe sent the following letter to Dr. Jane Henney, Commissioner of the Food and Drug Administration (FDA) concerning serious problems with the American Red Cross.

In papers filed on November 28, 2000 in the U.S. District Court for the District of Columbia, the FDA has documented long standing, widespread and dangerous practices by the American Red Cross (ARC) which have jeopardized the safety of the U.S. blood supply and which have violated a 1993 Consent Decree between the FDA and the ARC. In its brief, the FDA stated that "ARC has been out of compliance with the statute and CGMP [current good manufacturing practices] since at least 1985...FDA believes that additional

measures are essential to bring ARC into compliance with CGMP so that the public may be assured of safe blood and blood products." You are aware of many of these issues because of your attendance at an August 14 meeting at the FDA involving ARC President Dr. Bernadine Healy concerning these serious problems.

Based on the evidence presented by the FDA, it appears that a strong case can be made by the FDA for requesting that the ARC be held in contempt of court for repeated violations of the 1993 Consent Decree extending through the present. Unless the FDA exercises this legal responsibility, there is little evidence that the ARC will come into compliance with the terms of the 1993 Consent Decree or with U.S. laws and regulations concerning blood and blood products. As a

result, these dangerous practices are likely to continue to the detriment of the public health.

1993 Consent Decree

Because of repeated instances of dangerous blood-handling practices by a number of U.S. ARC regional blood banks, and a failure by the ARC to abide by a voluntary 1988 agreement with the FDA to solve these problems, the 1993 Consent Decree was entered which required the ARC to establish management control over blood service operations and to establish a quality control program.

Examples of problems which precipitated this Consent Decree included inspections following the 1988 voluntary agreement which found such serious violations of FDA laws and

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