

Health Letter

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June 2006 ♦ VOL. 22, NO. 6

Public Citizen's Health Research Group Ranking of State Medical Board Serious Disciplinary Actions: 2003-2005

Based on state-by-state data released on April 25th by the Federation of State Medical Boards (FSMB) on the number of disciplinary actions taken against doctors in 2005, combined with data from 2003-2004, Public Citizen's Health Research Group has calculated the rate of serious disciplinary actions (revocations, surrenders, suspensions and probation/restrictions) per 1,000 doctors in each state and compiled a national report ranking state boards by the rate of serious disciplinary actions per 1,000 doctors for the years 2003-5 (See Table 1).

Until two years ago, our ranking was based solely on the data from the most recent year. Because some small states do not have many physicians, an increase or decrease of one or two serious actions in a year can have a much greater effect on the rate of discipline in such states than it would in larger states. Therefore we now calculate the three-year average rate of discipline (for each year and the preceding two years) for all states and list them by rank for each three-year interval so that trends in rank over the past decade can more accurately be examined (see Table 2). Again, the newest ranking is based on the three-year average rate, not the rate for 2005 alone.

Our calculation of rates of serious disciplinary actions per 1,000 doctors

by state is created by taking the number of such actions for each state (the first two categories of the FSMB data) and dividing it by the American Medical Association data on nonfederal M.D.s as of December 2004¹ in that state (adding to this the number of osteopathic physicians² if the board is a combined medical/osteopathic board). We then multiply the result by 1,000 to get state disciplinary rates per 1,000 physicians. This rate calculation is done for each of the last three years (2003-2005), and the average rate for the three years is used as the basis for this year's state board rankings.

There were 3,255 serious disciplinary actions taken by state medical boards in 2005, slightly down (1.2%) from the 3,296 serious actions taken in 2004. The three-year state disciplinary rates ranged from 1.62 serious actions per 1,000 physicians (Mississippi) to 9.08 actions per 1,000 physicians (Kentucky), a 5.6-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 *continued on page 3*

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RANKING OF THE RATE OF STATE MEDICAL BOARDS' SERIOUS DISCIPLINARY ACTIONS IN 2005

Table 1: Ranking of Serious Doctor Disciplinary Action Rates by State Medical Licensing Boards, 2003-2005

Rank 2003-2005*	State	Number of Serious Actions 2005	Number of Physicians 2004**	Serious Actions per 1,000 Physicians from 2003-2005***
1	Kentucky	72	10814	9.08
2	Alaska	19	1691	8.49
3	Wyoming	7	1143	8.19
4	Ohio	235	36622	6.33
5	Arizona	81	14012	6.20
6	Oklahoma	36	6846	6.19
7	North Dakota	7	1771	6.07
8	Colorado	84	14266	5.75
9	West Virginia	25	4613	5.45
10	Missouri	48	16792	5.34
11	Montana	8	2529	5.30
12	Vermont	14	2589	5.28
13	Louisiana	54	13113	4.89
14	Utah	32	5643	4.84
15	Iowa	30	7320	4.77
16	Nebraska	31	4805	4.53
17	New York	362	85120	4.39
18	Illinois	211	40142	4.08
19	Oregon	55	11428	4.05
20	Georgia	81	22303	3.99
21	New Hampshire	17	4069	3.78
22	Alabama	38	10917	3.78
23	California	363	105766	3.56
24	Indiana	55	15399	3.52
25	Idaho	12	2863	3.50
26	North Carolina	105	24645	3.45
27	Texas	188	55073	3.29
28	Massachusetts	94	31738	3.22
29	New Mexico	14	5169	3.17
30	Tennessee	65	16863	3.14
31	Kansas	22	7480	3.02
32	Florida	182	51025	2.98
33	Pennsylvania	109	40832	2.80
34	Virginia	64	23296	2.65
35	New Jersey	64	32038	2.61
36	District of Columbia	11	4767	2.58
37	Connecticut	36	14395	2.50
38	Arkansas	26	6410	2.49
38	Rhode Island	16	4343	2.49
40	Michigan	65	26999	2.40
41	Washington	41	18894	2.22
42	Hawaii	15	4600	2.19
43	South Dakota	1	1983	2.18

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RANKING OF THE RATE OF STATE MEDICAL BOARDS' SERIOUS DISCIPLINARY ACTIONS IN 2005

