PUBLIC CITIZEN HEALTH RESEARCH GROUP

Health Letter

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Public Citizen's Ranking of State Medical Boards' Serious Disciplinary Actions, 2004-2006

Public Citizen has calculated the rate of serious disciplinary actions per 1,000 doctors in each state. Using state-by-state data released by the Federation of State Medical Boards (FSMB) on the number of disciplinary actions taken against doctors in 2006, combined with data from earlier FSMB reports covering 2004 and 2005, we have compiled a national report ranking state boards by the rate of serious disciplinary actions per 1,000 doctors for the years 2004-6 (Table 1) and for earlier three-year intervals (Table 2).

Because some small states do not have many physicians, an increase or decrease of one or two serious actions in a year can have a much greater effect on the rate of discipline in such states (and their ranks) than it would in larger states. To minimize such fluctuations, we therefore calculate the average rate of discipline over a three-year period: the year of interest and the preceding two years. Thus, the newest ranking is based on rates from 2004, 2005, and 2006, not the rate for 2006 alone.

Our calculation of rates of serious disciplinary actions is created by taking the number of such actions for each state (revocations, surrenders, suspensions, and probation/restrictions, the first two categories in the FSMB data) and dividing that by the American Medical Association (AMA) data on total M.D.s as of December 2005 in that state. We add to this denominator the number of osteopathic physicians for the 37 boards that are combined medical/osteopathic boards. We then multiply the result by 1,000 to get board disciplinary rates per 1,000 physicians. This rate calculation is done for each year and the average rate for the last three years is used as the basis for this year's state board rankings (Table 1). After we completed these calculations for 2004-2006, we then repeated these calculations for each of the three previous three-year intervals (2001-3, 2002-4, and 2003-5; Table 2).

There were 2,916 serious disciplinary actions taken by state medical boards in 2006, down 10.4 percent from the 3,255 serious actions taken in 2005. The national average disciplinary rate was 3.18, compared to 3.62 in 2005. The three-year state disciplinary rates ranged from 1.41 serious actions per 1,000 physicians (Mississippi) to 7.30 actions per 1,000 physicians (Alaska), a 5.2-fold difference between the best and worst states.

Worst States (those with the lowest three-year rate of serious disciplinary actions).

As can be seen in Table 1, the bottom 10 states, those with the lowest serious disciplinary action rates for 2004-2006, were, starting with the lowest: Mississippi (1.41 actions per 1,000 physicians); South Carolina (1.45); Minnesota (1.45); South Dakota (1.52); Nevada (1.68); Wisconsin (1.78); Washington (2.06); Delaware (2.22); Maryland (2.25); and Connecticut (2.34).

Table 2 shows that five of these 10 states (Delaware, Maryland, Minnesota, South Carolina, and Wisconsin) have been among the bottom 10 states for each of the last four three-year periods.

Nine states have experienced at least a 10-place drop in ranking between the 2001-3 ranking and the 2004-6 ranking: Alabama went from 13th to 26th; Georgia from 15th to 25th; Idaho from 14th to 24th; Mississippi from 20th to 51st; Nevada from 33rd to 47th; New Jersey from 24th to 40th; North Dakota from 3rd to 19th; South Dakota from 37th to 48th; and Virginia from 30th to 41st.

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RATES AND RANKINGS OF MEDICAL BOARDS'SERIOUS DISCIPLINARY ACTIONS, 2006

Table 1: Ranking of Serious Doctor Disciplinary Action Rates by State Medical Licensing Boards, 2004-2006

Rank 2004-2006*	State	Number of Serious Actions, 2006	Number of Physicians, 2005†,‡	Serious Actions per 1,000 Physicians, 2004-2006§
1	Alaska	6	1,777	7.30
2	Kentucky**	62	11,039	7.10
3	Wyoming**	7	1,170	6.37
4	Ohio**	195	37,247	6.01
5	Oklahoma	41	6,950	5.54
6	Missouri	62	17,126	5.43
7	Iowa**	42	7,374	5.32
8	Colorado**	57	14,666	5.24
9	Arizona	73	14,699	5.12
10	Nebraska**	24	4,866	4.91
11	Louisiana**	68	12,758	4.87
12	Illinois**	172	40,801	4.64
13	Vermont	14	2,624	4.62
14	West Virginia	18	4,681	4.47
15	Utah	19	5,857	4.30
16	North Carolina**	112	25,321	4.24
17	New York**	323	85,842	4.15
18	Montana**	9	2,607	4.05
19	North Dakota**	7	1,768	3.98
20	Oregon**	43	11,807	3.80
21	New Hampshire**	12	4,194	3.67
22	New Mexico	21	5,292	3.62
23	Arkansas**	35	6,545	3.61
24	Idaho**	8	3,017	3.35
25	Georgia**	57	22,941	3.34
26	Alabama**	34	11,167	3.32
27	California	301	108,053	3.27
28	Indiana**	46	15,735	3.25
29	Tennessee	47	17,349	3.17
30	Massachusetts**	100	32,512	3.15
31	Texas**	161	56,698	3.03
32	Pennsylvania	109	41,358	3.03
33	Hawaii**	21	4,705	3.02
34	Maine	20	4,095	2.95
35	Florida	113	52,324	2.93
36	Kansas**	16	7,588	2.87
37	District of Columbia**	16	4,873	2.80
38	Rhode Island**	10	4,458	2.75
38	Michigan	70	27,316	2.64
40	New Jersey**	84	32,662	2.59
41	Virginia	52	23,829	2.47
42	Connecticut**	34	14,616	2.34
43	Maryland	61	26,115	2.25
44	Delaware**	9	2,597	2.22
45	Washington	42	19,349	2.06
46	Wisconsin**	30	16,489	1.78
47	Nevada	8	5,196	1.68
48	South Dakota**	4	2,027	1.52
49	Minnesota**	18	16,766	1.45
50	South Carolina**	16	11,338	1.45
51	Mississippi**	7	6,166	1.41

