

Health Letter

SIDNEY M. WOLFE, M.D., EDITOR

MAY 2002 ♦ VOL. 18, NO. 5

Public Citizen's Health Research Group Ranking of State Medical Board Disciplinary Actions in 2001

Based on data Public Citizen's Health Research obtained from the Federation of State Medical Boards (FSMB) on the number of disciplinary actions taken in 2001 against doctors, we have calculated, for the 14th year in a row, 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 2001 (See Table 1, pg. 2). We also released a report at the same time detailing the results of a survey of 51 state medical board Web sites and rating their content and user-friendliness (see story on pg. 4).

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 2000 (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 per 1,000 physicians.

Nationally, there were 2,708 serious disciplinary actions taken by state medical boards in 2001, down slightly from the 2,746 serious actions taken in 2000. Since there were also more physicians practicing in 2000, the rate per 1,000

physicians decreased from 3.49 in 2000 to 3.36 in 2001.

State rates ranged from a high of 10.52 serious actions per 1,000 doctors (Arizona) to a low of 0.73 actions per 1,000 physicians (District of Columbia), a 14.4-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 lowest rate for #5, Kentucky being 6.32 serious disciplinary actions per 1,000 physicians or 0.632 percent, this would amount to a total of 5,089 (0.632 percent of 805,372 non-federal doctors) serious actions a year. This is 2,381 more serious actions than the 2,708 that actually occurred in 2001.

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

As can be seen in Table 1, the

bottom 15 states, those with the lowest serious disciplinary rates in 2001, were, starting with the lowest: the District of Columbia (0.73 per 1,000 physicians), Hawaii (.80), Delaware (.90), South Dakota (1.20), South Carolina (1.35), Wisconsin (1.69), Illinois (1.70), Minnesota (1.76), Maryland (1.78), Rhode Island (1.79), Indiana (1.94), Connecticut (1.95), Maine and Wyoming (both 1.98), and Washington (2.17). Of the 15 states with the worst serious disciplinary records, seven—Maryland, Hawaii, Delaware, South Dakota, Illinois, Minnesota, and Washington were also in the bottom 15 states in 2000 and 1999 (see Table 2, pg. 3). In 2001, the bottom 27 states all had rates of serious disciplinary action that were one-half or less than the rate of all of the top five states.

continued on page 2

C O N T E N T S

Survey of Doctor Disciplinary Information on State Web Sites

Find out how your state did for site content and user-friendliness. 4

Product Recalls

March 11 — April 10, 2002

Claritin, contact lenses and beach chairs are on our list this month. 7

Outrage of the Month

Possible Corruption at the American Heart Association

The Association's "Brain Attack" — Taking Millions from the Drug Industry

Find out how the drug industry influences guidelines about when you should be taking a particular drug. 12

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 the dangers of 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 patients are being injured or killed more often in states with poor doctor disciplinary records than in states with consistent top performances.

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): Arizona (10.52 per 1,000 physicians), Oklahoma (8.66), Alaska (8.57), Iowa (6.49), Kentucky (6.32), North Dakota (6.25), Idaho (6.22), Ohio (6.07), Utah (5.54), and Georgia (5.00). Five of these 10 states (Oklahoma, Alaska, Kentucky, North Dakota and Ohio) were also in the top 10 in 2000 and 1999 and one state, Alaska, has been in the top 10 for more than ten straight years. Oklahoma, 2nd this year, has been in the top 10 states for nine of the last ten years. North Dakota, 6th this year has been in the top 10 states for eight of the last ten years. Iowa and Ohio, 4th and 8th respectively this year have been in the top 10 for seven of the last ten years and Kentucky and Georgia, 5th and 10th this year have been in the top 10 for six of the last ten years (see Table 2, pg. 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. Other large states such as, New York, California and Michigan (14th, 25th and 29th respectively in 2001) have gone down from their previous rankings of 10th, 19th and 14th in 2000. But other large states such as Massachusetts, Texas, and Illinois, have fairly consistently been in the bottom half of the states for at least the past four or five years, although Massachusetts improved from 45th in 2000 to 27th/28th in 2001.

continued on page 4

Table 1

Ranking of Serious Doctor Disciplinary Actions By State Medical Licensing Boards — 2001