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Table 1: Ranking of Serious Doctor Disciplinary Action Rates by State Medical Licensing Boards, 2003-2005

Rank 2003-2005*	State	Number of Serious Actions 2005	Number of Physicians 2004**	Serious Actions per 1,000 Physicians from 2003-2005***
44	Maryland	60	25689	2.14
45	South Carolina	15	11063	2.06
46	Maine	7	4052	2.04
47	Nevada	11	4934	2.03
48	Wisconsin	23	16205	1.72
49	Minnesota	29	16322	1.65
50	Delaware	4	2536	1.63
51	Mississippi	11	6159	1.62

* Rank is calculated based upon an average of the disciplinary rates for 2003, 2004 and 2005.

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

***Action rate is calculated by averaging the action rates over the three-year period of 2003, 2004 and 2005.

MEDICAL BOARDS, *from page 1*

bottom 15 states, those with the lowest serious disciplinary action rates for 2003-2005 were, starting with the lowest: Mississippi (1.62 actions per 1,000 physicians), Delaware (1.63 per 1,000 physicians), Minnesota (1.65 per 1,000 physicians), Wisconsin (1.72 per 1,000 physicians), Nevada (2.03 per 1,000 physicians), Maine (2.04 per 1,000 physicians), South Carolina (2.06 per 1,000 physicians), Maryland (2.14 per 1,000 physicians), South Dakota (2.18 per 1,000 physicians), Hawaii (2.19 per 1,000 physicians), Washington (2.22 per 1,000 physicians), Michigan (2.40 per 1,000 physicians), Rhode Island (2.49 per 1,000 physicians), Arkansas (2.49 per 1,000 physicians), and Connecticut (2.50 per 1,000 physicians).

Table 2 shows that four of these 15 states, (Wisconsin, Minnesota, Delaware, and Hawaii) have been among the bottom 15 states for the last 10 three-year periods. In addition, Maryland and Connecticut have been among the bottom 15 states for nine of the last 10 three-year periods; Washington, for seven of the last 10 three-year periods; South Carolina, for six of the last 10 three-year periods, and Rhode Island, for five of the last 10 three-year periods. Four states have experienced at least a 20 place drop in ranking between the 1999-2001 ranking to the current ranking: Arkansas went from 15th to 38th;

Michigan went from 20th to 40th; Mississippi, from 9th to 51st; Nevada, from 22nd to 47th.

These data raise serious questions about the extent to which patients in many of these states with poorer records of serious doctor discipline are being protected from physicians who would likely be barred from practice in states with boards that are doing a better job of disciplining physicians. It is quite possible that in states with poor doctor disciplinary records, patients are being injured or killed more often by doctors who should have been disciplined than patients in states with consistently high disciplinary performance.

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

The top 10 states are (in order): Kentucky (9.08 actions per 1,000 physicians), Alaska (8.49 per 1,000 physicians), Wyoming (8.19 serious actions per 1,000 physicians), Ohio (6.33 per 1,000 physicians), Arizona (6.20 per 1,000 physicians), Oklahoma (6.19 per 1,000 physicians), North Dakota (6.07 per 1,000 physicians), Colorado (5.75 per 1,000 physicians), West Virginia (5.45 per 1,000 physicians), and Missouri (5.34 per 1,000 physicians). Nine of these 10 states were in the top 10 states in last year's ranking. Last year Missouri was ranked 11th.

As can be seen in Table 2, three of these 10 states (Wyoming, Oklahoma and Alaska) have been in the top ten for all ten of the three-year average periods listed. Six more of these top 10 states have been in the top 10 for at least six of the last 10 three-year periods: Colorado (6), Arizona, Kentucky and West Virginia (7), North Dakota and Ohio (9).

It is clear that state-by-state performance is spotty. Only one of the nation's 15 most populous states, Ohio, is represented among those 10 states with the highest disciplinary rates. Illinois and Pennsylvania, other states with large populations, have usually been near the bottom, although Illinois has improved more recently, ranking 18th. California and New Jersey have hovered around the middle.

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 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 following complaints
- The use of all available/reliable

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MEDICAL BOARDS, from page 3

data from other sources such as Medicare and Medicaid sanctions, hospital sanctions and malpractice payouts

- Excellent leadership
- Independence from state medical societies and other parts of the state government
- A reasonable legal framework for disciplining doctors ("preponderance of the evidence" rather than "beyond reasonable doubt" or "clear and convincing evidence" as the legal

standard for discipline).