* Rank is calculated based upon an average of the disciplinary rates for 2004, 2005, and 2006.
† Includes osteopathic physicians for boards with jurisdiction over both physicians and osteopaths.
‡ In previous reports we used non-federal physicians, but in this report we used data for total physicians because the American Medical Association no longer provides physician data broken down by federal/non-federal status.
§ Action rate for the period is calculated by averaging the action rates over the three-year period of 2004, 2005, and 2006.
** These states have a combined state medical and osteopathy board.

MEDICAL BOARDS, *from page 1*

Best States (those with the highest three-year rates of serious disciplinary actions).

The top 10 states for 2004-6 are (in order from the top down): Alaska (7.30 serious actions per 1,000 physicians); Kentucky (7.10); Wyoming (6.37); Ohio (6.01); Oklahoma (5.54); Missouri (5.43); Iowa (5.32); Colorado (5.24); Arizona (5.12); and Nebraska (4.91).

Seven of these 10 states (all but Iowa, Missouri, and Nebraska) have been in the top ten for all four of the three-year average periods in this report. Seven states have improved by at least 10 places from the 2001-3 ranking to the 2004-6 ranking. Most notable are Nebraska and Missouri, now both among the top 10 states. Nebraska improved from 28th to 10th and Missouri from 31st to 6th. Illinois improved from 35th to 12th; North Carolina from 41st to 16th; Tennessee from 44th to 29th; Pennsylvania from 45th to 32nd; and Hawaii from 51st to 33rd.

Discussion

These data demonstrate a remarkable variability in the rates of serious disciplinary actions taken by the state boards. Only one of the nation's 15 most populous states, Ohio, is represented among those 10 states with the highest disciplinary rates. Absent any evidence that the prevalence of physicians deserving of discipline varies substantially from state to state, this variability must be considered the result of the boards' practices. Indeed, the ability of certain states to rapidly increase or decrease their rankings (even when these are calculated on the basis of three-year averages) can only be due to changes in practices at the board level; the prevalence of physicians eligible for discipline cannot change so rapidly.

Moreover, there is considerable evidence that most boards are underdisciplining physicians. For example, in a report on doctors disciplined for criminal activity that we published in the last year, 67 percent of insurance fraud convictions and 36 percent of convictions related to controlled substances were associated with only non-severe discipline by the board.

In this report, we have concentrated on the most serious disciplinary actions. Although the FSMB does report less severe actions such as reprimands, it is not appropriate to provide such actions with equal weight as license revocations, for example. A state that embarks on a strategy of switching over time from revocations or probations to fines or reprimands for similar offenses should have a rate and a ranking that reflects this decision to discipline less severely.

A relatively recent trend has been for state boards to post the particulars of disciplinary actions they have taken on the Internet. In October 2006, Public Citizen's Health Research Group published a report that ranked the states according to the quality of those postings. The report showed variability in the quality of those websites akin to that reported for disciplinary rates in this report. There was no correlation between state ranking in the website report and state ranking in this disciplinary rate report (Spearman's rho = 0.0855; p=0.55). A good website is no substitute for a poor disciplinary rate (or vice versa); states should both appropriately discipline their physicians and convey that information to the public. However, no state ranked in the top 10 in both reports.

There is considerable evidence that most boards are under-disciplining physicians.

This report ranks the performance of medical boards by their disciplinary rates; it does not purport to assess the overall quality of medical care in a state or to assess the function of the boards in other respects. It cannot determine whether a board with, for example, a low disciplinary rate has been starved for resources by the state or whether the board itself has a tendency to mete out lower (or no) forms of discipline. From the patient's perspective, of course, this distinction is irrelevant.

What Makes a Difference?

Boards are likely to be able to do a better job in disciplining physicians if the following conditions are met:

- 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 reacting to complaints
- The use of all available/reliable data from other sources such as Medicare and Medicaid sanctions, hospital sanctions, malpractice payouts, and the criminal justice system
- Excellent leadership
- Independence from state medical societies
- Independence from other parts of the state government so that the board has the ability to develop its own budgets and regulations
- A reasonable legal standard for disciplining doctors ("preponderance of the evidence" rather than "beyond a reasonable doubt" or "clear and convincing evidence").