Rank 2001	State	Number of Serious Actions 2001	Total Number of Physicians 2000	Serious Actions Per 1,000 Doctors
1	Arizona	124	11,791	10.52
2	Oklahoma	55	6,353	8.66
3	Alaska	11	1,283	8.57
4	Iowa	44	6,784	6.49
5	Kentucky	60	9,500	6.32
6	North Dakota	10	1,599	6.25
7	Idaho	15	2,412	6.22
8	Ohio	201	33,138	6.07
9	Utah	28	5,056	5.54
10	Georgia	95	18,995	5.00
11	West Virginia	21	4,296	4.89
12	Alabama	47	9,954	4.72
13	Mississippi	25	5,346	4.68
14	New York	349	80,134	4.36
15	Oregon	40	9,473	4.22
16	Arkansas	24	5,738	4.18
17	Colorado	50	12,029	4.16
18	Nevada	16	3,893	4.11
19	Montana	9	2,205	4.08
20	Kansas	27	6,847	3.94
21	New Hampshire	13	3,480	3.74
22	Virginia	70	19,673	3.56
23	New Jersey	105	29,757	3.53
24	Louisiana	42	12,068	3.48
25	California	290	95,038	3.05
26	Florida	136	44,747	3.04
27/28	Missouri	47	15,572	3.02
27/28	Massachusetts	87	28,851	3.02
29	Michigan	68	24,901	2.73
30/31/32	New Mexico	11	4,327	2.54
30/31/32	Texas	122	47,994	2.54
30/31/32	North Carolina	53	20,851	2.54
33	Tennessee	35	14,954	2.34
34	Nebraska	10	4,290	2.33
35	Vermont	5	2,280	2.19
36	Pennsylvania	85	39,052	2.18
37	Washington	351	6,154	2.17
38/39	Maine	7	3,528	1.98
38/39	Wyoming	2	1,011	1.98
40	Connecticut	26	13,312	1.95
41	Indiana	27	13,929	1.94
42	Rhode Island	7	3,919	1.79
43	Maryland	39	21,883	1.78
44	Minnesota	25	14,218	1.76
45	Illinois	63	37,138	1.70
46	Wisconsin	24	14,241	1.69
47	South Carolina	13	9,607	1.35
48	South Dakota	2	1,672	1.20
49	Delaware	2	2,219	0.90
50	Hawaii	3	3,746	0.80
51	District of Columbia	3	4,134	0.73
	United States	2,708	805,372	3.36

Table 2

Ranking for Last 10 Years

Rank 2001	Rank 2000	Rank 1999	Rank 1998	Rank 1997	Rank 1996	Rank 1995	Rank 1994	Rank 1993	Rank 1992	State
1	7	21	38	19/20	5	10	17	16	22	Arizona
2	5	5	2	5	7	12	5	2	1	Oklahoma
3	2	1	1	2	6	8	2	8	7	Alaska
4	11	11	23	4	3	2	7	5	2	Iowa
5	3	6	14	7/8	14	14	4	4	16	Kentucky
6	1	2	11	9	2	34	10	3	5	North Dakota
7	50	4	25	30	21	36	30	37/38	23	Idaho
8	8	7	10	7/8	8	9	24	22/23	19	Ohio
9	6	33	20	25/26	16	38	46	39	43	Utah
10	9	15	12	23/24	19	4	8	10	9	Georgia
11	36	17	5	12	11	7	6	1	3	West Virginia
12	12	13	17	23/24	38	30	43/44	29	30	Alabama
13	13	8	3	1	1	1	9	9	6	Mississippi
14	10	14	16	16	18	17	29	34	39	New York
15	17	30	31	28/29	29	16	20	22/23	24	Oregon
16	15	12	4	13	15	23	28	26	18	Arkansas
17	31	10	18	6	4	5	12	6	8	Colorado
18	21	25	26	32	9	11	31	20	25	Nevada
19	42	32	34	11	13	18	3	14	10	Montana
20	37	45	44	41	12	46	22	37/38	20	Kansas
21	23	18	30	46	51	49	49	47	47	New Hampshire
22	18	22	40	34/35	50	41/42	32	30	37	Virginia
23	26	28	35	42	20	25	19	18	28	New Jersey
24	20	23	15	34/35	44	13	18	11	12	Louisiana
25	19	20	27	18	27	20	34/35	32	42	California
26	34	38	49	36	22	22	25	25	21	Florida
27/28	45	39	47	45	43	40	37	45	46	Massachusetts
27/28	25	31	48	17	30	37	13	12	13	Missouri
29	14	19	13	15	28	21	34/35	35	40	Michigan
30/31/32	41	27	8	50	23	15	43/44	49	33	New Mexico
30/31/32	32	26	43	33	48/49	35	36	40	34	North Carolina
30/31/32	38	34	28/29	37	35	19	23	28	29	Texas
33	35	49	51	48	48/49	31	38	44	49	Tennessee
34	39	50	28/29	43	24	41/42	15	50	38	Nebraska
35	16	9	6	25/26	10	6	39	17	15	Vermont
36	29	36	45	27	32	43	47	48	48	Pennsylvania
37	43	37	36/37	28/29	40	24	27	24	17	Washington
38/39	22	24	9	22	17	32	33	41	44	Maine
38/39	4	3	7	3	31	3	1	21	4	Wyoming
40	28	46	32	31	37	27	42	36	35	Connecticut
41	24	16	21	19/20	33	28	16	7	14	Indiana
42	33	35	24	10	25	26	26	42	41	Rhode Island
43	40	40	36/37	38	41	29	21	19	27	Maryland
44	46	48	42	51	47	39	45	33	31	Minnesota
45	44	43	41	21	46	45	40	31	36	Illinois
46	30	42	46	39	34	47	41	27	26	Wisconsin
47	27	29	22	40	45	44	14	15	11	South Carolina
48	49	44	19	14	42	33	11	13	32	South Dakota
49	47	51	50	47	26	48	48	43	51	Delaware
50	48	47	39	49	39	51	50	46	50	Hawaii
51		41	33	44	36	50	51	51	45	District of Columbia

