PUBLIC CITIZEN HEALTH RESEARCH GROUP

Health Letter

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Public Citizen's Health Research Group Ranking of State Medical Board Disciplinary Actions in 1999

Based on the Federation of State Medical Boards (FSMB) data on the number of disciplinary actions taken in 1999 against doctors, Public Citizen 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 extent to which they are taking serious disciplinary actions against doctors (See Table 1, page 2).

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 and dividing it by the American Medical Association data on nonfederal M.Ds as of December 1998 (adding to this the number of osteopathic physicians if the board is a combined M.D./D.O. board) then multiplying the result by 1,000 to get state disciplinary rates.

Nationally, there were 2,696 serious disciplinary actions taken by state medical boards in 1999, down slightly from the 2,732 serious actions taken in 1998. State rates ranged from 10.34 serious actions per 1,000 doctors (Alaska) to 0.96 per 1,000 physicians (Delaware), a 10.8-fold difference between the best and worst states. If all the boards did as good a job as the top five boards, the lowest rate for #5, Oklahoma being 5.95 serious disciplinary actions per 1,000 physicians or .595 percent, this would amount to 4,583 (.595 percent of 770,320 nonfederal doctors) serious actions a year, 1.7 times as many (1,887 more serious actions) as the 2,696 that actually occurred in 1999.

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

The bottom 15 states, those with the lowest serious disciplinary rates in 1999, were, starting with the lowest: Delaware 0.96 per 1,000 physicians), Nebraska (1.23), Tennessee (1.25), Minnesota (1.58), Hawaii (1.69), Connecticut (1.78), Kansas (1.82), South Dakota (1.92), Illinois (2.05), Wisconsin (2.06), D.C. (2.18), Maryland (2.42), Massachusetts (2.43), Florida (2.49), and Washington (2.49). Massachusetts, Tennessee, Minnesota, Wisconsin, Kansas, Hawaii, and Delaware were also in the bottom 15 states in 1997 and 1998. In 1999, the bottom 20 states all had rates of serious disciplinary action that were one-half or less than the rate of all of the top five states.

These data 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 likely that patients are being injured or killed more often in states with poor doctor disciplinary records than in states with consistent top performances.

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

Table 1 lists each state's ranking and rate in descending order. The top 10 states, or those with the highest rate of serious disciplinary actions per 1,000 physicians are (in order): Alaska (10.34/1,000 physicians), North Dakota (8.77), Wyoming (8.15), Idaho (7.02), Oklahoma (5.95), Kentucky (5.92), Ohio (5.90), Mississippi (5.87), Vermont (5.34), and Colorado (5.24). Five of these 10 states (Alaska, Oklahoma, Mississippi, Wyoming, and Ohio) were also in the top 10 in 1997 and 1998 and two, (Mississippi and Alaska) have been in the top 10 for nine straight years. Oklahoma, 5th this year, has been in the top 10 states for eight of the last nine years. Wyoming, 3rd this year, has been in the top 10 for seven of the last nine years and Vermont, 9th this year and Ohio, 7th this year, have been in the top ten for five of the last nine years (See Table 2, page 3).

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, as it also was in 1996, 1997 and 1998. Other large states such as, New York, Michigan and California (14th, 19th and 20th respectively in 1999) have shown improvement from 40th, 49th and 37th in 1991. But other large states such as Texas, Pennsylvania, Massachusetts and Illinois (34th, 36th, 39th and 43rd in 1999) have not done very much doctor discipline for many of the last 10 years.

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
- The use of all available/reliable data from other sources such as Medicare and Medicaid sanctions, hospital sanctions
- 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).

Table 1

Ranking of Serious Doctor Disciplinary Actions By State Medical Licensing Boards — 1999

Rank 1999	State	Number of Serious Actions 1999	Total Number of Physicians 1998	Serious Actions Per 1,000 Doctors
1	Alaska	12	1160	10.34
2	North Dakota	14	1596	8.77
3	Wyoming	8	981	8.15
4	Idaho	16	2278	7.02
5	Oklahoma	37	6216	5.95
6	Kentucky	54	9115	5.92
7	Ohio	190	32220	5.90
8	Mississippi	30	5107	5.87
9	Vermont	11	2061	5.34
10	Colorado	59	11253	5.24
11	Iowa	33	6602	5.00
12	Arkansas	27	5486	4.92
13	Alabama	45	9559	4.71
14	New York	366	77781	4.71
15	Georgia	82	17961	4.57
16	Indiana	60	13267	4.52
17	West Virginia	19	4249	4.47
18	New Hampshire	14	3309	4.23
19	Michigan	101	24001	4.21
20	California	367	90940	4.04
21	Arizona	42	11025	3.81
22	Virginia	70	18441	3.80
23	Louisiana	43	11581	3.71
24	Maine	11	3195	3.44
25	Nevada	11	3373	3.26
26	North Carolina	62	19615	3.16
27	New Mexico	13	4138	3.14
28	New Jersey	89	28432	3.13
29	South Carolina	27	8923	3.03
30	Oregon	27	8984	3.01
31	Missouri	45	15211	2.96
32	Montana	6	2036	2.95
33	Utah	13	4770	2.73
34	Texas	124	45707	2.71
35	Rhode Island	10	3784	2.64
36	Pennsylvania	97	38080	2.55
37	Washington	38	15254	2.49
38	Florida	105	42169	2.49
39	Massachusetts	67	27622	2.43
40	Maryland	51	21116	2.42
41	District of Columbia	9	4121	2.18
42	Wisconsin	28	13567	2.06
43	Illinois	73	35581	2.05
44	South Dakota	3	1562	1.92
45	Kansas	12	6577	1.82
46	Connecticut	23	12910	1.78
47	Hawaii	6	3555	1.69
48	Minnesota	21	13275	1.58
49	Tennessee	18	14412	1.25
50	Nebraska	5	4070	1.23
51	Delaware	2	2092	0.96
	Total	2696	770320	3.50

