PUBLIC CITIZEN HEALTH RESEARCH GROUP

Health Letter

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Public Citizen's Health Research Group Ranking of State Medical Board Serious Disciplinary Actions in 2003

Based on data from the Federation of State Medical Boards (FSMB) on the number of disciplinary actions taken in 2003 against doctors, Public Citizen's Health Research Group has calculated the rate of serious disciplinary actions (revocations, surrenders, suspensions and probation/restrictions) per 1,000 doctors in each state and compiled a national report ranking state boards by the rate of serious disciplinary actions per 1,000 doctors in the year 2003 **(See Table 1)**.

Our calculation of rates of serious disciplinary actions (revocations, surrenders, suspensions and probations/restrictions) per 1,000 doctors by state is created by taking the number of such actions (columns A and B from the FSMB data) and dividing it by the American Medical Association data on nonfederal M.D.s as of December 2002 (adding to this the number of osteopathic physicians if the board is a combined M.D./D.O. board). We then multiplied the result by 1,000 to get state disciplinary rates per 1,000 physicians.

Because some small states do not have many physicians, an increase or decrease of one or two serious actions in a year can have a much greater effect on the rate of discipline in such states than it would in larger states. Therefore, starting with this year, we are calculating the three-year average rate of discipline (for each year and the preceding two years) for all states and listing them by rank so that trends over the past decade can more accurately be examined **(see Table 2)**. As of next year (for the disciplinary data for 2004), we will only be reporting 3-year averages which, for next year, will be the average of the disciplinary rates for 2002, 2003 and 2004.

There were 2,992 serious disciplinary actions taken by state medical boards in 2003, up 4.5% from the 2,864 serious actions taken in 2002. State rates ranged from 1.46 serious actions per 1,000 physicians (Rhode Island) to 11.58 actions per 1,000 physicians (Kentucky), a 7.9-fold difference between the best and worst states. **If all the boards did as good a job as the lowest of the top five boards — the rate for #5, Oklahoma, being 7.88 serious disciplinary actions per 1,000 physicians or 0.788 percent — this would have amounted to a total of 6,638 (0.788 percent of 842,379 non-federal doctors) serious actions a year. This would be 3,646 more serious actions than the 2,992 that actually occurred in 2003, an increase of 121%.**

Worst States (those with the lowest rate of serious disciplines).

As can be seen in Table 1, the

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bottom 15 states, those with the lowest serious disciplinary action rates in 2003, were, starting with the lowest: Rhode Island (1.46 actions per 1,000 physicians), Wisconsin (1.66 per 1,000 physicians), Minnesota (1.67 per 1,000 physicians), Delaware (1.71 per 1,000 physicians), Michigan (1.77 per 1,000 physicians), Mississippi (1.77 per 1,000 physicians), Pennsylvania (1.96 per 1,000 physicians), Hawaii (1.97 per 1,000 physicians), Arkansas (2.00 per 1,000 physicians), Maryland (2.00 per 1,000 physicians), North Carolina (2.04 per 1,000 physicians), Maine (2.13 per 1,000 physicians), Florida (2.30 per 1,000 physicians), Illinois (2.54 per 1,000 physicians), and Kansas (2.57 per 1,000 physicians).

Table 2 shows that five of these 15 states, (Wisconsin, Minnesota, Tennessee, Delaware, and Hawaii) have consistently been in the bottom 15 states for nine consecutive 3-year average periods. Pennsylvania and Illinois have been in the bottom 15 states for eight of the last 3-year average periods. Large decreases in rates and rankings occurred for states such as Mississippi, in the top 10 states for seven consecutive 3-year averages until 2001 (the average of 1999, 2000 and 2001) but falling substantially since then to 20th for the latest 3-year average. Similarly Arkansas, in the top 10 states in the late 1990's, has fallen sharply to 29th since the 2000 3-year average in the last several years. Michigan, which was rated 14th or 15th in the late 1990's has sunk to 40th. Looked at another way, 10 of the bottom 15 states, as measured by the rate of discipline in 2003 alone, were also in the bottom 15 for 2003 using the new 3-year moving average (the average rates for 2001, 2002 and 2003).

These data again raise serious questions about the extent to which patients in many states with poorer records of serious doctor discipline are being protected from physicians who might well be barred from practice in states with boards that are doing a better job of disciplining physicians. It is extremely likely that

Table 1: Ranking of Serious Doctor Disciplinary Actions By State Medical Licensing Boards — 2003