Survey of Doctor Disciplinary Information on State Web Sites

State medical boards are responsible for taking actions against physician misconduct and making information about those disciplinary actions available to the public (see related story pg. 1). They should be using the Internet to provide detailed, user-friendly information on disciplined physicians to consumers. Public Citizen's Health Research Group conducted a study to describe the content and user-friendliness of Web sites for all 50 states and the District of Columbia. Only seven states received an "A" for content and 20 an "A" for user-friendliness, including six of the seven that received an "A" for content. However, 17 states received a "C" or lower for content and 23 did so for user-friendliness. There was a modest improvement between our previous survey in 2000 and the current survey.

Consumers use the Internet to fill their prescriptions, seek medical advice, and learn about medical research. Hospitals, health maintenance organizations, doctors, and pharmaceutical companies advertise on the Web. And the Internet presence of state medical boards—those entities charged with licensing and regulating medical doctors—is also on the rise.

The boards serve patients by en-

suring that, in order to be licensed, physicians meet minimum standards of training and competence. They are also required to discipline physicians who commit offenses such as incompetence, negligence, sexual misconduct, and violations of criminal laws. In addition to an insufficient number of disciplinary actions against doctors, many boards have not assumed an active role in disseminating adequate information about these disciplinary actions to patients, preferring all-too-often to shield physicians from adverse publicity. For years, patients have had to call or write the boards to learn whether their physician has been disciplined and, if so, why, how, and when.

Given the Internet's power to rapidly and inexpensively disseminate vast amounts of information to many people, it is logical that the boards provide disciplinary information on the web. If the data are sufficiently detailed, complete, and easily accessible, providing this information on the Internet would not only benefit patients, but also the boards, which would receive fewer time-consuming phone and mail queries from patients and might then be able to devote more time and resources to their vital en-

forcement duties.

In 2000, Public Citizen's Health Research Group (HRG) conducted a survey of state medical board Web sites to determine the status of disciplinary action information on the Internet. Recently—in April of this year—HRG re-surveyed the state medical boards.

Content

A grading scale was created to assess the content of disciplinary information each Web site provides on medical doctors. Although some Web sites include information on osteopaths, chiropractors, podiatrists and other medical professionals, we only evaluated content regarding medical doctors. An adequate amount of information on a given disciplinary action was defined as: 1) the physician's name; 2) the disciplinary action taken by the board; 3) the offense committed by the physician; 4) a concise summary narrative of the physician's misconduct; and 5) the full text of the actual board order. States that provided all five types of data earned a content grade of "A"; states that provided four of the five types of data earned a "B"; states that provided three of the five types of information

continued on page 5

RANKINGS, from page 2

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).

Given the importance of medical boards in protecting patients in a state from doctors who are not practicing medicine in the best manner and are thus endangering the lives and health of residents of those states, 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 and taking action, legislatively and through pressure on the medical boards, to increase the amount of discipline and, thus, the amount of patient protection.

received a "C"; states that reported two of the five types of information received a "D"; and states that named disciplined physicians but provided no details about the disciplinary action received an "F". States that reported no doctor-specific disciplinary information on their Web site earned an "X." The content score was assigned for information presented anywhere on the Web site, even if it was not present for all years for which data were posted or if it was difficult to locate.

User-friendliness

We also categorized the Web sites according to their user-friendliness—the ability of consumers to easily find the disciplinary information. We considered searchable databases, alphabetical listings of all physicians with a notation of who has been disciplined, and alphabetical listings of all disciplined physicians to be equally user-friendly. The scores were assigned as follows:

A: Content of searchable or listed disciplinary information is greater than or equal to information elsewhere on the Web site and the Web site provides one of the following: 1) a name-searchable database, 2) a single listing of all physicians, 3) a single listing of all disciplined physicians.