Table 2

Ranking of States 1991-1999: Serious Disciplinary Actions

Rank 1999	Rank 1998	Rank 1997	Rank 1996	Rank 1995	Rank 1994	Rank 1993	Rank 1992	Rank 1991	State
1	1	2	6	8	2	8	7	6	Alaska
2	11	9	2	34	10	3	5	13	North Dakota
3	7	3	31	3	1	21	4	9	Wyoming
4	25	30	21	36	30	37/38	23	34/35	Idaho
5	2	5	7	12	5	2	1	2	Oklahoma
6	14	7/8	14	14	4	4	16	5	Kentucky
7	10	7/8	8	9	24	22/23	19	23	Ohio
8	3	1	1	1	9	9	6	6	Mississippi
9	6	25/26	10	6	39	17	15	10	Vermont
10	18	6	4	5	12	6	8	17	Colorado
11	23	4	3	2	7	5	2	3	Iowa
12	4	13	15	23	28	26	18	29	Arkansas
13	17	23/24	38	30	43/44	29	30	31	Alabama
14	16	16	18	17	29	34	39	49	NewYork
15	12	23/24	19	4	8	10	9	4	Georgia
16	21	19/20	33	28	16	7	14	15	Indiana
17	5	12	11	7	6	1	3	8	West Virginia
18	30	46	51	49	49	47	47	44	New Hampshire
19	13	15	28	21	34/35	35	40	40	Michigan
20	27	18	27	20	34/35	32	42	37	California
21	38	19/20	5	10	17	16	22	22	Arizona
22	40	34/35	50	41/42	32	30	37	32	Virginia
23	15	34/35	44	13	18	11	12	7	Louisiana
24	9	22	17	32	33	41	44	46	Maine
25	26	32	9	11	31	20	25	26	Nevada
26	43	33	48/49	35	36	40	34	42/43	North Carolina
27	8	50	23	15	43/44	49	33	33	New Mexico
28	35	42	20	25	19	18	28	20	New Jersey
29	22	40	45	44	14	15	11	11	South Carolina
30	31	28/29	29	16	20	22/23	24	14	Oregon
31	48	17	30	37	13	12	13	12	Missouri
32	34	11	13	18	3	14	10	19	Montana
33	20	25/26	16	38	46	39	43	18	Utah
34	28/29	37	35	19	23	28	29	21	Texas
35	24	10	25	26	26	42	41	50/51	Rhode Island
36	45	27	32	43	47	48	48	47	Pennsylvania
37	36/37	28/29	40	24	27	24	17	24	Washington
38	49	36	22	22	25	25	21	27	Florida
39	47	45	43	40	37	45	46	48	Massachus.
40	36/37	38	41	29	21	19	27	42/43	Maryland
41	33	44	36	50	51	51	45	45	Dist. of Columbia
42	46	39	34	47	41	27	26	34/35	Wisconsin
43	41	21	46	45	40	31	36	36	Illinois
44	19	14	42	33	11	13	32	50/51	South Dakota
45	44	41	12	46	22	37/38	20	25	Kansas
46	32	31	37	27	42	36	35	30	Connecticut
47	39	49	39	51	50	46	50	41	Hawaii
48	42	51	47	39	45	33	31	28	Minnesota
49	51	48	48/49	31	38	44	49	38	Tennessee
50	28/29	43	24	41/42	15	50	38	39	Nebraska
51	50	47	26	48	48	43	51	16	Delaware

Do Not Use This Drug

Owners of Worst Pills, Best Pills *or subscribers to* Worst Pills, Best Pills News *know that we have advised "do not use" the widely-prescribed heartburn drug, Propulsid, for more than one and one-half years. This Health Research Group letter to the FDA Commissioner Dr. Jane Henney protests the deadly slowness of the process of clearing this dangerous drug off the market.*

Dear Dr. Henney:

We have obtained new FDA reports concerning 23 additional U.S. deaths since the beginning of this year from cardiac arrhythmias or sudden cardiac arrest/death associated with the use of the heartburn drug, Propulsid. These are in addition to the 80 previous FDA-announced heart rhythm-associated deaths (based on reports received through December 31, 1999) which formed the basis of the announcement on March 23rd to *eventually* stop the marketing of Propulsid. The continued occurrence of arrhythmia-associated fatalities, for a current total of 103 such deaths, further emphasizes the serious public health dangers of the FDA's going along with Johnson and Johnson's reckless decision to allow this deadly drug to remain in pharmacies for more than four more months, until mid-August. We insist that you order the removal of Propulsid from retail or wholesale channels of commerce within the next two weeks in order to prevent additional people from being killed. There are numerous safer alternatives to Propulsid, including: not eating or drinking alcohol within three hours of bedtime; elevating the head of the bed; a trial of antacids or H2 receptor antagonists such as Tagamet, Pepcid or Zantac; only if none of these are effective, a trial with a proton pump inhibitor such as Prilosec can be attempted.

The 23 newly-reported deaths (reported between January 1, 2000 and March 28th) occurred in people using Propulsid. All involved ventricular arrhythmias, non-specified arrhythmias, cardiac arrest or sudden death. The death reports included people of all ages ranging from a 9-month-old male infant to a 77-year-old man. Thirteen of the 23 people were under 60 years of age.