Most states are not living up to their obligations to protect patients from doctors who are practicing medicine in a substandard manner. Serious attention must be given to finding out which of the above bulleted variables are deficient in each state. Action must then be taken, legislatively and through pressure on the medical boards themselves, to increase the amount of discipline and, thus, the amount of patient protection. Without adequate legislative oversight, many medical boards will continue to perform poorly. ■

RANKING OF THE RATE OF MEDICAL BOARDS' SERIOUS DISCIPLINARY ACTIONS, 2001-6

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

	2003	2004	2005	2006
Alabama‡	13	17	22	26
Alaska‡	6	4	2	1
Arizona	2	7	6	9
Arkansas‡	29	45	39	23
California	22	22	23	27
Colorado‡	8	9	8	8
Connecticut‡	38	38	38	42
Delaware‡	50	50	50	44
District of Columbia‡	42	31	36	37
Florida	36	37	32	35
Georgia‡	15	18	20	25
Hawaii‡	51	51	42	33
Idaho‡	14	21	25	24
Illinois‡	35	25	18	12
Indiana‡	27	27	24	28
Iowa‡	12	12	15	7
Kansas‡	32	30	31	36
Kentucky‡	1	2	1	2
Louisiana‡	17	14	13	11
Maine	34	35	46	34
Maryland‡	48	47	44	43
Massachusetts‡	23	23	28	30
Michigan	40	39	40	39
Minnesota‡	47	48	49	49
Mississippi‡	20	41	51	51
Missouri‡	31	11	10	6
Montana‡	9	8	12	18
Nebraska‡	28	24	16	10
Nevada	33	46	47	47
New Hampshire‡	25	26	21	21
New Jersey‡	24	29	35	40
New Mexico	21	19	29	22
New York‡	18	16	17	17
North Carolina‡	41	34	26	16
North Dakota‡	3	3	7	19
Ohio‡	7	6	4	4
Oklahoma	5	5	5	5
Oregon‡	16	20	19	20
Pennsylvania	45	36	33	32
Rhode Island‡	46	44	37	38
South Carolina‡	43	43	45	50
South Dakota‡	37	33	43	48
Tennessee	44	40	30	29
Texas‡	26	28	27	31
Utah	10	13	14	15
Vermont	19	15	11	13
Virginia‡	30	32	34	41
Washington	39	42	41	45
West Virginia	11	10	9	14
Wisconsin‡	49	49	48	46
Wyoming‡	4	1	3	3

* Rank for each year is calculated based on an average of the disciplinary rates from that year and the preceding two years.

† Whereas in previous reports we used data on non-federal physicians, in this report we used data for total physicians because the American Medical Association no longer provides physician data broken down by federal/non-federal status. The data in this table are based on total physician data for all years. Differences in rank from previous reports are minor (see text).

‡ These states have a combined state medical and osteopathy board.

Product Recalls

April 18, 2007 — May 23, 2007

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

DRUGS AND DIETARY SUPPLEMENTS

The recalls noted here reflect actions taken by a firm to remove a product from the market. Recalls may be conducted on a firm's own initiative, by FDA request or by FDA order under statutory authority. 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*. Visit *www.recalls.gov* for information about FDA recalls and recalls issued by other government agencies.

Recalls and Field Corrections: Drugs — CLASS I

Indicates a problem that may cause serious injury or death

Name of Drug or Supplement; Problem; Recall Information

LIVIRO3 Natural Energy Enhancer Nutritional Supplement, 450mg Capsules; Unapproved New Drug; product to contain the undeclared ingredient Tadalafil, the active pharmaceutical ingredient in an FDA approved drug used to treat erectile dysfunction. Lot #1 exp. date 03/2006, Lot #2 exp. date 11/2008, Lot #3 exp. date 0/2009, Lot #4 exp. date 07/2009, Lot #5 exp. date 07/2009; NOTE: THIS IS WHAT WAS FOUND ON SAMPLE COLLECTED- Underneath the aluminum try that contains all 10 capsules of LIVIRO3 (found inside box), there are lot codes and expiration dated imprinted on it. The lot code for the FDA sample is LOT 0730 EXP 07/30/2009. There might be other lot codes since it appears that the lot code correspond with the expiration date. Note: Other codes pending; West Coast Laboratories Inc, Gardena, CA. Firm initiated recall is ongoing.

LEVIROL Sexual Performance Formula Dietary Supplement, a proprietary blend of: Epimedium (Epimedium sagittatum leaf); Unapproved New Drug; product found to contain the undeclared ingredient Aminotadalafil, an analogue of Tadalafil, the active pharmaceutical ingredient found in an FDA approved drug used for erectile dysfunction. Lot # 0606332 exp. date 06/2009, Lot # 0605143 exp. date 05/2009, Bactolac Pharmaceutical, Inc.