Rank 2003*	State	Number of Serious Actions 2003	Number of Physicians 2002**	Serious Actions Per 1,000 Doctors
1	Kentucky	116	10,021	11.58
2	Wyoming	12	1,051	11.42
3	North Dakota	17	1,658	10.25
4	Arizona	103	12,543	8.21
5	Oklahoma	51	6,474	7.88
6	Vermont	18	2,451	7.34
7	Montana	17	2,367	7.18
8	Alaska	10	1,437	6.96
9	West Virginia	30	4,415	6.80
10	Ohio	212	34,303	6.18
11	Colorado	69	12,676	5.44
12	Louisiana	68	12,604	5.40
13	Utah	25	5,156	4.85
14	New York	370	82,536	4.48
15	Alabama	45	10,192	4.42
16	Georgia	89	20,162	4.41
17	Oregon	45	10,271	4.38
18	Iowa	28	6,914	4.05
19	South Dakota	7	1,779	3.93
20	Nebraska	17	4,494	3.78
21	Indiana	55	14,713	3.74
22	California	365	99,720	3.66
23	Texas	184	50,701	3.63
24	Missouri	53	15,867	3.34
25	Massachusetts	98	29,852	3.28
26	South Carolina	33	10,140	3.25
27	New Hampshire	12	3,781	3.17
28	Idaho	8	2,587	3.09
29	Connecticut	39	13,948	2.80
30	Virginia	57	20,981	2.72
31	Washington	46	17,371	2.65
32	New Mexico	12	4,562	2.63
33	New Jersey	81	30,846	2.63
34	District of Columbia	11	4,190	2.63
35	Tennessee	41	15,795	2.60
36	Nevada	11	4,285	2.57
37	Kansas	18	7,014	2.57
38	Illinois	97	38,261	2.54
39	Florida	109	47,403	2.30
40	Maine	8	3,748	2.13
41	North Carolina	46	22,554	2.04
42	Maryland	46	22,956	2.00
43	Arkansas	12	6,008	2.00
44	Hawaii	8	4,056	1.97
45	Pennsylvania	78	39,886	1.96
46	Mississippi	10	5,659	1.77
47	Michigan	45	25,475	1.77
48	Delaware	4	2,337	1.71
49	Minnesota	25	14,964	1.67
50	Wisconsin	25	15,097	1.66
51	Rhode Island	6	4,118	1.46
National		**2,992**	**842,379**	**3.55**

* This rank is based on the rate of doctor discipline for 2003 alone

** Includes osteopathic physicians for boards with jurisdiction over both physicians and osteopaths

patients are being injured or killed more often in states with poor doctor disciplinary records than in states with consistently high performance.

Best States (those with the highest rates of serious disciplines).

The top 10 states are (in order): Kentucky (11.58 actions per 1,000 physicians), Wyoming (11.42 per 1,000 physicians), North Dakota (10.25 per 1,000 physicians), Arizona (8.21 per 1,000 physicians), Oklahoma (7.88 per 1,000 physicians), Vermont (7.34 per 1,000 physicians), Montana (7.18 per 1,000 physicians), Alaska (6.96 per 1,000 physicians), West Virginia (6.80 per 1,000 physicians), and Ohio (6.18 per 1,000 physicians).

As can be seen in Table 2, three of these 10 states (Wyoming, Oklahoma and Alaska) have been in the top ten for all nine of the three-year average periods listed. Ohio has been in the top 10 of these three-year average periods for seven of the last nine, Kentucky, North Dakota and West Virginia for six of the last nine, and Arizona for five of the last nine.

With the exception of Vermont, which has improved considerably over the past several years, all of the other nine top-10 states, as measured by the rate of serious disciplinary actions in 2003 alone, were also in the top ten as measured by the 2003 3-year average (2001, 2002 and 2003).

What Makes a Difference?

Boards are likely to be able to do a better job in disciplining physicians if most, if not all, of the following conditions are true:

- Adequate funding (all money from license fees going to fund board activities instead of going into the state treasury for general purposes)
- Adequate staffing
- Proactive investigations rather than only following complaints

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Table 2: Ranks Based on Average Doctor Disciplinary Rates Over Three Years*

State	1995	1996	1997	1998	1999	2000	2001	2002	2003
Alabama	40	39	36	27	18	14	12	11	13
Alaska	5	3	3	1	1	1	1	1	6
Arizona	11	9	7	13	28	18	5	3	1
Arkansas	28	24	16	9	5	8	15	20	29
California	31	32	20	22	22	23	25	24	22
Colorado	9	5	5	6	12	19	16	12	9
Connecticut	35	37	33	37	39	37	39	38	38
Delaware	48	47	44	49	50	50	50	49	50
District of Columbia**	51	51	49	40	42	N/A	N/A	N/A	41
Florida	26	19	22	44	46	44	33	36	37
Georgia	6	8	11	16	16	10	10	10	15
Hawaii	50	49	50	46	48	47	49	50	51
Idaho	36	36	34	25	13	22	14	18	14
Illinois	42	48	41	42	38	45	47	41	36
Indiana	14	20	25	26	19	20	27	32	33
Iowa	3	2	2	4	8	13	8	9	12
Kansas	33	29	38	36	45	43	32	30	30
Kentucky	8	11	12	12	10	5	4	5	2
Louisiana	12	18	26	28	23	21	24	19	17
Maine	39	35	23	14	17	17	29	28	34
Maryland	23	28	37	41	41	38	41	45	47
Massachusetts	46	41	46	48	46	46	37	34	23
Michigan	32	34	19	15	14	15	20	27	40
Minnesota	41	46	48	50	49	48	48	47	48
Mississippi	4	1	1	2	2	6	9	14	20
Missouri	16	26	31	35	34	34	28	29	31
Montana	10	12	15	20	25	36	30	16	8
Nebraska	37	27	40	28	43	40	45	35	28
Nevada	21	15	13	19	29	26	22	25	32
New Hampshire	49	50	51	47	30	25	18	23	24
New Jersey	19	17	24	34	37	30	26	21	25
New Mexico	38	30	27	23	27	24	34	26	21
New York	29	21	17	18	15	12	13	13	18
North Carolina	22	43	32	32	24	35	31	37	42
North Dakota	24	10	14	7	6	2	2	2	3
Ohio	15	13	8	10	7	7	7	7	7
Oklahoma	7	6	6	3	4	4	3	4	5
Oregon	18	16	21	30	31	28	23	17	16
Pennsylvania	47	45	39	39	40	39	36	39	45
Rhode Island	30	24	18	17	21	29	38	40	46
South Carolina	20	33	43	33	35	31	43	44	44
South Dakota	13	22	35	24	20	32	46	48	35
Tennessee	44	42	47	51	51	49	44	42	43
Texas	25	23	28	31	33	33	35	33	26
Utah	45	38	30	21	26	16	11	8	11
Vermont	16	14	10	11	11	9	19	31	19
Virginia	34	40	45	45	32	27	21	22	27
Washington	27	31	29	38	36	41	40	43	39
West Virginia	1	7	9	8	9	11	17	15	10
Wisconsin	43	44	42	43	44	42	42	46	49
Wyoming	2	4	4	5	3	3	6	6	4