When the announcement was made on March 23rd that Johnson and Johnson would stop the marketing and distribution of Propulsid by July 14th and allow it in pharmacies until mid-August, it was stated that there would be a "limited access" program set up in order to make the drug available for people with certain disorders such as diabetic gastroparesis, in which there is an impairment of emptying the stomach of food, and for other "off-label" conditions. None of these conditions are FDA-approved uses of the drug since there is not adequate data on the effectiveness of Propulsid for treatment of these medical problems. The argument for the limited access program was that there are no other drugs to which these patients will respond. This program will take the form of an Investigational New Drug Exemption (IND). There would have to be a certification that the patient had an EKG, had been tried on other alternatives first, and was not taking any of the 41 drugs which are contraindicated for use with Propulsid because of life-threatening interactions. There is no excuse, however, for taking so long to set up such a program and allowing four more months of, in essence, unlimited access to this dangerous drug while the limited access program is being set up.

In 1978, after our petition and a lawsuit to immediately ban the diabetes drug phenformin because it was causing a large number of deaths, the drug was immediately taken off the market. In a matter of weeks, not months, it was made available under an IND to those patients whose physicians thought there were no other alternatives. Although there had been hundreds of thousands of patients using the drug before it was banned, similar to the number estimated to be using Propulsid, only 3-4,000 used it under the provisions of the IND after it was removed from the market and that dwindled within several years. FDA officials have said that there are a similarly small number of patients who would qualify for Propulsid under the conditions of the new program.

Unless the FDA forces Johnson and Johnson to promptly clear this drug off drug store shelves, a large number of further preventable deaths are certain to occur in the United States, mainly in people for whom there are numerous alternatives for the treatment of gastroesophageal reflux disease (GERD), also referred to as "heartburn," the principal medical condition for which the drug is prescribed. We look forward to a prompt reply to this urgent request.

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Product Recalls

March 9—April 11, 2000

DRUGS & DIETARY SUPPLEMENTS

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.

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*
Acetic Acid Otic Solution, 2%, in 15 mL units, Rx non-aqueous solution used as an antibacterial and anti-fungal agent in the external ear canal, under labels: Major, Schein, Qualitest; Class III; Subpotency (15 month stability)	Lot Numbers: M235 EXP 4/00, M529 EXP 7/00, M558 EXP 8/00, M583 EXP 9/00, M655 EXP 1/01, M854 EXP 5/01; 73,737 bottles distributed nationwide; Thames Pharmacal Company, Inc., Ronkonkoma, New York
Antacid Calcium Regular Strength, 500 mg, OTC in 150 tablet bottles; Class III; Mislabeling—Supplement facts-labeling panel incorrectly lists calcium level per serving at 4000 mg	Lot Numbers: 9D02410 EXP 05/01, 9K02413 EXP 10/02; 13,846 bottles distributed nationwide; A&Z Pharmaceutical, Inc., Hauppauge, New York
Cafergot(r) Suppositories (ergotamine tartrate .2mg/caffeine 100 mg), Rx indicated as therapy to abort or prevent vascular headache; Class III; Subpotency—Ergotamine at 6-month stability testing	Lot #130B9188 EXP 4/01; 59,304 blister packs distributed nationwide; Novartis Pharmaceuticals Corporation, East Hanover, New Jersey
Clobetasol Propionate Topical Solution, 0.05%, in 25 mL bottles, Rx for the treatment of dermatoses of the scalp; Class III; Product exceeds degradant level at 6-month stability testing	Lot #D095 EXP 2/01; 876 bottles distributed nationwide; E. Fougera and Company, Melville, New Jersey
Diltiazem Hydrochloride Tablets, in 60 mg bottles of 100 and 500, Rx indicated for management of chronic stable angina and angina due to coronary artery spasm; Class III; Dissolution failure (stability)	Lot #662F01 EXP 5/00; 709,100 tablets distributed nationwide; Copley Pharmaceutical, Inc., Canton, Massachusetts
Hydrocortisone (1%) and Acetic Acid (2%) Otic Solution, in 10 mL bottles, Rx solution used as antibacterial and anti-fungal agent in external ear canal, under Thames label and Qualitest labels; Class III; Subpotency (18 month stability)	Lot Numbers: M494 EXP 12/99, M501 EXP 12/99, M530 EXP 2/00, M568 EXP 9/00, M581 EXP 9/00, M644 EXP 11/00, M775 EXP 3/01; 91,599 bottles distributed nationwide; Thames Pharmacal Company, Inc., Ronkonkoma, New York
Ibuprofen Caplets/Tablets, 200 mg, 100 and 500 unit bottles, OTC, packaged under labels: Discount Drug Mart, Bindley Western, Fred's; Class III; Misbranding—The carton and insert do not list the correct inactive ingredients	Lot Numbers: 9071040, 0019547, 9056970, and 9046736; 2,300 bottles estimated to be in the Ohio, Tennessee and Connecticut market for those shipped to Discount Drug; Granutec, Wilson, North Carolina
Lithobid (r) Slow Release Tablets (Lithium Carbonate), in 300 mg bottles of 100, Rx; Class II; Dissolution failure at stability testing	Lot #90573; 14,317 bottles distributed nationwide; Solvay Pharmaceuticals, Inc., Marietta, Georgia
Oxygen, compressed, in size H cylinders; Class III; Mislabeling—Incorrect lot number	Lot #266-01301-01-0201; 20 cylinders distributed in Puerto Rico; Air Products & Chemicals, Inc., Guayanilla, Puerto Rico