Most states are not living up to their obligations to protect patients from doctors who are not practicing medicine in the best manner and are thus endangering the lives and health of residents. 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, to increase the amount of discipline

and, thus, the amount of patient protection. Without adequate legislative oversight, inadequate constructive criticism of medical boards will continue to allow inadequate boards to perform poorly. ■

- ¹ Physician Characteristics and Distribution in the U.S. American Medical Association, 2006 Edition.
- ² Fact Sheet: American Osteopathic Association. Statistics as of August, 2004, available at http://www.do-online.osteotech.org/pdf/ost_factsheet.pdf

RANKING OF THE RATE OF STATE MEDICAL BOARDS' SERIOUS DISCIPLINARY ACTIONS IN 2005

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

	1996	1997	1998	1999	2000	2001	2002	2003	2004	2005
Alabama	39	36	27	18	14	12	11	13	16	22
Alaska	3	3	1	1	1	1	1	6	4	2
Arizona	9	7	13	28	18	5	3	1	6	5
Arkansas	24	16	9	5	8	15	20	29	44	38
California	32	20	22	22	23	25	24	22	22	23
Colorado	5	5	6	12	19	16	12	9	9	8
Connecticut	37	33	37	39	37	39	38	38	38	37
Delaware	47	44	49	50	50	50	49	50	50	50
District of Columbia**	51	49	40	42	N/A	N/A	N/A	41	30	36
Florida	19	22	44	46	44	33	36	37	37	32
Georgia	8	11	16	16	10	10	10	15	18	20
Hawaii	49	50	46	48	47	49	50	51	51	42
Idaho	36	34	25	13	22	14	18	14	21	25
Illinois	48	41	42	38	45	47	41	36	25	18
Indiana	20	25	26	19	20	27	32	33	27	24
Iowa	2	2	4	8	13	8	9	12	12	15
Kansas	29	38	36	45	43	32	30	30	31	31
Kentucky	11	12	12	10	5	4	5	2	2	1
Louisiana	18	26	28	23	21	24	19	17	14	13
Maine	35	23	14	17	17	29	28	34	35	46
Maryland	28	37	41	41	38	41	45	47	47	44
Massachusetts	41	46	48	46	46	37	34	23	23	28
Michigan	34	19	15	14	15	20	27	40	39	40
Minnesota	46	48	50	49	48	48	47	48	48	49
Mississippi	1	1	2	2	6	9	14	20	40	51
Missouri	26	31	35	34	34	28	29	31	11	10
Montana	12	15	20	25	36	30	16	8	8	11
Nebraska	27	40	28	43	40	45	35	28	24	16
Nevada	15	13	19	29	26	22	25	32	46	47
New Hampshire	50	51	47	30	25	18	23	24	26	21

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Poll: People Understand Systemic Problems at FDA

A Harris poll released on May 24th found that 58 percent of 2,371 people surveyed last week thought that the Food and Drug Administration (FDA) does only a fair or poor job ensuring the safety and efficacy of new prescription drugs, a significantly worse assessment than as recently as two years ago. This shows that the public has caught on to the systemic problems at the FDA — problems that jeopardize the health of millions of prescription drug users in this country.

The recent cascade of prescription drug disasters involving revelations of potentially deadly effects caused by new blockbuster drugs such as the painkillers Vioxx and Bextra, along

with news stories about the dual political influences on the FDA by the religious right (as with Plan B) and the drug industry (which paid the FDA more than \$250 million this year to review drugs, as called for by the 1992 Prescription Drug User Fee Act (PDUFA)) have worsened public opinion about the agency. This is likely why 82 percent of those polled thought FDA decisions were to a great extent or some extent influenced by politics rather than medical science.

Adverse drug reactions cause 100,000 deaths and 1.5 million hospitalizations annually, making this one of the five leading causes of death in the United States. Many of these

deaths and serious injuries could be prevented if patients were given prescriptions for safer but equally effective drugs.

These results come because drug companies cannot be trusted to provide accurate information to patients or doctors, and the FDA is now heavily funded directly by the drug industry and is therefore much less vigilant than it used to be. The survey also found that 76 percent of people were somewhat or very concerned about the FDA's ability to effectively communicate safety concerns about prescription drugs to doctors and the public. Thus, there is a need for other, more accurate sources of information about prescription drugs.