B: Content of searchable or listed disciplinary information is less than information elsewhere on the Web site, but is more than just the name of the disciplined physician and the Web site provides one of the three user-friendly formats listed in A.

C: Content of searchable or listed disciplinary information consists of the name of the physician only and the Web site provides one of the three user-friendly formats listed in A.

F: Disciplinary information is provided in reports, newsletters, or press releases, but not in a searchable database or list.

X: The Web site provides no disciplinary information.

Some board Web sites provide disciplinary information in more than one format. For example, a site might have both a searchable database of physician data and newsletters that report board actions. With such sites, it was

often the case that the different formats provided different types of information. User-friendliness scores of "A", "B", and "C" were assigned according to information in the name-searchable database, not that provided in newsletters, reports, or press releases.

On April 3, 2002, we examined the Web sites of all 50 states and the District of Columbia to assess their content and user-friendliness scores. In addition, we determined whether other information was present, including the date of a disciplinary action and the address, telephone number, license number, license issue date, license expiration date, and specialty of the physician. We also determined whether at least 10 years of data were present on the Web site.

Results

All 51 boards regulating medical

doctors now have some sort of Web site. Of these, 49 have Web sites providing doctor-specific disciplinary information (that is, the disciplined physicians are named). Although most of these boards have their own sites, a few states provide the data on the site of another regulatory body, such as the Department of Health. The remaining two states (South Dakota and Montana) have Web sites, but provide no disciplinary information. These two sites provide very basic information like board addresses, phone and fax numbers, and the roles and duties of the boards.

Only seven of the 51 boards (14 percent) earned an "A" for content. Twenty-seven (53 percent) received a "B"; four (8 percent) received a "C"; nine (18 percent) earned a "D"; two (4 percent) earned an "F"; and the two states (4 percent) that provided no

Table 1: Web Site Content Grades by State, 2002

<i>Content Grade</i>	<i>Number of States</i>	<i>Percentage of States</i>	<i>States</i>
A	7	14%	Arizona, Maryland, North Carolina, New York, Ohio, South Carolina and Virginia.
B	27	53%	Alaska, California, Colorado, District of Columbia, Florida, Iowa, Idaho, Illinois, Indiana, Kentucky, Massachusetts, Maine, Minnesota, Missouri, New Hampshire, New Jersey, New Mexico, Nevada, Pennsylvania, Tennessee, Texas, Utah, Vermont, Washington, Wisconsin, West Virginia and Wyoming.
C	4	8%	Connecticut, Delaware, Michigan, and Oklahoma.
D	9	18%	Alabama, Arkansas, Georgia, Hawaii, Kansas, Mississippi, Nebraska, Oregon and Rhode Island.
F	2	4%	Louisiana and North Dakota.
X	2	4%	Montana and South Dakota.

doctor-specific disciplinary information on their Web sites received an "X" for content

The formats in which data are presented vary substantially among the states. Of the 51 boards, 20 (39 percent) received a user-friendliness score of "A," eight (16 percent) received a "B," 17 (33 percent) received a "C," four (8 percent) received an "F" and two (4 percent) received an "X" (see Table 2, below). Of the 45 Web sites receiving an "A," "B" or "C," 42 Web sites feature a database from which physician disciplinary information can be retrieved by entering a doctor's name in a search engine; six sites post data in a single listing of disciplined physicians; and four sites offer both formats. One Web site offers both a searchable database and a list of all physicians with an indication of who had been disciplined.

More boards received an "A" for user-friendliness than for content (20 vs. 7). Six states (Arizona, Maryland, North Carolina, New York, Ohio and Virginia) received an "A" in both categories. Of the 34 states receiving content grades of "B" or higher, 19 (56 percent) received a "B" or higher on the user-friendliness scale.

Some board Web sites present additional information on physicians and the disciplinary actions against them. Sixteen boards report the physician's date of birth, 35 provide an address (business, home or unspecified), and 10 include a telephone number. Forty-seven boards provide the physician's license number. Thirty-seven report the license issue date and 38 report the license expiration date. Twenty-eight boards report a doctor's specialty. Forty-four boards provide the date that the disciplinary action

was taken. Thirty-nine boards provide at least 10 years of disciplinary information.

All states now have Web sites compared to 44 in 2000 and 49 of them provide doctor-specific disciplinary information compared to 41 in 2000. For the content grade, 28 of the 51 states (53 percent) had the same grade in 2000 and 2002, 15 (29 percent) improved their grades by one unit and nine (18 percent) improved their grades by two or more units. For the user-friendliness grade, 17 states (33 percent) not considered user-friendly in 2000 were considered user-friendly in 2002. No state's grade declined on either measure between 2000 and 2002.