DRUGS & DIETARY SUPPLEMENTS, *cont.*

Name of Drug or Supplement; Class of Recall; Problem	*Lot #; Quantity and Distribution; Manufacturer*
Rapid Clear Eye Wash, in 16-fluid ounce bottles, Rx for flushing or irrigating the eye; Class II; Misbranding—Product contains undeclared preservative-chlorhexidine gluconate	Item #90329 Lot #1006 EXP 01/02; 206 bottles distributed in Illinois; H.L. Burton Company, Inc., Buzzards Bay, Massachusetts
Skin care OTC items packaged in plastic jars and distributed under Gabriel SkinCare label: Aloe Care (Hydrocortisone cream), 32 ounce jar Blemish Control Mask (sulfur), 64 ounce jar SPF 16 Sunblock Gel, 4 ounce jar SPF 25 Sunblock Gel, 4 ounce jar SPF 30 Sunblock Lotion, 32 ounce jar SPF 30 Waterproof Sunblock Lotion, 32 ounce jars; Class II; Failure to perform active ingredient testing	All lot numbers; 505 units distributed nationwide and Puerto Rico; Gabriel Skin Care Distributors, Inc., Westlake, Ohio
Skin care OTC items packed in 32 and 64-ounce plastic jars used for the treatment of facial acne, distributed under the Gabriel SkinCare label: a) Blemish Control Gel 2.5%, in 32 ounce jars b) Blemish Control Gel 5%, in 32-ounce jars c) Blemish Control Gel 10%, in 32-ounce jars d) Blemish Wash, in 64-ounce jars e) Blemish Scrub, in 64-ounce jars; Class III; Misbranding and failure to perform active ingredient testing	Lot Numbers: a) 3612; b) 3435; c) 3582; d) 3312 and 3470; e) 3200 and 3569; 118 jars distributed nationwide and Puerto Rico; Gabriel Skin Care Distributors, Inc., Westlake, Ohio
Testosterone, micronized, non-sterile powder, in 5 gram bottles, Rx; Class III; Mislabeling—Some units may contain Testosterone Propionate Powder	Lot #9M6014 EXP 2/04; 1,062 bottles distributed nationwide; Paddock Laboratories, Inc., Minneapolis, Minnesota
Urinary Antiseptic Film Coated Tablets, (Methenamine 40.8 mg), in 100 and 1,000 tablets bottles, under labels: Contract Pharmacal Corporation, Major Pharmaceuticals, Breckenridge Pharmaceutical; Class III; Tablet discoloration	Lot Numbers: 081230 EXP 2/00, 081323 EXP 3/00, 081493 EXP 4/00, 083889 EXP 10/00, 084325 EXP 1/01, 084326 EXP 1/01, 084685 EXP 4/01, 091564 EXP 5/01, 091648 EXP 6/01, 091896 EXP 7/01 and 092891 EXP 8/01; 69,376 units (100-count bottles), 1,776 units (1000-count bottles) and 1,864.9 million bulk tablets distributed nationwide; Contract Pharmacal Corporation (CPC), Hauppauge, New York
Voltaren(r)-XR Extended Release Tablets (Diclofenac Sodium), 100 mg, in 100 count bottles, Rx used for chronic therapy of osteoarthritis and rheumatoid arthritis, and for the treatment of ankylosing spondylitis; Class III; Dissolution failure (release rate) at 4 and 8 hour time period(s)	Lot # 104A7322 EXP 9/01; 9,750 bottles distributed nationwide; Novartis Pharma AG, Stein, Switzerland, Recalled by NovPharm, Suffern, New York.

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*
Mechanical Wheelchair; Class II; Poor design—User can fall backwards and there is potential for injury	Code XTR-4586; 756 units distributed nationwide and internationally between 11/5/98 and 1/10/00; Sunrise Medical Inc., Fresno, 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*
AC Converters; Product presents an electrical shock hazard because the unplugged end of the cord is energized when the other end is plugged in	Labeled in part, "UP/DOWN AC CONVERTER...220V...110V...TAIWAN."; 18,000 sold in small electronic stores in California, Colorado, Missouri, Ohio, Oklahoma, Oregon and Texas; Coast Electronics Supply, Cerritos, California (800) 262-7818