Recalls and Field Corrections: Drugs — CLASS II

Indicates a problem that may cause temporary or reversible health effects; unlikely to cause serious injury or death

Name of Drug or Supplement; Problem; Recall Information

Children's Mucinex Cough (Guaifenesin, USP 100mg/5mL and Dextromethorphan HBr 5mg/5mL), Cherry Flavor Liquid, Misbranded; calibrated dosage dispensing cup may be confusing to consumers as measurements are shown in units of teaspoon and tablespoon while dosages are all listed in teaspoons. Lot #s 605007, 605008, 605009, 605021, 605022, 605023, 605024, 605025, 605026, 605027, 605028, 605029, 607001, 607002, 607003, 607004, 607005, 607006, 607007, 607008, 607009, 607010, 607011, 608011, 608012, 608013, 608014, 608015, 608016, 608017, 608018, 608019, 608020, 608021, 608022, 608028, 609007, 609008, 609009, 609010, 609011, 609012, 609013, 609014, 609015, 609016, 609017, 609018, 609019, 609020, 609021, 609022, 610003, 610004, 610005, 610006, 610007, 610008, 610009, 610010, 610011, 610012, 610013, 610014, 610015, 610016, 610017, 610018, 610019; QPharma, LLC.

Children's Mucinex Expectorant (Guaifenesin, USP, 100mg/5mL), Grape Flavor Liquid; Misbranded; calibrated dosage dispensing cup may be confusing to consumers as measurements are shown in units of teaspoon and tablespoon while dosages are all listed in teaspoons. Lot #s 605010, 605011, 605012, 606001, 606002, 606003, 606004, 606005, 606006, 606007, 606008, 606009, 606010, 606011, 606012, 606014, 606015, 606016, 606017, 606018, 606019, 606020, 608004, 608005, 608006, 608007, 608008, 608009, 608010, 608031, 608032, 609001, 609002, 609003, 609004, 609005, 609006, 609023, 609024, 609025, 609026, 609027, 609028, 609029, 609030, 609031, 609032, 609033, 609034, 609035, 610023, 610024, 610025, 610026, 610027, 610028, 610029, 610030, 610032; QPharma, LLC.

Recalls and Field Corrections: Drugs — CLASS II *cont'd.*

Name of Drug or Supplement; Problem; Recall Information

Dramamine Less Drowsy Formula (Meclizine hydrochloride), 25 mg Tablets; Labeling; immediate container label incorrectly states dosing at 1-2 tablets every 4 to 6 hours not to exceed 8 tablets in 24 hours. Label should state dosing at 1-2 tablets daily or as directed by a doctor. Lot #s 81948 exp. date 12/31/2009, Lot # 84515 exp. date 12/31/2009, Lot # 87295 exp. date 8/31/2010 (value pack), McNeil Consumers Healthcare.

Grifulvin V® (griseofulvin) microsize oral suspension, 125 mg/5mL, 4 fl oz glass bottles; Product may contain glass fragments. Lots #s 5CA136, exp. date 03/31/2007; 5CA138, exp. date 03/31/2007; 5CA139, exp. date 03/31/2007; 5CA143, exp. date 03/31/2007; 5CA144, exp. date 03/31/2007; 5CA145, exp. date 03/31/2007; CA146, exp. date 03/31/2007; 5CA147, exp. date 03/31/2007; 5CA148, exp. date 03/31/2007; 5CA149, exp. date 03/31/2007; 5CA150, exp. date 03/31/2007; 5CA 151, exp. date 03/31/2007; 5CA164, exp. date 03/31/2007; 5CA165, exp. date 04/30/2007; 6CA616, exp. date 03/31/2008; 6DA636, exp. date 04/30/2008; 6DA637, exp. date 04/30/2008; 6DA638, exp. date 04/30/2008; 6DA640, exp. date 04/30/2008; 6DA646, exp. date 04/30/2008; 6DA647, exp. date 04/30/2008; 6DA648, exp. date 04/30/2008; 6DA649, exp. date 04/30/2008; 6DA657, exp. date 04/30/2008; 6EA670, exp. date 05/31/2008; 6GA731, exp. date 07/31/2008; 6HA846, exp. date 07/31/2008; 6HA851, exp. date 08/31/2008; 6HA868, exp. date 07/31/2008; 6HA873, exp. date 09/30/2008; 6HA874, exp. date 08/31/2008; 6JA936, exp. date 09/30/2008; 6JA937, exp. date 09/30/2008; 6KA987, exp. date 09/30/2008; 6KA988, exp. date 09/30/2008; 6KA989, exp. date 09/30/2008; 6MA193, exp. date 11/30/2008; Ortho-McNeil Pharmaceutical, Inc.

PAXIL CR Tablets, (Paroxetine HCl), 12.5mg Controlled-Release Tablets, 30 tablet bottles; Incorrect Package Insert. Medical Guidance leaflet may have an incorrect dosage strength (25mg). Lot # 9-6P06 exp. date 02/29/2008, Lot # 14-6P06 exp. date 05/31/2008, Lot # 15-6P06 exp. date 05/31/2008, Lot # 16-6P06 exp. date 05/31/2008; Smithkline Beecham Pharmaceuticals Co.