Conclusion

All 51 state medical boards now have Web sites and 49 of them provide some doctor-specific disciplinary information on the Internet. However, 45 state medical boards continue to provide disciplinary information whose content or user-friendliness is inadequate compared to the six states that received an "A" in both categories. In two cases, such information was entirely absent.

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

Disappointingly, only seven states (Arizona, Maryland, North Carolina, New York, Ohio, South Carolina and Virginia) earned an "A" for the content of information featured on their Web sites. Six of these states (all but South Carolina) also earned an "A" for user-friendliness.

Some boards report other important information that is of interest to patients. For example, the California, Florida, Idaho, Massachusetts, and Tennessee boards provide data on malpractice claims. The California, Florida, Idaho, and Massachusetts sites also

continued on page 11

Table 2: Web Site User Friendliness Grades by State, 2002

User Friendliness Grade	Number of States	Percentage of States	States
A	20	39%	Arkansas, Arizona, Delaware, Hawaii, Idaho, Illinois, Kentucky, Maryland, Maine, Michigan, North Carolina, Nebraska, New Hampshire, New York, Ohio, Rhode Island, Tennessee, Virginia, Wisconsin and Wyoming.
B	8	16%	California, Colorado, Connecticut, Florida, Iowa, Kansas, Massachusetts and Oklahoma.
C	17	33%	Alaska, Alabama, Georgia, Indiana, Louisiana, Minnesota, Missouri, Mississippi, North Dakota, New Jersey, New Mexico, Oregon, Pennsylvania, South Carolina, Texas, Utah and Vermont.
F	4	8%	District of Columbia, Nevada, Washington and West Virginia.
X	2	4%	Montana and South Dakota.

Product Recalls

March 11—April 10, 2002

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

DRUGS & DIETARY SUPPLEMENTS

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

Class I Recalls

Name of Drug or Supplement; Problem

Pharmacy Compounded Inhalation Solutions in 3 mL plastic squeeze dispensers as follows: a) Albuterol 2.5 mg/lpratropium 0.5 mg/Dexamethasone 0.4 mg/3ml, b) Albuterol 2.0 mg/lpratropium 0.5 mg/3ml, c) Albuterol 2.5 mg/Cromolyn 20 mg/3ml, d) Albuterol 1.0 mg/lpratropium 0.5 mg/3ml, e) Albuterol 5.0 mg/lpratropium 0.5 mg/3ml. ; Microbial contamination (*Serratia species bacteria*)

SanPharma Brand Mucor Drops 4X (homeopathic medicine eyedrop) 0.34 fl oz bottles; Microbial contamination (*Stenotrophomonas maltophilia*)

Welder's Eyedrops (Aloeflex) NET WT. 1 fl. oz. (Aloe Vera juice); Microbial contamination (*Acinetobacter calcoaceticus-baumannii*)

Lot #: Quantity and Distribution; Manufacturer

a) Lot: 112001BAID; b) Lot: 112601CAI; c) Lot: 112601LAC; d) Lot: 112601NAI; e) Lot: 112801DAI; 4,200 units distributed in California and Colorado; Med-Mart Pharmacy, Bakersfield, California

Code 11 2003; At least 55 bottles distributed in California, Wisconsin, New Mexico, Idaho, Montana, Michigan, Colorado, Florida, Texas, Washington, and Hawaii; BioResource, Inc. Cotati, California

Product is not coded, or if coded, coding is unknown. All codes were recalled; 28 bottles distributed in Texas; Tennis Elbow Corporation, Dickinson, Texas. Recalled by Aloe Flex Enterprises, Dickinson, Texas

Name of Drug or Supplement; Class of Recall; Problem

Allegra Tablets (fexofenadine HCl) 60 mg., 2-tablet blister packages (30-ct. boxes) physician samples, Rx only; Class III; Product was not manufactured in conformance with its New Drug Application (NDA) specifications, lacking particle size and friability testing

Aspirin and Codeine Phosphate Tablets, 325mg/30mg, 100 tablet bottles, Rx only sold under the Vintage, Qualitest, and URL labels; Class III; Codeine Phosphate component may not maintain potency throughout labeled expire date

Claritin-D 12 Hour Extended Release Tablets, (5 mg loratadine/120 mg pseudoephedrine sulfate), Rx only, 100 tablet bottles, 100 unit dose tablets, and 30 tablet blister packs; Class III; Dissolution failure; pseudoephedrine sulfate component (5th hour/18 month stability)

Lot #: Quantity and Distribution; Manufacturer

Lots 1027124 and 1027842, EXP 2/3/03, Lot 1028789 EXP 2/4/03; 117, 071/30-ct. boxes distributed nationwide; Aventis Pharmaceuticals, Inc., Kansas City, Missouri