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RANKING OF THE RATE OF STATE MEDICAL BOARDS' SERIOUS DISCIPLINARY ACTIONS IN 2005

continued from page 4

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

	1996	1997	1998	1999	2000	2001	2002	2003	2004	2005
New Jersey	17	24	34	37	30	26	21	25	29	35
New Mexico	30	27	23	27	24	34	26	21	19	29
New York	21	17	18	15	12	13	13	18	17	17
North Carolina	43	32	32	24	35	31	37	42	34	26
North Dakota	10	14	7	6	2	2	2	3	3	7
Ohio	13	8	10	7	7	7	7	7	7	4
Oklahoma	6	6	3	4	4	3	4	5	5	6
Oregon	16	21	30	31	28	23	17	16	20	19
Pennsylvania	45	39	39	40	39	36	39	45	36	33
Rhode Island	24	18	17	21	29	38	40	46	45	39
South Carolina	33	43	33	35	31	43	44	44	43	45
South Dakota	22	35	24	20	32	46	48	35	32	43
Tennessee	42	47	51	51	49	44	42	43	41	30
Texas	23	28	31	33	33	35	33	26	28	27
Utah	38	30	21	26	16	11	8	11	13	14
Vermont	14	10	11	11	9	19	31	19	15	12
Virginia	40	45	45	32	27	21	22	27	33	34
Washington	31	29	38	36	41	40	43	39	42	41
West Virginia	7	9	8	9	11	17	15	10	10	9
Wisconsin	44	42	43	44	42	42	46	49	49	48
Wyoming	4	4	5	3	3	6	6	4	1	3

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

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

Product Recalls

April 22, 2006 — May 23, 2006

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.

CLASS I Recalls

Indicates a problem that may cause serious injury or death

Name of Drug or Supplement; Problem; Recall Information

Max Ten Dietary Supplement, product contains Ma-Huang Extract (10mg naturally-occurring ephedra alkaloids); This product contains ephedrine alkaloids. All lots, Maxlabs.

Nature's Treat Energy Plus Dietary Supplement, 23.4 mg ephedrine group alkaloids and 79.2mg caffeine alkaloids; This product contains ephedrine alkaloids. All lots, Nature's Treat, Inc.

POLL, from page 5

That is why we created the Web site www.WorstPills.org. We aim to guide patients and their doctors away from the worst pills — the 185 drugs that consumers should not use — and instead recommend other, safer drugs. These "Do Not Use" drugs represent one-fourth of the top 200 selling drugs in the country.

Rather than the FDA looking out for consumers, it was Public Citizen who warned people not to use each of the last nine prescription drugs taken off the market. Our warnings

came as much as three years before these drugs were removed. Two-thirds of the 28 prescription drugs we have formally asked the FDA to ban have been taken off the market.

For example, we warned our readers not to use Vioxx in early 2001, more than three years before it was pulled from the market. We have recently warned people not to use the weight reduction drug orlistat because it causes pre-cancerous lesions in the intestine of animals given the drug. Despite this, the FDA recently sent GlaxoSmithKline, which is seeking

approval for over-the-counter use of the drug, an "approvable" letter, often a signal that the drug will soon be approved. Once again, the FDA is falling down on the job.

Two things should be done: First, PDUFA must be repealed so the drug industry no longer pays the agency that regulates it. Second, congressional oversight of the agency must be significantly boosted.

Only by taking these steps can the FDA begin to fulfill one of its most important duties, which is to protect the public from dangerous drugs. ■

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THE PUBLIC CITIZEN HEALTH RESEARCH GROUP

Health Letter

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

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Annual subscription price is \$18.00 (12 issues). Mail subscriptions and address changes to Health Letter, Circulation Department, 1600 20th St., NW, Washington, D.C., 20009. Our Web site address is www.citizen.org/hrhg.