CONSUMER PRODUCTS, *cont.*

Name of Product; Problem	*Lot #; Quantity and Distribution; Manufacturer*
Baby Wipe Warmers; Cracks in the interior tub of these wipe warmers can allow water to contact the electrical components, resulting in consumers receiving an electric shock	Prince Lionheart style 0224; 152,000 sold nationwide from February 1998 through December 1999; Advance Thermo Control (ATC), Hong Kong. Recalled by Prince Lionheart Inc., Santa Maria, California (888) 843-8718
Bounce 'n Play Activity Dome (Recall to repair); Resembles pop up tent. Nylon bands that hold surface level can detach allowing surface to tilt, causing an infant to slide and be trapped in a position in which it is difficult to breathe	Model 79534, all codes that end with 8 and codes that end with 9 and begin with numbers 001 through 286; 235,000 sold nationwide from December 1998 through March 2000; Fisher-Price, East Aurora, New York (800) 505-0600 www.fisher-price.com
Cradle Swing with Detachable Carrier (Recall to repair); When used as a carrier, the locks for the handle can unexpectedly release, causing the seat to flip forward	Model numbers 79321 and 79322; 105,000 sold nationwide from March 1997 through January 1999; Fisher-Price, East Aurora, New York (800) 505-0600 www.fisher-price.com
Electronic Skeet Shoot Games; cartridges can be defective, and can cause the projector to overheat, melt and smoke, presenting a risk of burns to consumers;	Projecting game system including Duck Shoot and Deer Hunter; 435,000 sold nationwide from October 1998 through March 2000; Toymax Inc., Plainview, New York (800) 477-6215 www.toymax.com
Folding Wooden Chairs; The screws holding the chair's front leg folding mechanism can work loose causing the chair to collapse, resulting in injury	B.W. Home brand white wood with rush seat; 1,800 sold nationwide from January 1999 through January 2000; Boston Warehouse Trading Corp., Norwood, Massachusetts (888) 923-2982
Futons; Some futons may fail cigarette ignition resistance tests, in violation of the federal Flammable Fabrics Act, because the flame retardant inside the futons may not have been evenly disbursed. This could result in burn injuries, should one of these futons catch fire	Model numbers 605, 608, 611, and 613, sold under the brand names of Gold Bond, IKEA, and Verlo. All are covered in a natural off-white color; 47,000 sold nationwide from May through October 1998; The Standard Mattress Co., Hartford, Connecticut (888) 512-6169
Jogging Strollers; Stroller's brake can fail, causing the stroller to unexpectedly roll away resulting in injury to child	InSTEP and HEALTHRIDER brand single and double jogging strollers, model numbers: ZS100, ZD200, ZS100WS, ZD200WS, ZS100HR, ZD200HR, PR100 or PR200; 44,000 sold nationwide from December 1998 through July 1999; InSTEP LLC, Mendota Heights, Minnesota (800) 242-6110 www.instep.net
Lamps (children's decorative); Lamps can short circuit posing a fire hazard	The "Little Ones" wooden accent lamps in six different styles: an airplane, alphabet letters (ABC), numbers (123), baseball with bat, train and sailboat; 280,000 sold at Kmart stores nationwide from January 1993 through March 2000; Kmart, Troy, Michigan (800) 63KMART
Lighters; Can leak butane when they are ignited, causing an excessive burst of flame from the tip or other areas of the lighter	All purpose, refillable 9 inches long with red, green or blue plastic handle; 213,000 sold nationwide at Michael's Stores from July 1998 through January 2000; Michael's Stores Inc., Irving, Texas (877) 562-3816 www.michaels.com
Rattles; Shape and size of the rattle's handle allow it to become lodged in the throats of babies, posing a choking hazard	Precious Keepsakes silver-plated "New Baby" rattle spinning ball on ornate handle with a bear and a bow; 13,400 sold nationwide from November 1998 through December 1999; Russ Berrie & Co. Inc., Oakland, New Jersey (800) 272-7877
Upright Vacuum Cleaners; Power cord insulation can tear where cord attaches to the vacuum, exposing bare wires and posing a risk of shock and burns to consumers	PowerClean model 3540-1 (black) and PureAir model 3540-2 (blue), PureAir Deluxe model 3541 (purple) and PureAir Platinum model 3541-P (purple); 207,000 sold nationwide from July 1998 through March 2000; BISSELL® Homecare Inc., Grand Rapids, Michigan (888) 445-6688 www.bissell.com/recall/recall_press_release.htm
Wooden Pull Toys; Wheels can break off and the bead can detach from the pull string, posing small parts choking hazards to young children	Wooden Pull Along Bead Coaster, part of a toy box set from "Childhood Classics Wooden Chest & Toy Collection;" 4,900 sold nationwide at Zany Brainy stores from November 1999 through February 2000; Maxim Enterprise Middleboro, Massachusetts (888) 266-2946. Zany Brainy Inc., web site www.zanybrainy.com

Loyalty in Government Service—To Whom?

Several physicians from the Food and Drug Administration (FDA) were being harassed by their superiors for expressing their views that the dangerous diabetes drug, Rezulin, should be removed from the market—they were right and it was belatedly removed. Because of this, the following letter was sent by Dr. Sidney Wolfe to HHS Secretary Donna Shalala.

Table 1 - Drugs Approved in the US in 1996 - 1997 and Subsequently Withdrawn for Safety Reasons

Brand/ Generic Name	Date Withdrawn	Date Approved	Reason	Comments
Rezulin/ troglitazone	3/00	1/97	Liver toxicity—The FDA has concluded that Rezulin use has "possibly or probably" resulted in 90 liver failures, including 63 deaths and 7 nonfatal organ transplants.	FDA Medical Officer opposed the drug's approval.
Raxar/ grepafloxacin	10/99	11/97	Heart rhythm disturbances resulting in at least 7 deaths.	8th fluoroquinolone antibiotic approved. QT prolongation (abnormal electrocardiogram) known before approval.
Duract/ bromfenac	6/98	7/97	Liver toxicity resulting in at least 4 deaths and 8 transplants.	20th nonsteroidal anti-inflammatory drug (NSAID) approved. Liver toxicity known before approval.
Posicor/ mibefradil	6/98	6/97	Drug interactions causing fatal heart rhythm disturbances.	9th calcium channel blocker approved for high blood pressure.
Redux/ dexfenfluramine	9/97	5/96	Hundreds of cases of primary pulmonary hypertension (PPH) and thousands of cases of heart valve damage.	PPH known before approval.
Withdrawn except for hospitals and nursing homes				
Trovan/ trovafloxacin	6/99	12/97	Liver toxicity that resulted in 9 deaths or liver transplants.	9th fluoroquinolone antibiotic approved since 1986. Liver toxicity known before approval.