Lot Numbers 129089A, 129089B, 129089C, 129089D, 108080A, 108080B, 108080C, 108080E, 108080F, 108080G, 011120A, 011120B, 011120C, 011120E; 58,368 units distributed in Alabama; Vintage Pharmaceuticals, Huntsville, Alabama

All lots with the prefix number of "0" or "1" (representing the years 2000 and 2001 respectively). Also lots 9-JRP-313, 9-JRP-338, 9-JRP-2040, 9-JRP-2041 and 9-JRP-2042; 7,875,653 units distributed in Texas, Pennsylvania, California, Delaware and Virginia; Schering Corp., Kenilworth, New Jersey

Name of Drug or Supplement; Class of Recall; Problem

Lot #: Quantity and Distribution; Manufacturer

Claritin-D 12 Hour Extended Release Tablets, (5 mg loratadine/120 mg pseudoephedrine sulfate), Rx only, Packaged in 20 tablet, 14 tablet, 60 tablet and 10 tablet bottles; Class III; Dissolution failure (at manufacturer, Schering Corp); pseudoephedrine sulfate component (5th hour/18 month stability)

Numerous lots; 84,392 tablets distributed nationwide; Allscripts Healthcare Solutions, Libertyville, Illinois

Compazine Tablets 5 mg (prochlorperazine), bottles of 100 tablets and blister packages of 100 tablets (2x5 blister cards); Class III; Subpotent

Lots 12-1C66J and F12-1C66 EXP 10/31/03; 13,025 bottles of 100 tabs and 2,400 ctns 100's distributed nationwide; SKB Pharmaceutical Co., Cidra, Puerto Rico. Recalled by SmithKline Beecham Pharmaceuticals, Philadelphia, Pennsylvania

Epinephrine Mist Kit, epinephrine inhalation aerosol, 5.5 mg/mL 1/2 fl. oz., Kit contains nebulizer/actuator packaged with vial. Refill packaged in 0.5 ounce plastic coated glass vials; Class III; Failure to test purified water ingredient for all microbial specifications

Numerous lots; 4,333,356 units distributed nationwide; Armstrong Laboratories, Inc., West Roxbury, Massachusetts. Recalled by Alpharma USPD, Baltimore, Maryland

Exelon Capsules (rivastigmine tartrate), 4.5 mg, 60 capsule bottles, Rx only, labeled as Manufactured by: Novartis Farmaceutica, S.A. Barcelona, Spain for Novartis Pharmaceuticals Corporation, East Hanover, New Jersey; Class II; Mis-packaging — (3.0 mg capsule in 4.5 mg labeled bottle)

Lot 115D1784 EXP 12/04; 10,069 bottles distributed nationwide and in Puerto Rico; Novartis Pharmaceuticals Corporation, Suffern, New York

Eye-Saver Concentrate, sodium chloride (eye wash), plastic bottles, 121.5 fl. oz. (0.95 gallons) per bottle, 1/case, packaged under the SPEAKMAN brand label; Class II; Lack of assurance of sterility

All lot numbers are recalled; 50,346 cases distributed in Delaware; Chester Labs, Inc., Cincinnati, Ohio

Meclizine Tablets 25 mg, 30 tablets per bottle, Rx only; Class II; Mispackaging at repacking firm; bottles labeled as 25 mg actually contain 12.5 mg tablets

Lot 00037 EXP 6/30/03; 33 bottles distributed in Oklahoma, Tennessee and Wisconsin; Par Pharmaceutical, Spring Valley, New York. Recalled by Quality Care Products, L.L.C. Temperance, Michigan

Necon 1/50-28 Tablets (norethindrone 1.0 mg and mestranol 0.05 mg.; Class III; Subpotent for mestranol component (stability)

Lot 51001X99 EXP 12/02, 51001B00 EXP 3/03, 51001D00 EXP 4/03, 51002D00 EXP 4/03; 27,844 distributed nationwide and in Puerto Rico; Watson Pharmaceuticals, Inc., Corona, California

Oxygen, compressed in size C, D and E in steel and aluminum cylinders; Class II; Good Manufacturing Practice (GMP's) deviations including, but not limited to, failure to test product for purity and identity

Lots 020501/4, 020502/5, 020503/4 and 020504/5; 70 cylinders distributed in Georgia; Southern Welding Supply Co., Inc., Savannah, Georgia

Premarin Tablets (conjugated estrogens tablets) 0.625 mg, Rx only, bottles of 100, 1,000 and 5000; Class III; Failure to meet dissolution specifications

Lot Numbers: 9001566, 9010254, 9010255 EXP 07/03; 47,024 bottles of 100; 9,255 bottles of 1,000; and 1,408 bottles of 5,000 distributed nationwide; Wyeth-Ayerst Laboratories, Rouses Point, New York