Recall Note

A misbranding incident at Heartland Repack Services, LLC, has resulted in a recall of 81 drugs. There is the possibility of multiple product packaging mix-ups. An OTC drug, prescription drug, or nutritional supplement other than what is indicated on the product labeling may be inside the packaging. Ask your pharmacist to find out if your sample is part of the recalled batch.

Carbamazepine 200MG and Carbamazepine Chew 100MG; Carbidopa Levodopa 10/100MG, 25/100MG, and 25/250MG; Carbidopa Levodopa ER 50/200MG; Carisoprodol 350MG; Chlordiazapoxide 25MG, Chlorpromazine 10MG, 200MG, 25MG, and 50MG; Cimetidine 400MG; Clindamycin 300MG; Clomipramine 50MG; Clonazepam 0.5MG, 1MG, and 2MG; Clonidine HCL 0.1MG and 0.2MG, and 0.3MG; Colchicine 0.6MG; Cyclobenzaprine 10MG; Cyproheptadine 4MG; Diazepam 10MG, 2MG, and 5MG; Dicyclomine 10MG and 20MG; Digitek 0.125MG and 0.25MG; 32) Diltiazem 120MG, 30MG, 60MG, and 90MG; Diltiazem ER 120MG, 180MG, 240MG, and 300MG; Diphenhydramine 25MG; Diphenoxy W/Atrop 2.5/.025MG; Dipyridamole 25MG, 50MG, and 75MG; Docusate Calcium 240MG; Docusate Sodium 100MG; Doxazosin 1MG, 2MG, 4MG, and 8MG; Doxepin 50MG; Doxepin HCL 10MG and 25MG; Enalapril 10MG, 2.5MG, 20MG, and 5MG; Famotidine 20MG; FAMOTIDINE 40MG; Fludrocortisone 0.1MG; Fluoxetine 10MG, 20MG, and 40MG; Fluphenazine 10MG, 1MG, 2.5MG, and 5MG; Folic Acid 1MG; Furosemide 20MG, 40MG, and 80MG; Gabapentin 100MG Capsule, 100MG Tablet, 300MG Capsule, 300MG Tablet, and 400MG Capsule; Gemfibrozil 600MG, Glipizide 10MG and 5MG; Glyburide 2.5MG and 5MG.

CONSUMER PRODUCTS

Contact the Consumer Product Safety Commission (CPSC) for specific instructions or return the item to the place of purchase for a refund. For additional information from the Consumer Product Safety Commission, call their hotline at (800) 638-2772. The CPSC web site is *www.cpsc.gov*. Visit *www.recalls.gov* for information about FDA recalls and recalls issued by other government agencies.

Name of Product; Problem; Manufacturer and Contact Information

Anima-Bamboo Collection Games. The toys in the Anima – Bamboo Collection Games sets could contain lead paint, which is toxic if ingested by young children and can cause adverse health effects. Target, (800) 440-0680 or www.target.com.

Boomboxes. When left plugged into an electrical outlet and the off switch is not firmly in place, Coby-Brand USB/MP3/CD Boomboxes can overheat, posing a fire hazard. Coby Electronics Corp., (800) 524-9219 or www.cobyusa.com.

Bunny Books. The seam on the bunny's left hind leg of the Discovery Bunny Books can open exposing a plastic squeaker toy contained inside a cloth bag, posing a choking hazard to young children. Bookspan, (888) 793-6514 or www.bookspan.com.

Car Seats/Carriers. When used as an infant carrier, the handle of the Evenflo Embrace™ Infant Car Seat/Carriers can unexpectedly release, causing the seat to rotate forward. When this happens, an infant inside the carrier can fall to the ground and suffer serious injuries. Evenflo Company Inc., (800) 490-7497 or www.embracehandle.com.

Carpet Tiles. Pin-like needles can be embedded in the Heartfelt Carpet Tiles, posing a puncture wound hazard to consumers. InterfaceFLOR LLC, (866) 219-2197 or www.florcatalog.com.

Children's Capri Pants. The buttons inside the waistband of the Little Girls Capri Pants with Snap Roll Cuff can detach, posing a choking hazard to young children. Mervyns, (800) 637-8967 or www.mervyns.com.

Children's Clog Shoes. Plastic rivets used to attach the strap to the Children's Airwalk® Compel Shoes can detach, posing a choking hazard to young children. Payless ShoeSource, Inc., (800) 654-0697 or www.payless.com.

Children's Clothing. The decorative fish buttons on the Three Piece Short Sets could detach, posing a choking hazard. Samara Brothers LLC, (800) 985-9975 or www.samararecall.com.

Children's Jewelry. Children's Necklaces, Bracelets and Rings contains high levels of lead. Lead is toxic if ingested by young children and can cause adverse health effects. Spandrel Sales and Marketing Inc., (877) 213-0500 or www.ssmvending.com.

Children's Jewelry. Children's Religious Fish Necklaces contain high levels of lead. Lead is toxic if ingested by young children and can cause adverse health effects. Oriental Trading Company Inc., (800) 723-6155 or www.orientaltrading.com.