CLASS II Recalls

*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

Amoclan (Amoxicillin and Clavulanate Potassium Powder for Oral Suspension USP), 200mg/28.5mg per 5mL; Discoloration (clavulanic acid — 9 month stability). Lot - Exp. Date: AG007A, 03/2007; AG010A, 06/2007; AG011A, 06/2007; AG006B, 03/2007; AG008B, 03/2007; AG009B, 06/2007; AG011B, 06/2007; AG007C, 03/2007; AG008C, 03/2007; AG009C, 06/2007; AG010C, 06/2007; AG011C, 06/2007, West-ward Pharmaceuticals Corp.

a) **Analpram HC Cream 2.5%** (hydrocortisone acetate 2.5% and pramoxine HCl 1%); b) **Analpram HC Cream 2.5%** (hydrocortisone acetate 2.5% and pramoxine HCl 1%) Professional sample; c) **L.M.X.5 (lidocaine 5%) Anorectal Cream**; d) **Analpram HC Cream 1%** (hydrocortisone acetate 1% and pramoxine HCl 1%); Reports of adverse events: The firm redesigned the applicator and, since the design change, patients have reported being injured by the applicator upon use. a) multiple lots and expiration dates; b) Lots 05145A exp. 05/07, 05079B exp. 04/07, 05080B exp. 04/07, and 05081B exp. 04/07; c) Lots 04021A exp. 04/06 and 05085A exp. 04/08; d) Lots 04135A exp. 08/07, 04136A exp. 08/07, 04186A exp. 11/07, 04189A exp. 11/07, 04190A exp. 11/07, 04191A exp. 11/07, 04201A exp. 12/07 and 04202A exp. 12/07, Ferndale Laboratories, Inc.

KL153 T-Tanna DM Suspension (Antihistamine/Decongestant Antitussive) Chlorpheniramine Tannate/ 4.5mg, Pseudoephedrine Tannate/ 75mg, Dextromethorphan Tannate/ 25mg, Cotton Candy Flavor; Superpotent: Out of specification results were detected. Batches GB780, GB791, GB953, GB957, Kiel Laboratories.

NOW XyliWhite Mouthwash; an all natural, fluoride-free oral rinse; A breakdown in the product's preservative system allowed the growth of *Enterobacter gergoviae* bacteria in the mouthwash. Lot numbers 735906 and 736424, NOW Foods, division of The Fruitful Yield, Inc.

Nugest 900 Topical Cream, Progesterone USP; Unapproved New Drug; over the counter cream contains Progesterone, USP. Lot number: 51311, Nutraceuticals.

a) **Pharmagenx brand Ventilean dietary supplement** sold as a liquid in 4 ounce (120 ml) and 8 ounce (240 ml) plastic bottles, plastic ampoules labeled 'VENTILEAN 10 ml (2Srv.)'; b) Pharmagenx brand Ventilean LipoGels (soft gelatin capsules); Some lots of the product were found to contain Clenbuterol a drug not approved for human use in the United States. All lots; Pharmagenx AKA Vita Shots.

a) **Tizanidine Hydrochloride Tablets**, 4 mg; b) **Tizanidine Hydrochloride Tablets**, 2 mg; Dissolution Failure. Multiple lots and expiration dates, Teva Pharmaceuticals.

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

Audio-visual carts. Apollo® Steel Wide-Body Carts were sold without a safety belt which helps prevent heavy equipment from becoming unstable and falling from the cart's upper shelf. Equipment falling on nearby consumers can cause serious injuries and death. Apollo® Presentation Products, (800) 777-3750 or www.apolloavproducts.com.

Bicycle child carriers. If the seat of the Schwinn Deluxe Bicycle Child Carriers is not fully seated on the rack, the plastic guide tabs on the carrier can break. If these tabs break, it could cause the seat to fall off. This poses a risk of serious injury to a child seated in the carrier. PTI Sports Inc., (800) 515-0074, customerservice@ptisports.com or www.schwinnbike.com.

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Name of Product; Problem; Manufacturer and Contact Information

Bicycle helmets. Product testing has demonstrated that Trek Anthem C Elite and Anthem C Elite WSD Model Bicycle Helmets do not comply with CPSC safety standards for impact resistance. Consumers could suffer impact head injuries in a fall. Trek Bicycle, (800) 373-4594.

Candle kits. In "Fireplace in a Box" Candle Kits, the mini fireplace which houses the candle can ignite, posing a fire hazard. Running Press Book Publishers, (800) 343-4499 or www.perseusbooksgroup.com/runningpress.

Children's jewelry. The recalled Juicy Couture Children's Jewelry contains high levels of lead. Lead is toxic if ingested by young children and can cause adverse health effects. Liz Claiborne Inc., (866) 879-7877 or www.juicycouture.com/recall.