Trandate Tablets (labetalol hydrochloride), 300 mg, packaged in 100 unit bottles and 100 unit dose packages (10x10 tablets) indicated in the management of hypertension; Class III; Dissolution failure (at stability testing)

Lots OZP1108 and 9ZM2082A; 9,468 units distributed nationwide; Glaxo Wellcome, Zebulon, North Carolina. Recalled by Prometheus, San Diego, California

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

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

Name of Device; Class of Recall; Problem

Contact Lenses (Torisoft Daily Wear Soft); Class II; Experimental design tool was used to manufacture product

Power Chairs; Class II; The wheel bolt can loosen and cause the wheel to separate from chair

Lot #: Quantity and Distribution; Manufacturer

Codes 1290275, 1297633, 1291090, 1295628, 1295636, 1296202, 1298017, 1298014; 18 lenses distributed in Arizona, Louisiana, Michigan, Minnesota, New Jersey, New York, Ohio, Utah and Virginia; Ciba Vision Corp., Duluth, Georgia

Product names: Chauffeur Littlest Viva, Chauffeur Littlest Viva Plus, Rascal Model 250, Rascal Model 255, Rascal Model 410, Rascal Model 415, Chauffeur Model 250 and Chauffeur Model 255. The TurnAbout power chairs include the product names: TurnAbout and TurnAbout Heavy Duty. Serial codes from JS001011 to JS010742, manufactured between March 1, 1999 and September 28, 2001; 8,293 chairs distributed nationwide and internationally; Electric Mobility Corp., Sewell, New Jersey

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

Contact the Consumer Product Safety Commission (CPSC) for specific instructions or return the item to the place of purchase for a refund. For additional information from the Consumer Product Safety Commission, call their hotline at 1-800-638-2772. The CPSC web site is <http://www.cpsc.gov>.

Name of Product; Problem

Children's Soap Making Kit; Soap may get too hot when heated in the microwave oven and leak from the plastic container posing a burn hazard

Circular Saws; Spindle on the saw may slip, causing the blade to contact the lower guard, posing a hazard to the consumer from an exposed blade

Dietary Supplements; Supplements being recalled are not packaged in child-resistant packaging as required under the Poison Prevention Packaging Act

Electric Heaters; Electrical connections inside of the heater can become loose, causing the heater's metal frame to become energized, posing a serious electric shock hazard to consumers

Fireplace Screens; Paint on the metal mesh can ignite when exposed to a direct flame, posing a serious fire hazard

Gas Ranges, Recall to Repair; Ranges could tip over if a heavy weight is placed on an open oven door, posing a risk of burn injuries

Girl's Capri Pant and Shirt Set; Buttons in the center of the embroidered flowers on the shirt can detach, posing a choking hazard

Lot #: Quantity and Distribution; Manufacturer

Models 4054 and 4121; 124,400 sold nationwide from August 1997 through December 2001; Rose Art Industries Inc., Livingston, New Jersey (800) 272-9667 www.roseart.com

7 1/4 inch heavy-duty, lightweight models DW368, DW368K and DWCSK; 55,000 sold nationwide from July through December 2001; DeWALT Industrial Tool Co., Baltimore, Maryland (888) 839-3559 www.DeWALT.com

Nature's Valley, Women's Formula Multivitamin; 14,000 sold nationwide from July 2001 through February 2002; Leiner Health Products, Carson, California (800) 421-1168

Models 797 or 797 DFT; 107,000 sold nationwide from October 2000 through February 2002; Lakewood Engineering & Manufacturing Co., Chicago, Illinois (888) 858-3506

Wal-Mart Home Trends 2-Paneled Fireplace Screens model 500RR; 600 sold at Wal-Mart from September through December 2001; Pascal Products Company Ltd., Jackson, Mississippi (601) 362-6813

Dynasty gas ranges model number DGRSC, 30, 36, and 48-inch units; 7,200 sold nationwide from January 1996 through December 2001; Jade Products Inc., Commerce, California (888) 607-5694 www.dynastyrange.com

Greendog style 8088, sizes 12, 18 and 24 months; 1,000 sold nationwide from January through February 2002; Federated Merchandising Group, New York, New York (877) 874-2812

OUTRAGE, from page 12

required before potentially dangerous interventions are accepted (tPA is well-known to cause potentially fatal bleeding in the brain). Moreover, the NINDS and Genentech, which funded a portion of the trial, have steadfastly refused to provide the raw data to other researchers so they can perform their own analyses of this controversial trial. And a study of tPA use in actual clinical practice, as opposed to in the artificial setting of a clinical trial, demonstrated a massive 16 percent rate of bleeding into the brain and a rate of in-hospital deaths that was double what was calculated for patients not receiving the drug.