Dear Secretary Shalala:

It is urgent for you and other leaders in HHS—and all government agencies—to re-read and strongly urge the implementation and enforcement of a 1958 Congressional Resolution entitled The Code of Ethics for Government Service (175 72 Stat B12, 1958) which states that "Any person in Government Service should put loyalty to the highest moral principles and to country above loyalty to persons, party or Government department." In addition, the Code of Federal Regulations governing basic obligations of public service (5 CFR Subpart A section 2635b.101) states that government "employees shall disclose waste, fraud, abuse and corruption to appropriate authorities." These guidelines have not been followed by those FDA officials who have harassed FDA physicians in the context of the recent controversy concerning Rezulin.

Yesterday, Rezulin, the fourth drug of 39 new drugs approved in 1997—under conditions which many FDA physicians describe as lowered safety standards—was taken off the market. Rezulin has caused at least 63 people to die of liver failure and has been responsible for hundreds of other cases of severe liver toxicity. The number of drugs already pulled off the market (Posicor, Duract, Raxar and Rezulin) from those approved in 1997 is twice as many as in any previous year of approval, that having happened once, wherein two of the 30 drugs approved in 1985 have been taken off the market. In no other year of drug approvals between 1970 and now, has more than one drug eventually had to be removed from the market. A fifth drug also approved in 1997, Trovan, an antibiotic now banned in Europe, has been banned in this country except for hospitalized and nursing home patients. A sixth drug, approved in 1996—the weight reduction drug Redux—has also been banned because of often-fatal primary pulmonary hypertension and heart valve damage. (See chart on the this page.) In many of these cases, there was either opposition by FDA employees to the

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Reducing Dangers to Pregnant Women

In early February, responding to the Food and Drug Administration (FDA)'s dangerous decision to allow promotion of untested herbs and other dietary supplements for pregnancy-related conditions such as morning sickness and edema of pregnancy, Dr. Sidney Wolfe and several other physicians asked the FDA to reverse this decision. One week later, the FDA announced that it agreed and temporarily reversed the policy, announcing that a public meeting would be held in order to solicit the views of others on this important topic. The following testimony was given by Dr. Wolfe at an FDA hearing on March 30th:

The FDA's regulation, issued under the 1994 Dietary Supplement Health and Education Act of 1994 (DSHEA), and put forth in final form on January 6th of this year, categorized "ordinary morning sickness" and "leg edema associated with pregnancy" as common conditions that are not "diseases." Under the dangerous provisions of 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 immediately to amend the rule explicitly to include morning sickness and edema of pregnancy as diseases. Although these are the only two pregnancy-related conditions which are explicitly mentioned, we are opposed to the idea that any claims for a pregnancy-related condition—be it structure/function or disease masquerading as non-disease such as nausea/vomiting or edema of pregnancy—be allowed to escape regulation as drugs. The exceptions, of course are vitamins (other than vitamin A supplements) and iron because there is actual evidence of deficiencies of these chemicals in pregnant women.

Moreover, morning sickness and edema of pregnancy and other problems associated with pregnancy, when severe enough to cause a woman to seek treatment, cannot be considered "normal." Rather, in that circumstance, 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. Morning sickness can progress to hyperemesis gravidarum (extreme and persistent vomiting) and severe dehydration and become life-threatening for mother and infant. Thus, even if pregnancy were properly categorized as a "life stage or process" comparable to adolescence or menopause—which it is not—these conditions would be diseases, under the FDA's own reasoning.

Even if the FDA decides, based on concerns about maternal and fetal harm, to disallow all pregnancy-related claims, this is not enough. Given that millions of Americans use herbals/dietary supplements, even in the absence of claims for treating problems of pregnancy, pregnant women may continue to use the supplements they started to use before they became pregnant. Thus, all supplements should be required to carry a warning "*Do Not Use If You Are Pregnant*" unless there is clear evidence from well conducted studies that there are no adverse reproductive effects. Given that three such chemicals, caffeine, ephedra and vitamin A are known to cause birth defects or other adverse effects on reproduction and that few of the others have been tested, the combination of unknown reproductive toxicity and unknown benefit should serve to disallow their sale without the above pregnancy warning. A time limit should be placed for allowing the companies to conduct and submit to the FDA the reproductive toxicity studies necessary to determine these risks.

Since the generation of women who are now in the child-bearing age range are much more likely than their counterparts five or ten years ago to use the Internet as a source of information, it is instructive to look at the confusing, often conflicting information concerning herbals and pregnancy posted on the Web, usually by companies selling herbals/food supplements.

On one web site is a list of herbals recommended for use by pregnant women. It includes such substances as black cohosh, blue cohosh (both to be used only during the third trimester), cleavers and horsetail. The company sponsoring this web site is Snowbound Herbals. (Sbherbals.com/usefulinpregnancy.html)

On another web site, information compiled by an RN and an Ob/Gyn discusses "Herbs to Avoid During Pregnancy and Breast Feeding." Among a list of herbals which are said to be too dangerous to use by pregnant women are several herbals also mentioned on the above list as recommended for use by pregnant women. These are "Black Cohosh: Can cause abortion. Diuretic;" "Blue Cohosh: Can cause abortion, induce contractions, diuretic;" "cleavers: Strong diuretic—not good for diabetics either;" "Horsetail: Diuretic, astringent."

Even more confusing is the fact that on another part of Snowbound Herbals web site, under a section entitled "Herbs to Avoid in Pregnancy," two of the herbs to avoid, fennel "uterine stimulant, essential oils" and Lavender "essential oils and bitter principles" are ones recommended as "useful for pregnancy" on the above-mentioned portion of their web site.

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. 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

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PREGNANCY DANGERS, *from page 9*
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 and birth defects. 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: *"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 or any other pregnancy-related claims will be unaccompanied by any assurance that the products will not cause birth defects or other kinds of fetal toxicity.