Children's Rings. Children's Rings with Dice or Horseshoes contain high levels of lead. Lead is toxic if ingested by young children and can cause adverse health effects. These rings were subject to the July 2004 recall of 150 million pieces of children's metal jewelry. The firm placed the recalled rings that it had pulled from stores back into circulation. Cardinal Distributing Co. Inc., (800) 368-2062 or www.vendingdepot.com.

Children's Rings. Children's Turquoise Rings contain high levels of lead. Lead is toxic if ingested by young children and can cause adverse health effects. Cardinal Distributing Co. Inc., (800) 368-2062 or www.vendingdepot.com.

Children's Take-Apart Townhouses. Small magnets used to connect the wooden pieces to the sides of the IQ Preschool™ Take-Apart Townhouse can fall out. Magnets found by young children can be swallowed or aspirated. If more than one magnet is swallowed, the magnets can attract each other and cause intestinal perforations or blockages, which can be fatal. Small World Toys, (800) 421-4153 or www.smallworldtoys.com.

Children's Toys. Ball Rattles, Wrist Rattles, and Wind-Up Toys contain small parts, posing a choking hazard to young children. Tri-Star International Inc., (510) 856-8785.

Clip-On Baby Books. The metal clip used to attach the Baby Buddy Clip-on Books to a stroller or article of clothing can break, posing a choking hazard to young children. Golden Ocean International Enterprise Ltd., (800) 509-2997 or www.bookspan.com.

Coast Spas. Coast Spas with Franklin Electric Motors have a circulating pump and motor assembly, which can overheat and pose a fire hazard. Coast Spas Manufacturing Inc., (877) 534-5255 or www.spamotorretrofit.com.

Dishwashers. Liquid rinse-aid can leak from its dispenser onto the GE Dishwasher's internal wiring which can cause an electrical short and overheating, posing a fire hazard to consumers. GE Consumer & Industrial, (877) 607-6395 or www.geappliances.com.

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Name of Product; Problem; Manufacturer and Contact Information

Electric Heaters. A poor electrical connection within the Holmes® Oil-Filled Electric Heaters can lead to overheating. This poses fire and thermal burn hazards. The Holmes Group, (800) 306-2471 or www.holmesoilfilledheaterrecall.com.

Emergency Lights. A circuit board in the Contractor's Choice FasTest(tm) High Capacity Emergency Lighting Units could malfunction, preventing the lights from illuminating in the event of a power failure. This could result in a failure to provide adequate lighting to guide building occupants to an exit in the event of an emergency. Cooper Lighting Inc., (800) 954-7228, or www.cooperlighting.com.

Gardening Gloves. The stamp-painted logo on the backside of the Budding Gardener Complete Gardening Set contains high levels of lead. Lead is toxic if ingested by young children and can cause adverse health effects. MTD Products Inc, (888) 848-6038 or www.troybilt.com.

Gas Grills. Char-Broil Two-Burner Gas Grills Model 463720407 could have an incorrect heat shield that does not fit the grills. Without the correct heat shield, the propane tank, hose, and regulator could overheat and damage these components, presenting a risk of fire and burn to consumers, if a propane leak occurs. Char-Broil LLC, (866) 671-7988 or www.charbroil.com.

Gas Grills. Some Perfect Flame Four-Burner Gas Grills could be missing a hose that connects the grill manifold to the side burner, which poses a risk of fires and burn injuries to consumers. Sagittarius Sporting Goods, (888) 804-7455.

Halogen Table Lamps. Halogen Table Lamps can short circuit, posing a fire hazard. L G Sourcing, Inc., (866) 284-9162 or www.lowes.com.

Heated Massage Recliners. The control device that adjusts the heat and massage settings of Berkline Heated Massage Recliners can overheat, posing a burn hazard to consumers. Berkline Benchcraft LLC, (800) 717-7091 or www.berkline.com.

Kitchen Stools. Rooster Kitchen Stools can unexpectedly collapse during use, causing a consumer to fall to the floor. CBOCS Distribution Inc., (800) 333-9566 or www.crackerbarrel.com.

Lamps. The light sockets on Currey & Company Table Lamps have a defect, which poses electrical shock and fire hazards. Currey & Company, (866) 577-6430 or www.curreyco.com.

Laptop Computer Batteries. Rechargeable lithium-ion batteries containing Sony-made cells used in Acer notebook computers can overheat, posing a fire hazard to consumers. Acer America Corporation, (800) 503-2330 or www.acerbatteryrecall.com/AcerWeb.

Off-Road Motorcycles. The seal around the fuel tank of Off-Road Motorcycles can loosen allowing fuel to leak, posing a fire hazard to consumers. KTM North America Inc., (888) 985-6090 or www.ktmnorthamerica.com.

Pier 1 Glassware. Orange/Red Glassware Pieces can crack or break unexpectedly, posing a laceration hazard. Pier 1 Imports at (800) 245-4595 or www.pier1.com.