* Each year, a disciplinary rate was calculated. For each year, a moving average rate was calculated by adding the rate in that year to the rate in the two preceding years and dividing by three. This rate was then ranked. The ranking in the column marked "2003" thus represents the ranking of that states average rate over the period 2001-2003.

** The District of Columbia did not provide data for 2000

Product Recalls

March 18 — April 17, 2004

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.

DRUGS AND 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 probability that the use of or exposure to the product will cause serious adverse health consequences or death. Class II recalls may cause temporary or medically reversible adverse health consequences. A Class III situation is not likely to cause adverse health effects. If you have any of the drugs noted here, label them "Do Not Use" and put them in a secure place until you can return them to the place of purchase for a full refund. You can also contact the manufacturer. If you want to report an adverse drug reaction to the FDA, call (800) FDA-1088. The FDA web site is *www.fda.gov*.

Name of Drug or Supplement; Class of Recall; Problem	*Lot #; Quantity and Distribution; Manufacturer*
Aspirin and Codeine Phosphate Tablets, USP, 325 mg/60 mg, 100 count bottles; Rx only; Class III; Stability Failure: Product is exceeding the stability specification for free Salicylic Acid.	Lot No.101304A; Exp. 3/2004; 4,392 bottles distributed nationwide; IVAX Pharmaceuticals, Miami, FL
a) **Bromhist-DM Drops**, (Brompheniramine Maleate 1 mg, Pseudoephedrine Hydrochloride 15 mg, and Dextromethorphan Hydrobromide 4 mg), Rx Only; Class III; and b) Bromhist Pediatric Drops, Brompheniramine Maleate 1 mg, Pseudoephedrine Hydrochloride 15 mg. Rx Only; Class III. Mislabeling: Bromhist-DM drops packaged in Bromhist Pediatric Drops carton. Carton is not labeled to contain Dextromethorphan Hydrobrimide 4mg/mL.	a) and b) Lot No. P03106; Exp.1/2006; 1,221 units distributed nationwide; Great Southern Laboratories; Houston, TX
Butalbital, Aspirin & Caffeine Tablets,USP, 50mg-Butalbital/325mg-Aspirin/40mg-Caffeine; 100 count bottles; Class III; Stability Failure: Product lacks stability for Butalbital drug ingredient.	Numerous lots; 96,113 bottles distributed nationwide; Alpharma Purepac, Elizabeth, NJ

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MEDICAL BOARDS, *from page 3*

• The use of all available/reliable data from other sources such as Medicare and Medicaid sanctions, hospital sanctions and malpractice payouts

• Excellent leadership

• Independence from state medical societies and other parts of the state government

• A reasonable statutory framework for disciplining doctors (preponderance of the evidence rather than beyond reasonable doubt or clear and convincing evidence as the legal standard for discipline).

It is clear that state-by-state performance is spotty. Only one of the nation's 15 largest states, Ohio, is represented among those 10 states with the highest disciplinary rates. Illinois and Pennsylvania, other large states, have consistently been near the bottom and California and New Jersey have hovered around the middle. Massachusetts, consistently in the bottom 15 states for the three-year averages until the 2001 three-year average, has improved substantially since then.

Given the importance of medical boards in protecting patients from doctors who are not practicing medicine in the best manner and are thus endangering the lives and health of residents, most states are not living up to this obligation. Serious attention must be given to finding out which of the above variables are deficient in each state. Then action must be taken, legislatively and through pressure on the medical boards, to increase the amount of discipline and, thus, the amount of patient protection.