Children's necklaces. The recalled necklaces contain high levels of lead, posing a serious risk of lead poisoning and adverse health effects to young children. Selected Trading Corp., (800) 336-6292, www.selected-trading.com, or mrubin@selected-trading.com.

Electric bass. If the battery is improperly installed in the Ibanez Bass, the bass can overheat causing internal damage and a fire hazard. Hoshino USA Inc., (800) 669-8262 or www.ibanez.com.

Exercise benches. The Hoist Exercise Benches' front frame assembly (with the foot rest) can fail to lock into place allowing users who grab the bench to position themselves to get their fingers entrapped between the front and back frame assemblies. This poses laceration and amputation hazards. Hoist Fitness Systems Inc., (866) 849-4797, www.hoistfitness.com, www.bodygearfitness.com, benchrecall@hoistfitness.com, or benchrecall@bodygearfitness.com.

Hunting tree stands. The j-hook attachment of the tree strap on Ameristep Patriot and Outfitter Hang-on Tree Stands can fail, which can cause the tree stand to collapse. Consumers using these stands could fall and suffer serious injuries or death. Primal Vantage Company Inc., (800)374-7837, www.ameristep.com, or www.treestandcustomerservice.com.

Ladder extensions. If the knob securing the Walk-Through Railing Ladder Extension unit to the ladder is not tight, it can detach and fall when the ladder is being removed or lowered. The unit could hit a bystander, causing serious head injuries. American Innovations Corp., (888) 912-9888 or www.ladderinnovations.com.

Light fixtures. Two nuts in a mounting mechanism of Low Bay TG Series Lighting Fixtures were not attached. The fixture could detach, fall and possibly hit consumers. Lithonia Lighting division of Acuity Lighting Group Inc., (800)-745-1788 or www.lithonia.com.

Menorahs. If a candle burns all the way down in the M&M'S® Brand Menorah, the plastic Menorah could ignite and present a fire hazard. Masterfoods USA, (800) 849-4867.

Metal charms. Metal charms (enclosed with certain DVDs) contain high levels of lead. Lead is toxic if ingested by young children and can cause adverse health effects. Twentieth Century Fox Home Entertainment, (877) 541-2229 or www.dvdcharmrecall.com.

Outdoor candles. The Outdoor Candle's wax can catch fire causing a high flame and posing a fire and burn hazard. IKEA Home Furnishings, (888) 966-4532 or www.ikea-usa.com.

Pool ladders. The plastic step support clips on Simple Set Pool Ladders can be assembled upside down, causing the ladder steps to break under a user's weight. Aqua-Leisure Industries, (866) 807-3998 or www.aqualeisure.com.

Slingshot. If the slingshot band of the "The Natural" Slingshot slips out of its frame during use, the ball at the end of the tubing can strike the user, resulting in serious facial injuries. Daisy Manufacturing Co., (800) 713-2479 or <http://www.daisy.com>.

Smoke alarms. First Alert® ONELINK™ Battery-Powered Smoke and Combination Smoke/Carbon Monoxide (CO) Alarms can drain the power from batteries rapidly, causing premature low battery power. Consumers will be alerted to the low battery power and the need to replace the battery by a chirping of the unit. If the batteries on the smoke/CO alarm are not replaced before the battery power terminates, the alarm will not detect smoke in the event of a possible fire and the presence of carbon monoxide. BRK Brands Inc., (800) 323-9005 or www.firstalert.com.

Smoke detectors. The Tyco Fire & Security Smoke Detectors could experience reduced sensitivity to smoke in conditions of high humidity and high temperature. If this occurs, these detectors could delay detecting the presence of smoke in the event of a fire. Tyco Fire & Security, (866) 376-8207 or www.tycofireandsecurity.com/Internet/fireddetection.jsp.

Exercise Status and Future Dementia

A very exciting study was published in the May 22nd issue of the Archives of Internal Medicine that found a correlation between physical function and the evolution of dementia in a large group of people who were dementia-free at the start of the study. A co-author of the study is Dr. Eric Larson, who wrote the Preface to the latest edition of *Worst Pills, Best Pills*. Dr. Larson is a Professor of Medicine at the University of Washington and Director of the Group Health Cooperative's Center for Health Studies. The study involved 2288 people who were 65 years and older who did not suffer from dementia. Participants were enrolled from 1994 to 1996 and followed through October 2003.