In addition to the lack of meticulous evaluation of the safety and effectiveness of the ingredients which are supposed to be in these herbals/diet supplements, there is the additional problem with this dangerously under-regulated industry of contamination. In a study recently published in the September 17, 1998 issue of the *New England Journal of Medicine* scientists from the California Department of Health reported that 32 percent of 260 herbal products purchased off the shelves in California stores were contaminated with lead, arsenic or undeclared pharmaceuticals such as digitalis. Especially for the developing child, these toxic substances can be extremely dangerous.

The Presidential Executive Order of April 21, 1997, "Protecting Infants and Children from Environmental Health and Safety Hazards," speaks clearly to the recognition of the unique vulnerability of fetuses, infants and children. Because of its recognition of this heightened vulnerability to various chemicals, it requires all agencies of the federal government to take into account the unique vulnerabilities of infants and children in setting standards and issuing regulations.

Beyond this current battle concerning pregnancy-related conditions and labeling of all supplements against use in pregnancy is the larger issue of DSHEA itself. How many more people will have to be injured or killed by essentially unregulated dietary supplements such as ephedra and many others before DSHEA is significantly amended if not repealed. This law is a dangerous step back into the 19th century just as we are entering the 21st century.

LOYALTY *from page 8*
approval of these drugs (Redux and Rezulin), unsuccessful urging of stronger product warnings on approval (Duract) or inadequately-heeded opposition from several FDA advisory committee members (Posicor).

Rather than encouraging FDA physicians and other scientists to be vigilant and try to stop these disasters from occurring before approval or encouraging them to speak up to urge that if post-marketing dangers become apparent, drug withdrawal should occur, there have been several recent incidents in which FDA medical officers have been harassed because of their concerns about drug safety. Robert Misbin, MD and Leo Lutwak, MD, both medical officers in FDA's Metabolic-Endocrine Drug Division, have been summoned before an FDA Internal Affairs Committee because of their opposition to the continued marketing of Rezulin. Yesterday, the agency conceded that they were right.

The morale among FDA scientists in CDER (the Center for Drug Evaluation and Research) is lower than I have seen at any time in the last 29 years. A survey we did of FDA CDER medical officers in late 1998 found 27 instances in which the medical officer thought a drug should not be approved but it was, over their objection. These FDA doctors also cited 14 instances in which they were told not to present data at FDA advisory committee meetings which might adversely affect the chance of a drug being approved.

For many dedicated FDA scientists, the atmosphere has become poisoned and repressive. I strongly urge the widespread dissemination and discussion of the above Code of Ethics and obligations of public service and for sanctions to be brought against those agency personnel who are responsible for interfering with the duty of other employees to voice their concerns about serious problems with drug safety or other similar matters. Until this is done, the FDA will continue to make additional serious mistakes regarding drug safety and other issues, much to the detriment of the health of people in this country. I look forward to a prompt response to this letter.

OUTRAGE, *from page 12*
tobacco, most, if not all of these stands cannot be scientifically supported. Moreover, they usually coincide with the position of industry. Is this coincidence or are Dr. Koop's positions influenced by money? He says they are not. I believe he suffers from a pathological dose of naivete, since he has repeatedly told reporters, when faced with questions of apparent conflict of interest, that "it never occurred to me that it could be a conflict of interest."

One example of Dr. Koop's advocacy for corporate interests against the interests of patients involves the widely-promoted allergy drug, Claritin, manufactured by Schering-Plough. In 1999, Dr. Koop sent a letter to members of the U.S. House of Representatives urging passage of legislation that would extend Schering-Plough's patent on Claritin for an additional three years. If passed, this law would yield well over $1 billion in additional profits to Schering-Plough by depriving Americans, for an additional three years, of the chance to purchase a generic version of the drug at a much lower price. Curiously, Dr.

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OUTRAGE *from page 10*

Koop did not mention in his letter to Congress that the Koop Foundation had been given a $1 million grant from Schering-Plough.

Lest this seem like an extraordinary failure to disclose a conflict of interest, we might be reassured by a statement from Schering-Plough that: "We did not pay him to do that." The same spokesman went on to say, according to the *Washington Post*, that Dr. Koop had long taken positions favorable to the drug company [Schering-Plough] and that the two simply were backing "policies of mutual interest."

Dr. Koop's spokeswoman was similarly reassuring. She said, "Dr. Koop does not work on behalf of any pharmaceutical company."

Another example of a strange concurrence between Dr. Koop's opinion and an industry's need for 'independent' corroboration involves the controversy over powdered latex gloves, used by health workers everywhere. Dr. Koop entered the controversy with scientifically insupportable positions, including congressional testimony, trivializing the serious occupational health dangers posed by the gloves. His conclusions were barely distinguishable from those of a major glove manufacturer, Allegiance. Dr. Koop had, coincidentally, received more than $600,000 in consulting fees from WRP Corporation, another major glove maker.

Another example involves the giant pharmaceutical company Warner-Lambert, which has been in serious trouble because of its diabetes drug, Rezulin, which was finally taken off the market on March 21 by the Food and Drug Administration, two years after it was removed from the market in the United Kingdom. As of now, with many cases not reported, there have been 90 cases of liver failure, including 63 deaths, associated with Rezulin use.

Well before the drug was removed from the market last week, Warner-Lambert needed some help to restore its Rezulin-tarnished image, and it found a way to partner with an American icon—through DrKoop.com. Several months ago, according to the *Wall Street Journal*, Warner-Lambert became the sponsor, for an undisclosed amount of money, of the portion of the web site called the "Diabetes Center." It was hardly surprising that the day after the FDA announced its recommendation against Rezulin, DrKoop.com posted an article from the *New York Post* that makes it seem like a mistake to remove this dangerous drug from the market. More disturbing, no other articles on the site lay out in detail the case against Rezulin.