DRUGS AND DIETARY SUPPLEMENTS *cont.*

Name of Drug or Supplement; Class of Recall; Problem	*Lot #; Quantity and Distribution; Manufacturer*
Clobetasol Propionate Cream, USP, 0.05%, 30 gram tubes, Rx only; Class III. Impurities/Degradation products; Presence of Benzophenone and Irgacure 184 from the varnish coating on tubes.	Lot Nos. 19877 (Exp. 8/04) and 19987 (Exp. 11/04); 55,280 units distributed nationwide; Teva Pharmaceuticals USA; North Wales, PA
Dakin's Solution 0.25% By Century Half Strength, (0.25% sodium hypochlorite), 473 mL 16 Fl. oz.; Class II; Subpotent: Stability assay failed to meet specification limits.	Lot No. 871; Exp. 10/27/2004; 1,200 distributed nationwide; Century Pharmaceuticals, Inc; Indianapolis, IN
Diltia XT Capsules (diltiazem HCl extended-release capsules, USP) Once-A-Day Dosage, 240 mg, 100 count bottles, Rx Only; Class II. Mislabeling: The recalled product lot was labeled with the incorrect expiration date of November 2004 rather than actual expiration of November 2003.	Lot No. 550C039; Exp. 11/04; 6,552 distributed nationwide; Andrx Pharmaceuticals, Inc.; Fort Lauderdale, FL
a) **FreshLook ColorBlends(r), Daily wear soft (hydrophilic) contact lens**, BC: Median, DIA: 14.5, Rx Only, Sterile, Class III b) FreshLook(r) Colors, Daily wear soft (hydrophilic) contact lens, BC: Median, DIA: 14.5, Rx Only, Sterile, Class III c) FreshLook(r) Enhancers, Daily wear soft (hydrophilic) contact lens, BC: Median, DIA: 14.5, Sterile, Class III d) FreshLook(r) Toric, Daily wear soft (hydrophilic) contact lens, BC: Median, DIA: 14.5, Sterile, Class III. The lens inside the package does not match the prescription information labeled on the primary package.	Numerous lots; 7420 6pk, 1000 2pk, 1720 single blister distributed nationwide and universally; Ciba Vision Corporation; Duluth, GA
Halls Sugarfree Citrus Blend Mentho-Lyptus Cough Drops, (Menthol 5mg), Vapor Action Formula, 25 Drops; Class II. Mislabeling: Presence of undeclared yellow #5 color additive.	Lot No. 03114E; 960 cases distributed nationwide; Cadbury Adams USA Llc; Parsippany, NJ
Levothroid Tablets (levothyroxine sodium tablets, USP) 50 mcg., 100-ct. bottles, Rx Only Class II. Subpotent.	Lot No.30265; Exp. April 30, 2004; 14,207 bottles distributed nationwide; Forest Pharmaceuticals, Inc.; Earth City, MO
MGP Promethazine with Codeine Cough Syrup; (Promethazine Hydrochloride 6.25 mg/5mL and Codeine Phosphate 10 mg/5mL; 4 oz. Bottles; Rx Only; Discoloration, (18 month stability).	Lot Nos. 25016A, 25091A, 25103A, 25408A, 25409A,25457A, 25525A; 149,505 bottles distributed nationwide; Morton Grove Pharmaceuticals, Inc.; Morton Grove, IL
Microgestin Fe 1/20 (Norethindrone Acetate and Ethinyl Estradiol Tablets, USP and Ferrous Fumarate Tablets), 28-Day Regimen, Each white tablet (21) contains 1 mg norethindrone acetate and 20 mcg ethinyl estradiol. Each brown tablet (7) contains 75 mcg ferrous fumarate, 6 Tablet Dispensers, 28 Tablets Each, Rx only; Class III. Subpotent; ethinyl estradiol component (18 month stability).	Lot No. 63001H02; 21,005 distributed nationwide; Watson Pharmaceuticals, Inc.; Corona, CA
Orphegesic Forte Tablets (Orphenadrine Citrate, Aspirin, and Caffeine Tablets) 50 mg/770 mg/60 mg, 100 and 500 tablet bottles, Rx only; Class III. Subpotent; caffeine (9-month stability test).	Lot Nos. 037407 and 037408, Exp. 3/2005; 7,648 bottles distributed nationwide; Par Pharmaceutical, Inc.; Spring Valley, NY
Perphenazine Tablets, USP, 2mg, 100 count bottles and 500 count bottles, Rx only; Class II. Impurities/Degradation Products.	Lot Nos. 076092A and 076092B; Exp. 10/2004; 1.699 bottles/100 ct bottles & 144/500 ct bottles distributed nationwide; Vintage Pharmaceuticals, Inc.; Charlotte, NC
PREMARIN (conjugated estrogens tablets, USP), 0.625 mg, 1000 count bottles, Rx only; Class III. Dissolution Failure.	Lot No. A57921; Exp. 10/05; 48 bottles distributed nationwide; Richmond Division of Wyeth; Richmond, VA

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DRUGS AND DIETARY SUPPLEMENTS *cont.*

Name of Drug or Supplement; Class of Recall; Problem	*Lot #; Quantity and Distribution; Manufacturer*
Questran Powder (Cholestyramine for Oral Suspension, USP) 4 grams cholestyramine resin, USP per scoopful, 378 G (168 G anhydrous cholestyramine) Cans, Rx Only; Class III; Superpotent (6 month stability).	Lot No. 3A63688; 18,571 cans distributed in NY; Bristol-Myers Squibb Co.; New Brunswick, NJ
Tebamide Suppositories, (Trimethobenzamide HCl) 100 mg, Pediatric Suppositories, 10 count boxes, Rx Only; Class III. Subpotent; benzocaine (stability).	Lot No. 2137-6; Exp. 6/04; 36,096 boxes distributed nationwide; G & W Labs, Inc.; South Plainfield, NJ
VANTIN Tablets (cefpodoxime proxetil tablets), 200 mg, 20 tablet bottle, Rx only; Class I. Mislabled; bottles labeled as Vantin 200 mg may actually contain Lanoxin 0.25 mg.	Lot No. K08210301; Exp. 04/2008; 500 bottles distributed nationwide; Graham Development Inc.; Oneonta, NY
Zyprexa Tablets (Olanzapine), 15 mg and 20 mg, 60 tablet bottles, Rx only, Class II; Counterfeit : An unknown number of bottles bearing these lot numbers are counterfeit, in that they have been repackaged, relabeled and/or may contain different strengths or mixed strength tablets differing from their labeled contents and/or bear extended expiration dates, as the source of the repacked and/or relabeled bottles is unknown.	Lot Nos. 7EF27A, 7EF28A; (Exp. 8/1/05); 7ED87A, 7EE34A; (Exp. 7/1/05); 67 bottles distributed nationwide; FPP Inc; Cincinnati, OH