The study was conducted by the same researchers who published another study on exercise and dementia, the results of which appeared in the February 2006 edition of *Health Letter*. That study followed patients for an average of six years and found that patients who exercised three times per week were less likely to be subsequently diag-

nosed with dementia.

In this study, researchers evaluated each patient's physical capabilities at the start of the study ("at baseline") and followed their health for a number of years. For people who scored lower (10 points or less) on a performance-based physical function test at baseline, the age-adjusted incidence of subsequent dementia was 53.1 per 1000 person-years. In sharp contrast, those who scored higher than 10 points on the physical function test had an age-adjusted incidence of subsequent dementia of only 17.4 per 1000 person-years.

The authors cautious conclusions from the study were that:

...findings suggest that poor physical function may precede the onset of dementia and Alzheimers Disease and higher levels of physical function may be associated with a delayed onset; slow gait might be an earlier sign and poor handgrip a later sign of development of dementia in older people. If confirmed, this study might also help explain the association of

physical exercise with a reduced risk of dementia, suggesting that exercise, by improving and maintaining physical function, might benefit cognitive function through a connection between the two.

They concluded by stating that "Even though this study demonstrated a temporal relationship between physical function and future dementia, we do not know the causal pathway of functional decline and the development of dementia. We speculate that physical decline and cognitive decline may be inseparable during the development of dementia."

While these data do not support expansive conclusions about the role of exercise in preventing the onset of dementia, they do lend support to the already well-understood fact that exercise and physical activity provide a multitude of health benefits. Work with your doctor to develop a physical activity schedule that will help keep you healthy and strong! ■

CONSUMER PRODUCTS cont.

Name of Product; Problem; Manufacturer and Contact Information

Strollers. The plastic hinge on the handlebar of Phil & Teds e3 Twin Buggy can crack or break causing the handlebar to detach while in use. This poses a risk of injury to young children. Regal Lager Inc., (800) 593-5522, info@regallager.com, or www.regallager.com.

Swing seats. These Sling Swing Seats can unexpectedly break in half, causing the users to fall to the ground. Rainbow Play Systems Inc., (800) 724-6269 or www.rainbowplay.com.

Swing sets. Defective bolts on Adventure Playsets Wooden Swing Sets could cause the swing set frame to detach from the fort structure, posing a fall hazard to the user. Adventure Playsets, dba Backyard Ventures Inc., (800) 856-4445, www.adventureplaysets.com, or custservice@adventureplaysets.com.

Toy phones. The push buttons on the Cordless Push Button Toy Telephone can detach, posing a choking hazard to young children. Marvel Education Co., (866) 460-8769 or marvel_ed@yahoo.com.

Utility vehicles. The rear brake caliper used on the Arctic Cat Prowler XT Off-Highway Utility Vehicle could leak brake fluid, resulting in reduced braking ability at the rear wheels. The front wheel brakes are unaffected by this condition. Arctic Cat Inc., (800) 279-6851 or www.arctic-cat.com.

Study Finds Glucosamine, Chondroitin Ineffective for Joint Pain

In the most recent edition of our book *Worst Pills, Best Pills*, we listed the dietary supplements glucosamine and chondroitin as Do Not Use, primarily because most of the studies testing them were poorly designed (e.g., too small, too short, too unstandardized in their diagnoses of arthritis). In better-designed studies, the supplements generally proved ineffective. However, we noted that the National Institutes of Health was conducting a major randomized trial that might resolve the controversy once and for all. The results are now in.

In that study, published in the *New England Journal of Medicine* (Feb. 23, 2006, pp. 795-808), researchers randomly assigned patients with osteoarthritis (the most common form of arthritis in older persons) of the knee to glucosamine, chondroitin, both, neither (an inactive placebo) or celecoxib (Celebrex). Patients were followed for 24 weeks and the impact upon the severity of their knee pain was measured.

The segment of patients who experienced a 20 percent decrease in their

pain scores was 60 percent in the placebo group, 64 percent in the glucosamine group (i.e., only 4 percent better than placebo), 65 percent in the chondroitin group, 67 percent in the combined glucosamine/chondroitin group and 70 percent in the Celebrex group. Only Celebrex proved statistically superior to placebo. (Because of its association with heart attacks and strokes, we list Celebrex as a Do Not Use drug and instead recommend generic ibuprofen or aspirin, which are not toxic to the heart.)