Pre-Lit Palm Trees. If the electrical connectors of the Pre-Lit Palm Trees are not fully inserted, they can overheat and pose electric shock and fire hazards. iObjectSolutions Inc., (866) 962-7382 or CustomerService@christmaslightsetc.com.

Snowmobiles. The right and left front suspension shock towers of Model Year 2006 FS Classic, FS Touring, FST Classic, FST Touring and FST Switchback Snowmobiles can separate due to inadequate welding during the manufacturing process. Separation of the welded joints can result in stiffer steering or the shock mount failing suddenly, causing the rider to lose control of the snowmobile and crash. Polaris Industries Inc., (800) 765-2747 or www.polarisindustries.com.

Soft Blocks Towers. The plastic covering on the Soft Blocks Tower Toys (on Graco(r) Baby Einstein(r) discover and play(tm) Activity Centers) can detach, posing a choking hazard to infants. Graco Children's Products Inc., (800) 345-4109 or www.gracobaby.com.

Toy Cell Phones. The metal pin inside the hinge of the Parents® Magazine Record-A-Voice Toy Cell Phones flip-top can fall out, posing a choking hazard to young children. Battat, Inc., (800) 247-6144 or cellrecall@battatco.com.

Toy Sets. Surface paints on the Invincibles Transport Converters Toy Sets contain high levels of lead. Lead is toxic if ingested by young children and can cause adverse health effects. Toy Century Industrial Ltd., (800) 866-3605 or www.aafes.com.

Youth Model ATVs. Long Chang Lion 90cc All-Terrain Vehicles (ATVs) lack adequate tire labeling, tire pressure gauge, adequate stop engine switch and other safety requirements which could result in injury to consumers. Stateside Powersports, (888) 801-4424 or support@statesidepowersports.com.

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heart failure, the information in the *NEJM* report is different because it links Avandia to heart attacks for the first time. (Actos was not analyzed in the *NEJM* report).

Although they sound similar, heart failure and heart attack describe two different conditions. Heart failure occurs when the heart can no longer pump enough blood to the other organs in the body. It can have a variety of causes including high blood pressure, narrowed arteries that supply blood to the heart muscle, primary disease of the heart muscle itself, infection of the heart valves and/or heart muscle itself, or a past heart attack. Symptoms can include exercise intolerance and swelling of the legs.

A heart attack, on the other hand, is the death of heart muscle due to the sudden blockage of an artery that supplies that muscle. Coronary arteries bring blood and oxygen to the heart muscle; stoppage of the blood flow injures the muscle and can cause muscle death. Heart muscle death is irreversible, and the dead heart muscle is replaced by scar tissue. If this damage is severe enough, heart failure can ensue.

The cause of the link between Avandia and the increased risk of heart attacks is not clear, but could be due to an increase in low-density lipoprotein (LDL, or "bad") cholesterol caused by the drug. Elevated LDL cholesterol levels are associated with an increase in heart attacks.

Despite prior knowledge of serious cardiac problems, the FDA thus has failed to require GlaxoSmithKline to adequately warn about the dangers of this drug that should be, at best, a last-choice treatment for type-II diabetes.

Alternatively, the heart attacks may be related to the well-known propensity of the glitazones to cause heart failure.

In addition, there have been reports of glitazone-induced anemia (low red blood cell count), which can also increase the risk of a heart attack.

The *NEJM*'s findings are not based on a single experiment in which the authors interacted with the patients in the study; rather it combined the data from 42 previous trials, some of them unpublished. The results are based on a relatively small number of events, which means that small changes in the classification of events could affect results, but it is not clear whether this would bias the results for or against Avandia.

Nonetheless, the findings are worrisome because of the high incidence of cardiovascular events in patients with diabetes even if they are not using such drugs. Because exposure of such patients to Avandia is widespread, a further increase in cardiovascular risk could have a substantial impact on the public's health. An FDA analysis of the existing studies and a larger controlled trial are pending.

The Current Regulatory Issue

In the summer of 2006, GlaxoSmithKline approached the FDA with analyses similar to those in the *NEJM*, but the company discounted their significance and the FDA succumbed. Despite prior knowledge of serious cardiac problems, the FDA thus has failed to require GlaxoSmithKline to adequately warn about the dangers of this drug that should be, at best, a last-choice treatment for type-II diabetes.

Do the results of this recent Avandia study apply to other glitazones, such as pioglitazone (Actos)? Actos is a related agent and is also widely used to treat type-II diabetes. Like Avandia, Actos also caused serious damage to the heart in animal

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studies. Actos was not included in the *NEJM* study, but other data indicate that Actos may have similar effects to Avandia in terms of increased heart failure. Public Citizen is also concerned about Actos, and has listed it as a Do Not Use drug since 2004, in part because it also causes liver toxicity.

Public Citizen obtained an internal FDA memo dated almost five years ago concerning heart failure from Avandia and Actos in the first two years of postmarketing surveillance for these drugs. The July 16, 2002, memo from FDA staff in the Division of Drug Risk Evaluation evaluated cases of heart failure that were serious enough to require hospitalization. Their analysis of these adverse reaction reports found 47 cases in which the use of Avandia (25 cases) and Actos (22 cases) resulted in serious heart failure. In the majority of these cases, the heart failure improved with the cessation of treatment with these drugs, strengthening the case that the drug was in fact the cause of the heart failure.