MEDICAL DEVICES

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

Name of Device; Class of Recall; Problem	*Lot #; Quantity and Distribution; Manufacturer*
MediSense Precision QID Blood Glucose Test Strips, sold in boxes of 50 and 100; Class II; Potential counterfeit product/box.	Numerous lots; Unknown number of units sold nationwide, in Puerto Rico and the Bahamas; AmeriSource Bergen; Chesterbrook, PA

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 (800) 638-2772. The CPSC web site is *www.cpsc.gov*.

Name of Product; Problem	*Lot #; Quantity and Distribution; Manufacturer*
Air Hockey Tables. The blower motor, located under the table, has an opening large enough for a child's finger, posing a laceration hazard.	Arctic Flash, Arctic Wind and Air Elegance model air hockey tables; approximately 15,000 sold nationwide since 1994; Valley Dynamo; Richland Hills, TX; (800) 304-2929
Bunk Beds. A metal "j" hook on the guardrails can become dislodged, allowing the guardrail to slide or move out of position. This can allow the guardrail to detach from the bunk bed or allow the occupant to roll off the top bunk.	The top bunk guardrails on Ethan Allen Ryan and P.J. Bunk Beds have item numbers 35-5659-4, 36-5659-3 or 36-5659-4; about 2,000 sold at Ethan Allen stores nationwide from June 2003 through December 2003; Ethan Allen;of Danbury, CN; (888) 339-9398; www.ethanallen.com

CONSUMER PRODUCTS *cont.*

Name of Product; Problem	*Lot #; Quantity and Distribution; Manufacturer*
Chair and Table Sets. A metal rod can protrude through the fabric and its sharp edges could cause scratches or cuts.	"Poof" Chair and Table Sets include two semi-circular chairs and one circular table in blue, red, and yellow fabric; 155 sold nationwide and in Canada from June 2003 through January 2004; Palliser Furniture Ltd., Winnipeg, Manitoba, Canada; (877) 840-7396; charper@palliser.ca
Children's Easter Books. A sponge "touch-and-feel" item inside the book can detach or small pieces can be torn away, posing a choking hazard to young children.	My Easter Basket Book; About 5,000 sold nationwide from February 2004 through March 2004; Kingfisher Publications PLC, a UK-based subsidiary of Houghton Mifflin Company; Boston, MS; (800) 289-4371; toll-free at (800) 289-4371; trade_customer_service@hmco.com
Compact Utility Tractors. Some of the steel bolts used to secure Roll Over Protective Structure (ROPS) to the tractor's real axle can shear off, decreasing the strength of the ROPS and its ability to protect the operator in the event of a roll over incident.	John Deere Compact Utility Tractors; 300 sold by Authorized John Deere dealers nationwide during January and February 2004; John Deere; Moline, IL; (800) 537-8233; www.johndeere.com
Cribs. An incorrect screw (used to attach the movable gate) was provided for the assembly of some of these cribs. The crib cannot be assembled using this screw. However, if consumers have substituted their own screw, it may not properly hold the movable gate in place. The result is a potential risk that a child could fall from the crib or become entrapped between the gate and the mattress.	Isabella model cribs; 318 sold nationwide from November 2003 through February 2004; Stanley Furniture Company Inc.; Stanleytown, VA; (888) 839- 6822
Electric Heaters. Electrical connections inside of the heater can become loose. This could cause the metal portion of the heater to become energized, posing a serious shock hazard to consumers.	"Sun-Sational" Deluxe Radiant Heaters; 150,000 sold nationwide from August 1996 through February 2004; Lakewood Engineering & Manufacturing Co.; Chicago, IL; (888) 858-3506; www.lakewoodeng.com
Home Entertainment Wall Units. The control box for the touch dimmer lighting mechanism can overheat, posing a fire hazard to consumers.	Encore! Home Entertainment Wall Units. 400 sold nationwide from July 2003 through January 2004; APA Marketing Inc.; Commerce, CA; (866) 220-9395 ext. 212
Lawn Mowers, Lawn Tractors and Garden Tractors. Plastic components on these lawn mowers and lawn tractors can crack if they are struck by an object thrown from the blade. Objects can be ejected from the mower unexpectedly and could hit nearby consumers.	Murray lawn mowers, lawn tractors, and garden tractors; About 8,000 sold nationwide from November 2003 through February 2004; Murray, Inc.; Lawrenceburg, TN; (800) 316-1073; www.murray.com

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THE PUBLIC CITIZEN HEALTH RESEARCH GROUP
Health Letter

The Health Research Group was co-founded in 1971 by Ralph Nader and Sidney Wolfe in Washington, D.C. to fight for the public's health, and to give consumers more control over decisions that affect their health.

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Our Web site address is **www.citizen.org/hrg**.