None of this deterred the AHA. Perhaps this was because Genentech had contributed a tidy \$2.5 million toward the building of the Association's headquarters in the early 1990s. Or perhaps it was because the company showered the AHA with \$11 million

*Genentech had
contributed a tidy
\$2.5 million
toward the
building of the
Association's
headquarters in the
early 1990s.*

over the course of the decade. Or because when eight of nine panel members supported the AHA's upgrading of its tPA recommendation, six of the majority had ties to the manufacturer (two of them initially denied any connection). But then all eight were known to support tPA from their previous publications. A paper on the subject requested by the AHA of the lone dissenter, Dr. Jerome Hoffman, was never published and his name was mysteriously erased from the list of panelists.

In the mid-1990s, the AHA unleashed its "brain attack" campaign, in which it sought to elevate stroke to the emergency status of a heart attack, and with it the need for administering tPA. But it seems that the association had already suffered its own "brain attack" earlier in the decade, when it first put its hand out to accept Genentech's largesse.

SURVEY, from page 6

report disciplinary actions taken by hospitals against physicians. We believe that all states should include such data, but did not include it as part of our grading scheme.

Finally, there is no relationship between the content of medical boards' Web sites and their rates of serious disciplinary actions (see story on pg. 1). A relatively high rate of discipline hardly excuses a state from getting disciplinary information out in a complete and user-friendly manner. Conversely, having a complete, user-friendly Web site is no substitute for a higher rate of discipline. Both are needed.

Recommendations

Public Citizen's Health Research Group recommends that all state medical boards adopt high uniform standards for the content and user-friendliness of disciplinary information on the Internet.

1) Each board should have a Web site that links to a database of physician information. For each physician

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

2) Patients should be able to retrieve all data concerning a specific physician by entering a physician's name and/or license number in a search engine or by perusing an alphabetical list.

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

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

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

6) If a court overrules or vacates a board action and exonerates the phy-

sician and the court decision is final, information on that action should be removed from the database. While an appeal is pending, or while a remanded action is being considered, information on the action and the court's decision should continue to be reported in the database.

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

A copy of Public Citizen's full reports on state board Web sites, including the Web address and link to each board's Web site, and ranking state medical boards are available at <http://www.citizen.org/hrgh/healthcare/articles.cfm?ID=7383> or by writing to us at 1600 20th Street, NW, Washington, DC 20009.

Possible Corruption at the American Heart Association

The Association's "Brain Attack"—Taking Millions from the Drug Industry

As clinical medicine has become increasingly complex, doctors (and patients) have come to rely more and more on clinical guidelines developed by blue-ribbon panels of experts convened by the National Institutes of Health, the World Health Organization and other respected bodies. A parallel trend has been the increasing funding of biomedical research by private industry, accompanied by sporadic howls of protest as evidence piles up of drug company suppression of research results unfavorable to their products, legal threats against those guilty of simply wishing to publish their findings, creation of fake patient groups (see the November 2000 issue of the *Health Letter*),

and ghost-writing of medical journal articles.

The two trends have now come together in the form of drug industry attempts to manipulate clinical practice guidelines. In an article in the March 23, 2002 issue of the *British Medical Journal*, journalist Jeanne Lenzer lays bare the evidence that the biotech firm Genentech inordinately skewed the American Heart Association's (AHA's) guidelines on the use of "clot-busters" like Genentech's tPA (also known as alteplase or Activase), the only Food and Drug Administration-approved treatment for acute stroke.

Until August 2000, the AHA maintained that the use of tPA for the most

common kind of stroke was optional. However, following the publication of a National Institute for Neurological Diseases and Stroke (NINDS) trial, the AHA switched from "optional" to "definitely recommended." In that study, stroke patients receiving tPA were 1.7 to 2.1 times more likely than patients receiving an inactive placebo to have a favorable clinical outcome after three months.

For a number of justifiable reasons, the NINDS study has not met with universal acceptance: the placebo and treatment arms were different in critical respects at baseline and the results have not been replicated, a practice that is generally

continued on page 11

Printed on recycled paper.

CHAA44

Enclose your check or money order made out to Health Letter.

One year \$18
 Two year \$30
 Three year \$42

SUBSCRIPTION

NAME _____

ADDRESS _____

CITY, STATE _____

ZIP _____

MOVING? SUBSCRIPTION? ADDRESS _____

CORRECTION? Please enter corrections or subscription information below. Return current mailing label. Mail to ~~Health Letter~~

Health Letter, Public Citizen Health Research Group
1600 20th Street, N.W., Washington, D.C. 20009

Non-Profit Org.
U.S. POSTAGE
PAID
Wash., DC
Permit No. 8314