"The Great Defender of Petrochemical Companies" on DrKoop.com

Dr. Koop's web site also has a special partnership with the American Council on Science and Health (ACSH), which is heavily funded by the chemical, auto, oil and food industries. Like Dr. Koop, ACSH and its president, Dr. Elizabeth Whelan, have advocated strongly against tobacco. But on most other issues pitting questions of public health against the interests of industry, ACSH sides with its patrons. It is fair to say that much of the organization's work is nothing less than propaganda, offering chemical manufacturers an 'independent' source for reassuring the public that most chemicals are benign, or for attacking anyone who would suggest otherwise.

ACSH is one of the least credible voices on environmental health issues, yet DrKoop.com relies heavily on the organization for its material on such topics. The web site and its archives contain some 100 articles and releases by ACSH staffers or consultants. Common themes include the trivializing of animal-test evidence of cancer and other dangers posed by toxic chemicals. ACSH is consistent in its wrongheaded certitude that pesticides and other petrochemical-derived chemicals such as PCBs, formaldehyde, phthalates (a key ingredient in plastics), and dioxins are much more innocuous than indicated by many thorough and independent scientific reviews of their toxicology.

In a 1992 memo obtained by *Consumer Reports* in which she bemoaned the loss of funding from the Shell Oil Company Foundation, Dr. Whelan indicated why the public is rightfully suspicious of the industry front group that claims to be a consumer advocate. She wrote, "When one of the largest international petrochemical companies will not support ACHS, ***"the great defender of petrochemical companies,"*** one wonders who will." (Emphasis added.) So much for independence and the credibility that goes with it.

The reason Dr. Koop would affiliate his web site with such a notorious band of opinions-for-hire is hard to guess. But the fact is that his reputation is sullied as much by the association with ACSH as it is by the apparent financial advantages that have come with supporting the positions of powerful corporations.

Morally Reckless

As John Fletcher, Emeritus professor of ethics at the University of Virginia, told the *Washington Post* after reviewing the facts concerning the controversy, Dr. Koop has been "morally reckless with the trust that had been invested in him." This is the most generous interpretation.

Dr. Koop is riding on the reputation he built as Surgeon General, but today it looks more like he's cashing in through crass commercialism. Unless he stages a radical turnaround, Dr. Koop's place in history will be that of another self-serving huckster instead of the valuable public advocate and educator he was as Surgeon General.

TOMPAINE.com Editor's Note: Dr. Koop's Response

A spokesperson with drkoop.com declined to comment on the allegations made by TOMPAINE.com against Dr. Koop and the web site. "This is not news," she told us. In the interest of fairness the following are Dr. Koop's responses to other journalists:

Re: Latex Surgical Gloves

Dr. Koop confirmed to the *New York Times* that his foundation had received a $1 million grant from Schering-Plough, "but he said the company's money did not influence his public positions. 'I never disclosed the grant because I did not think it was an issue. I'm not a lobbyist, de facto or otherwise. I did not receive any payment for my work. Most foundations accept grants from private sources. There was no quid pro quo." Moreover, Dr. Koop pointed out to the *Washington Post* that he based his case on behalf of the gloves on a study he believed came from the Centers for Disease Control and Prevention. He found out later that it came from a glove manufacturer.

Re: Claritin

Dr. Koop told the *Washington Post*: "You might think I'm naive, but it never occurred to me that it could be a conflict of interest," since the company's contribution went to the foundation and does not benefit him directly.

DRKOOP.CON? America's Family Doctor and His Conflicts of Interest, Part II

The following article written by Dr. Sidney Wolfe appeared on the web site TOMPAINE.com which publishes articles on a variety of progressive issues. Dr. Wolfe's article was advertised in an ad in the New York Times *on March 29, 2000.*

Dr. C. Everett Koop long ago surpassed TV doctor Marcus Welby as the best-known and most-trusted physician in the nation. His Quaker-style beard, air of integrity, and baritone voice make him memorable, as did his record as United States Surgeon General under presidents Ronald Reagan and George Bush.

Dr. Koop earned our trust by bucking the narrow ideology of the Reagan Administration. Reagan right-wingers thought they were appointing a reliable conservative to the post that has been called "America's family doctor." But soon after he was confirmed in the position, Dr. Koop showed his maverick's stripes by repeatedly and forcefully denouncing the health effects of smoking—though the tobacco industry was then (and remains) among the GOP's most reliable patrons—and by bringing to national attention the burgeoning AIDS crisis.

Despite his exemplary work as Surgeon General, it seems that Dr. Koop has since become a family doctor with corporate conflicts of interests. He has given his name and the reputation that goes with it to a for-profit web site, DrKoop.com, that is now one of the most-visited such sites on the Internet. He presides over a namesake charitable foundation, consults with private companies, and occasionally offers congressional testimony.

A growing number of critics have challenged Dr. Koop recently, criticizing him for trading on his reputation as an independent-minded, squeaky clean ombudsman even while shilling for several health care corporations with less than public-spirited goals.

What has happened to the Dr. Koop who once acted as our national conscience on important health care issues?

A Pathological Dose of Naivete

Dr. Koop and his aides consistently claim that there is no evidence that the "scientific" positions he takes on behalf of various companies or the alliances he makes with questionable organizations are influenced by the money his foundation or his for-profit web site get from these enterprises.

But leaving aside the exemplary work he has done and continues to do on

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