The Antidepressant Fluoxetine (PROZAC) and Suicidal Ideation — Déjà vu 1991

Fourteen years ago, in May 1991, the Health Research Group petitioned the Food and Drug Administration (FDA) to require a warning in the professional product labeling, or package insert, of fluoxetine (PROZAC) concerning the risk of suicidal impulses in patients using the drug. Fluoxetine belongs to the family of antidepressants known as selective serotonin re-uptake inhibitors, or SSRIs.

Our petition was based on a number of published case reports of people who had developed self-injurious thoughts and behavior, often not long after starting to use fluoxetine. At the time we filed our petition, other widely prescribed SSRIs such as sertraline (ZOLOFT) or paroxetine (PAXIL) were not on the market.

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CONSUMER PRODUCTS *cont.*

Name of Product; Problem	*Lot #; Quantity and Distribution; Manufacturer*
Mountain bicycles. The rear shock absorber allows the aluminum, dual-suspension frame to flex severely, causing the frame to become unstable and break, posing the risk of injury to riders.	Mongoose aluminum 20-inch-wheel "D-XR AL" mountain bicycles; about 14,000 sold nationwide from September 2003 through March 1, 2004; Pacific Cycle Inc.; Madison, WI; (877) 564-2261
Snail Push Toys. The screw securing the toy handle to the push toy could detach, posing a choking hazard.	Wood push toy with moveable parts painted purple, green, yellow, or orange; about 900 old only at Babies "R" Us stores from July 2003 through November 2003; Babies "R" Us; Wayne, NJ; (800) 804-5419; www.toysrusinc.com/productrecall
Toy Trucks. A problem with the circuit board causes the toy truck to overheat, posing a fire and burn hazard.	Radio-control toy trucks. 287,000 sold nationwide from July 2003 through February 2004; Nikko America Inc.; Plano, TX; at (866) 232-6013; www.nikkoamerica.com/recall
TV/VCR Carts. The carts can tip over and injure or kill children and adults when the cart and the television fall.	TV/VCR carts sold in kit to be assembled; oak and cherry finish; 29.5 inches wide, 18 inches deep, 27 inches high; 592,000 sold nationwide from January 1993 through December 1999; Sauder Woodworking Co.; Archbold, Ohio; (888) 800-4590; www.sauder.com
Votive Candles. These votive candles can burn with a high flame or irregular flame posing a fire hazard to consumers.	"Real Essence" votive candles, specifically Rosewood Tea; Lilac Blossom; Vintage Leather; Brushed Suede; Warm Vanilla Sugar; Sweet Cinnamon Pumpkin; Spiced Cider; and Amber Myrrh; 733,000 sold nationwide from March 2003 through February 2004; Bath & Body Works and The White Barn Candle Company; Columbus, OH; (800) 395-1001
Wall Sconces. The tie-downs, which secure the electrical wires to the mounting bracket, may come loose, causing the wire to touch the bulb and pose a fire hazard to consumers.	Alabaster Wall Sconce Lights, model nos. AL-3208, AL-5008, and AL-5108. 1,400 sold nationwide from January 1998 through November 2003; Brass Light Gallery Inc.; Milwaukee, WI; (888) 212-4953
Water Bottles. The pull-up, black plastic drinking spout can detach, posing a choking hazard to young children.	Black plastic water bottles in green canvas sport's holder; "H&M" is written on the bottle. 6,300 distribed nationwide as free premium with purchase of children's wear between February 2004 and March 5, 2004; H&M; New York, NY; (877) 439- 6261; www.hm.com
Window Air Conditioners. If the outside fan blade becomes blocked when operating in the heating mode, this unit could present a fire hazard.	8,000 BTU window air conditioners with electric heat; 13,500 sold nationwide from January 2003 through February 2004; Fedders Corporation; Liberty Corner, NJ; (866) 857-8015; www.fedders.com/safetyrecall

FLUOXETINE, *from page 8*

The warning we sought said:

"A small minority of persons taking fluoxetine have experienced intense, violent, suicidal thoughts, agitation, and impulsivity after starting treatment with the drug. Some of the people involved had no prior history of depression or suicidal thoughts and were being treated with fluoxetine for other problems (e.g. obsessive-compulsive disorder). Whether development of such symptoms is coincidental or drug-related is still under investigation. Fluoxetine should only be used under careful medical supervision, and patients are advised to consider alerting relatives and friends to their use of fluoxetine and the risk of suicidal obsession and self-injurious behavior."

On March 22, 2004, the FDA issued a Public Health Advisory on the use of antidepressants in children and adults warning that close observation of these patients is needed because of the possibility of worsening depression or the emergence of suicidal thoughts. The drugs included in the warning were bupropion (WELLBUTRIN), citalopram (CELEXA), fluoxetine, fluvoxamine (LUVOX), mirtazapine (REMERON), nefazodone (SERZONE), paroxetine, sertraline, escitalopram (LEXAPRO) and venlafaxine (EFFEXOR). It should be noted that the only drug that has received approval for use in children with major depressive disorder is fluoxetine (Prozac). Several of these drugs are approved for the treatment of obsessive-compulsive disorder in pediatric patients, for example, sertraline, fluoxetine, and fluvoxamine. Fluvoxamine is not approved as an antidepressant in the U.S.