In their memo, the FDA scientists recommended that both labels "should include mention of these postmarketing reports."

Although in the following years the FDA modified the labeling to include more detailed mention of clinical trials showing increased risk of cardiovascular events, the label has never been updated to include the information from the original postmarketing reports. Since 2002, even more postmarketing reports have linked Actos and Avandia to heart failure. There are now a total of 1182 cases reported to the FDA with these two drugs (689 for Avandia, 493 for Actos; 803 involving hospitalization – 415 for Avandia, 388 for Actos).

Because of inadequate warnings about Actos and Avandia and massive advertising campaigns, the drugs' popularity has grown so that 11 million prescriptions were filled for each drug in the United States in 2006 alone.

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Glitazones' Risks

Both Actos and Avandia are associated with a number of side effects. Weight gain is a consistent finding with all the glitazones. This occurs because these drugs promote the conversion of sugar to fat; resulting in the production of new fat cells in the body. Weight gain is also attributable to accumulation of fluid in the legs, ankles, and lungs caused by heart failure. Even in the absence of heart failure, fluid can accumulate in the legs.

Other reported side effects with these drugs include liver damage, liver failure, and visual impairment.

Furthermore, Avandia and Actos are not as effective as other diabetes drugs in lowering blood sugar. In nine out of the 10 head-to-head trials comparing glitazones to other antidiabetic drugs, the glitazone tested was less effective.

Preferable Alternatives to Actos and Avandia

The combination of diet and exercise is the safest, most effective treatment available for the vast majority of adult-onset diabetics. More than 90 percent of type-II diabetics are overweight. In many cases, blood sugar levels return to normal and symptoms go away when a diabetic patient loses enough weight.

People often find diets that are very complicated or very different from what they are used to are hard to follow. Gradual dietary change will frequently reduce weight and lower blood sugar. Doctors and dietitians can help patients plan an easy-to-follow diet that will help to control diabetes. The diet for a type-II diabetic is based on the same nutritional principles that apply to patients without diabetes. Special foods ("dietetic") and unbalanced fad diets are unnecessary and sometimes dangerous. The basic plan should be to avoid sugar and instead eat a diet high in starch and fiber.

Many people are already eating a diet that is partly appropriate for diabetics. Only small changes may be needed. For instance, doctors recommend eating fewer simple sugars by substituting sugar-free drinks, graham crackers, or bread sticks for soft drinks, snack foods, and cookies.. Substituting fish, chicken, turkey, vegetable dishes for red meat (beef, pork, lamb) reduces the intake of cholesterol and saturated fat. This in turn reduces the risk of atherosclerosis (hardening of the blood vessels).

A regular exercise program is also recommended for diabetics. Exercise helps to lower blood sugar and to reduce weight. It does not have to be strenuous; walking is the best form of exercise for many people. Because some complications of diabetes can limit one's ability to exercise, it is important for diabetics to consult their doctor to be sure the chosen form of exercise is safe.

However, in cases where additional medicinal therapy is necessary, Public Citizen recommends tolbutamide (Orinase), glipizide (Glucotrol), tolazamide (Tolinase), or metformin as preferable alternatives to Actos and Avandia. Public Citizen recommends use of these drugs but reminds consumers that they are by no means an adequate substitute for a healthy diet and regular exercise. ■

OUTRAGE OF THE MONTH

Avandia

Not-So-New News of Heart Problems With the Popular Diabetes Drug

The New England Journal of Medicine (NEJM) precipitated an enormous amount of public attention recently when it published a report linking the popular diabetes drug rosiglitazone (Avandia) to a 43 percent increase in the risk of heart attacks. This study has attracted a lot of attention because 9.4 percent of the adult population is diabetic and 11 million prescriptions were filled in the U.S. last year for Avandia. With 125 million prescriptions for oral diabetes drugs filled every year, information regarding new risks grabs public attention.

The Basics

Avandia is a drug approved to treat type-II diabetes. It is a member of the thiazolidinedione (glitazone) family of antidiabetic drugs (also known as glitazones), which are thought to work by increasing the body's sensitivity to insulin. There is only one other glitazone currently sold in the US, pioglitazone (Actos), and, like Avandia, it is widely prescribed. Public Citizen has listed both Actos and Avandia as Do Not Use drugs since 2004 due to serious concerns about congestive heart failure, swelling and weight gain.

This is not the first time cardiovascular disease has been attributed to the glitazones.

The News

This is not the first time cardiovascular disease has been attributed to the glitazones. In animal studies done prior to its approval, one of the most consistent findings was damage to the heart. In the first six years following FDA approval, there were 689 cases of heart failure reported to the FDA in patients using Avandia. This is certainly an undercount as physicians are not required to report such reactions to the government.

Although it has long been known that both Actos and Avandia cause

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