While that should be the death knell for these supplements, some still find reason to believe. Supplement defenders point out that glucosamine hydrochloride was used in the study while most supplements on the market contain glucosamine sulfate, and so the unfavorable study findings might only apply to the hydrochloride. There is no evidence for this proposition. Proponents had long argued that it was glucosamine itself, a component of cartilage, that would be effective. But, regardless of the form of the chemicals, both glucosamine and chondroitin are

so heavily metabolized after being eaten that essentially no drug even makes it to the joints. The reason the researchers used the hydrochloride form was that the sulfated forms on the market were not sufficiently pure or consistently manufactured.

The other potential lifeline for the supplements was the finding that, among the minority of patients with more severe pain, the combination of glucosamine and chondroitin was effective, although the individual components and Celebrex were not. This was an odd finding because Celebrex was effective in the full study. However, this analysis appears to have been what researchers call post hoc: it was not planned before the study. Such analyses are notoriously difficult to interpret and often lead to findings that are subsequently debunked.

The bottom line is this: in the most rigorous study to date, there was no evidence of effectiveness for glucosamine, chondroitin or the two together. We continue to recommend against the use of these unregulated supplements. ■

OUTRAGE, from page 12

health care equation but they do drain money from transactions involving pharmaceuticals, thereby meeting the second leech definition above. No other country in the world has a health care system with this component.

There is virtually no regulation of PBMs at the federal or state level. Doctors, hospitals, pharmacists, pharmacies, nurses and insurance companies are all regulated; why not PBMs? Moreover, there are competitive concerns when the four largest firms in this business (PCS, Express Scripts, Medco and Care Mark) have about a combined 80 percent market share.

PBMs also switch patients from one drug to another, and, in one case, Caremark sent letters urging doctors to switch patients from a

generic drug for ulcers costing 20 cents per day to Celebrex which costs 10 times as much and is no more effective. Many lawsuits against PBMs are now pending.

Meanwhile health care costs continue to rise even when they are grossly out of proportion compared to other countries.

It is a jolt to learn that 14.6 percent of the gross domestic product in the United States is attributable to health care while Japan spends 7.9 percent and the United Kingdom devotes only 7.7 percent of its gross domestic product to this activity.

Doctors and hospitals began to have *de facto* price controls with the advent of Medicare and Medicaid in 1966. That expanded with managed care in the '70s and '80s until today

90 percent of private physicians' and hospital income as well as prescription business has price controls determined by the payor.

All the mischief connected with pharmacy benefit managers would be solved with price controls on pharmaceuticals at the federal level.

Every other substantial country in the world has some kind of government price controls on pharmaceutical manufacturers. This policy assures that any savings realized go to the government and taxpayers rather than being diverted to profits of a middleman.

This is a textbook example of unfettered free enterprise giving capitalism a bad name. Isn't anyone running for public office this year? ■

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Pharmaceuticals Need Price Controls

David R. Work has been executive director of the North Carolina Pharmacy Board for 30 years. He is retiring at the end of April. His words are his own and do not necessarily reflect the opinion of the Board. The following is an article reprinted from the Apr. 8, 2006 edition of The Chapel Hill Herald.

The Random House Unabridged Dictionary, Second Edition, contains the following definition: Leech (lech), n-1. Any blood sucking or carnivorous aquatic or terrestrial worm... 2. A person who clings to another for personal gain, esp. without giving anything in return and usually with the implication or fact of exhausting the other's resources; parasite.

Every couple of years the media rediscover this blood-sucking worm used as a treatment for an obscure disease. Some natural remedy stores

Every other substantial country in the world has some kind of government price controls on pharmaceutical manufacturers.

and Asian markets have leeches available for purchase in the United States.

The second description of leech is in modern medicine but the media

haven't focused on them, at least not yet.

A pharmacy benefit manager serves as a middleman between health plans and pharmaceutical manufacturers. All health plans have a formulary, which is a list of drugs that beneficiaries can get at a low or no extra cost to them. PBMs claim to save money for health plans and set drug formularies; they negotiate prices while collecting payments from pharmaceutical manufacturers for placing specific drugs on formularies. Critics note the benefit to the drug manufacturer when their more expensive product is listed on a formulary and a lower cost equivalent is available.

Pharmacy benefit managers do not actually purchase drugs, or make diagnoses, prescribe drugs, provide patient care or pharmaceutical goods and services. They add nothing to the

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