The FDA has requested changes to the professional product labeling, or package inserts, for these drugs to reflect the Public Health Advisory. The labeling changes are consistent with recommendations made to the FDA at a meeting of the Psychopharmacological Drugs Advisory Committee (PDAC) and the Pediatric Subcommittee of the Anti-Infective Drugs Advisory Committee, held on February 2, 2004. The possibility of suicidality associated with the use of antidepressant drug products in the pediatric population was also the subject of two previous FDA communications on June 19, 2003, and on October 27, 2003.

Health care providers should carefully monitor patients receiving antidepressants for possible worsening of depression or suicidality, especially at the beginning of therapy or when the dose either increases or decreases.

Other warnings included in the FDA's March 22nd advisory were:

• Health care providers should carefully monitor patients receiving antidepressants for possible worsening of depression or suicidality, especially at the beginning of therapy or when the dose either increases or decreases. Although FDA has not concluded that these drugs cause worsening depression or suicidality, health care providers should be aware that worsening of symptoms could be due to the underlying disease or might be a result of drug therapy.

• Health care providers should carefully evaluate patients in whom depression persistently worsens, or emergent suicidality is severe, abrupt in onset, or was not part of the presenting symptoms, to determine what intervention, including discontinuing or modifying the current drug therapy, is indicated.

• Anxiety, agitation, panic attacks, insomnia, irritability, hostility, impulsivity, akathisia (severe restlessness), hypomania, and mania have been reported in adult and pediatric patients being treated with antidepressants for major depressive disorder as well as for other indications, both psychiatric and nonpsychiatric. Although the FDA has not concluded that these symptoms are a precursor to either worsening of depression or the emergence of suicidal impulses, there is concern that patients who experience one or more of these symptoms may be at increased risk for worsening depression or suicidality. Therefore, therapy should be evaluated and medications may need to be discontinued when symptoms are severe, abrupt in onset, or were not part of the patient's presenting symptoms.

• If a decision is made to discontinue treatment, certain of these medications should be tapered rather than stopped abruptly (the professional labels for these drugs give specific details).

• Because antidepressants are believed to have the potential for inducing manic episodes in patients with bipolar disorder, there is a concern about using antidepressants alone in this population. Therefore, patients should be adequately screened to determine if they are at risk for bipolar disorder before initiating antidepressant treatment so that they can be appropriately monitored during treatment. Such screening should include a detailed psychiatric history, including a family history of suicide, bipolar disorder, and depression.

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• Health care providers should instruct patients, their families and their caregivers to be alert for the emergence of agitation, irritability, and the other symptoms described above, as well as the emergence of suicidality and worsening depression, and to report such symptoms immediately to their health care provider.

What You Can Do

DO NOT ABRUPTLY DISCONTINUE ANY OF THE ANTIDEPRESSANTS MENTIONED IN THIS ARTICLE — DISCONTINUATION OF THESE DRUGS SHOULD TAKE PLACE ONLY UNDER MEDICAL SUPERVISION.

Patients and parents whose children are using any of the drugs mentioned above should consult the prescribing physician immediately.

Saline Spray: Do Try This at Home

As spring approaches, it brings with it flowers, pollen, and allergies. While there are a plethora of over-the-counter and prescription medications for symptomatic relief of allergic symptoms, sometimes the simplest solutions are the most effective. They are certainly the cheapest!

Saline nasal sprays, mists, and washes are a safe, simple combination of salt and water that can be extremely helpful in relieving nasal stuffiness, congestion, and dryness. Normal (isotonic) saline has the same concentration of salt as is normally found in the body and is therefore very gentle. There are several commercial preparations of saline, such as Ocean (made by Fleming), Little Noses (by Vetco), and Simply Saline (by Blairex Laboratories). These solutions often contain preservatives which can be irritating, however, so making your own saline at home may be both medically and economically preferable.

The recipe is simple: mix 1/2 teaspoon uniodized salt (the iodine can be irritating) with 8 ounces (one cup) of water that has been boiled and is still warm. You may add one small pinch of baking soda to decrease stinging. Allow the mixture to cool to body temperature before using. You can use an ear bulb syringe to squirt the saline up your nostrils.

There is no limit to how often you can use normal saline to irrigate your nose. A minimum of four times per day until symptoms resolve is generally recommended. Saline can be used for more than just allergy sufferers; it can relieve nasal congestion caused by the common cold, and can be helpful for babies, whose small noses become congested easily. Store commercial saline at room temperature with the lid on tightly. Keep homemade saline in the refrigerator for up to 24 hours and then throw it out and make a new batch if needed. Wipe the tip of the applicator with a clean, damp tissue and replace the cap right after use. Do not share your saline with others.

High pollen counts can also cause itchy, watery eyes. While there are expensive allergy eye drops you can buy, you may want to try this simple home remedy. Fill your bathroom sink with cool or tepid water. Holding your breath, submerge your face. Open your eyes underwater and blink a few times. That's it! Rinsing your eyes is refreshing and rinses away pollen. It is an easy, but surprisingly effective, therapy.

OUTRAGE, *from page 12*

resold. Incredibly, this is not possible for pharmaceuticals. A document could easily circulate with the batch of drugs with each resale, greatly reducing the possibility for counterfeiting or adulteration, because the perpetrator could be more easily identified. Such a document, called a pedigree, was mandated by Congress in the Prescription Drug Marketing Act (PDMA) of 1987. Even the pharmaceutical companies support it, presumably because it would protect their brands from being tarred by counterfeit knockoffs. In 1988, the FDA issued a guidance document that laid out its interpretation of the PDMA. However, the FDA did not even propose a regulation to implement the PDMA until 1994 and a final regulation was not completed until 1999. In fact, the final regulation was very similar to the 1988 guidance. It was only at that point that complaints from the drug wholesaling industry began in earnest. Ironically, it is among these very wholesalers that the counterfeiters lurk. Nonetheless, the FDA has "delayed" implementation of the rule five times; through these accumulating stalling tactics, the FDA has so far succeeded in frustrating the intent of Congress for 17 years.

Historically, the path from a pharmaceutical manufacturer to a consumer was relatively simple: manufacturers sold to wholesalers who sold to hospitals or pharmacists who administered medications or filled prescriptions. Over the years, this path has become circuitous. Secondary wholesalers might obtain the drugs from one of the three major (primary) wholesalers and then sell it to hospitals or pharmacists. Sometimes primary wholesalers obtain drugs from the secondary wholesalers. Occasionally, second-

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ary wholesalers may procure the drugs from the manufacturer themselves. These circuitous roots to the patient, combined with the lack of a pedigree, provide the opportunity for counterfeiters and other fly-by-night operators to insert themselves into the process. In the process, quality assurances may be lost as drugs are not properly stored, for example.

This is where it starts to get a bit technical. At the time the PDMA was enacted, Eli Lilly had contracts with more than a dozen wholesalers, which were the sole companies through which Lilly sold its products. To accommodate Lilly, Congress considered these wholesalers to be "authorized" and limited the PDMA's pedigree requirement to "unauthorized" wholesalers. Congress defined authorized wholesalers as those "with whom a manufacturer has established an on-going relationship to distribute such manufacturer's products." But the FDA, in interpreting the PDMA in its never-implemented regulations, took a much broader view of what defined an "authorized" wholesaler: a wholesaler with at least two transactions with a particular pharmaceutical company in a 24-month period and a contract with that manufacturer. Obviously, this is not a very stringent definition, but even that was not good enough for the secondary wholesalers. They simply ignored the guidance and disregarded the requirement for the contract. Thus, any wholesaler with two transactions with a company over two years would be considered "authorized" and thus exempt from the pedigree requirement. In current practice, therefore, most wholesalers simply consider themselves to be authorized, effectively gutting the PDMA.

Congress also required that a pedigree be maintained on "each prior sale, purchase or trade," a requirement the FDA interpreted as applying to "all parties to each prior transaction ... starting with the manufacturer." This seems logical and consistent with Congress' intent. But the secondary wholesalers prefer to interpret the pedigree requirement in the guidance (and the final regulation) as reaching back in the distribution chain only as far as the last authorized wholesaler; thus each time a drug passes through the hands of an authorized wholesaler (using the least restrictive definition, of course), the slate (and the requirement for a pedigree) would be wiped clean.

This important public health issue has thus been in limbo since 1987, with the FDA never implementing its regulations but nonetheless assailing counterfeiters and importers who are aided and abetted by the FDA's failure to regulate. Meanwhile, the secondary wholesalers practice business as usual — all at the cost of potentially exposing U.S. patients to counterfeit and adulterated drugs.

If the agency believes that the PDMA somehow needs revision, then it is incumbent upon it to approach the Congress and make that case. It is not acceptable to simply defy the Congress by writing overly permissive regulations and then never implement them. One final note: In its most recent Federal Register notice delaying the implementation of the 1999 regulations, the FDA further delayed any action until December 1, 2006.

FDA Frustrates Intent of Congress for 17 Years

HRG Deputy Director Peter Lurie, MD, MPH delivered this address before the Taskforce on Drug Importation March 19, 2004.

Thank you for the opportunity to address the Taskforce on the controversial issue of drug importation. From Public Citizen's perspective, drug importation will never be more than a band-aid solution to the underlying problem: out-of-control drug prices. As is well known, drug prices in foreign countries are often half of what they are for identical drugs in the United States. The reason for this is simple: unlike every other industrialized country, the United States refuses to negotiate drug prices or, as is done in Britain, negotiate a guaranteed profit margin for pharmaceuticals. In fact, we are in many respects going in the opposite direction; the recently passed Medicare prescription drug legislation actually prevents the Medicare program from using its massive purchasing power to negotiate lower drug prices.

These spiraling drug prices have driven consumers to look to foreign countries, particularly Canada, to obtain prescription drugs at affordable prices. Were it not for this importation, we would likely not be seeing the degree of concern currently being professed at the Food and Drug Administration (FDA), in particular, over the problem of counterfeit medications. Counterfeits are a long-standing problem in U.S. health care, predating the importation debate by decades. The problem is not restricted to imports; domestically manufactured drugs are also all-too-frequently counterfeited or adulterated.

Yet, while the FDA continues to raise concern over counterfeiting, in part by producing misleading reports that exaggerate the problem or focus on the importation dimension of it alone, the agency is in fact part of the problem. A law that was designed to cut down on counterfeiting has, 17 years after it was passed, still not been implemented, thanks to industry-inspired delays at the FDA.

The current situation can be appreciated by analogy. If a car develops a safety problem, the manufacturer has the ability to track down each car from, for example, that model-year to inform the current owner of the problem, no matter how many times the car has been

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