PUBLIC CITIZEN Health Letter

SIDNEY M. WOLFE, M.D., EDITOR JUNE 2011 – VOL. 27, No. 6

Ranking of State Medical Board Serious Disciplinary Actions, 2008-2010

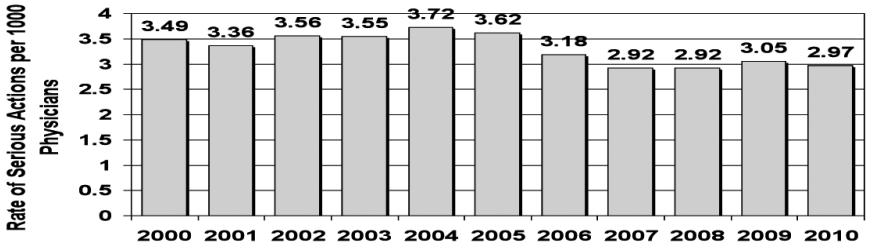
Using an analysis of data recently released by the Federation of State Medical Boards (FSMB) on all disciplinary actions taken against doctors in 2010, Public Citizen has calculated the national rate of serious disciplinary actions (revocations, surrenders, suspensions and probation/restrictions) taken by state medical boards in 2010. This rate of serious actions per 1,000 physicians is slightly lower than the rate in 2009 and continues to be significantly lower than the peak for the past 10 years (see the "Annual Rate" chart at right).

The rate in 2010 — 2.97 serious actions per 1,000 physicians — is still 20 percent lower than the peak rate in 2004 of 3.72 serious actions per 1,000 physicians. If the national rate of doctor discipline per 1,000 doctors had remained as high in the year 2010 as it was in 2004, there would have been a total of 745 additional serious disciplinary actions in 2010 taken against U.S. physicians than there actually were. With a typical doctor having between 500 and 1,000 or more patients in their practice, the positive impact of this on the large number of patients going to these doctors would be enormous.

The most recent three-year average state disciplinary rates (2008-10) ranged from 1.29 serious actions per 1,000 physicians (Minnesota) to 5.98 actions per 1,000 physicians (Louisiana), a 4.6-fold difference between the best and worst state doctor disciplinary boards (see "Methods" on page 6 for the details of our calculations).

Table 5 on page 4 shows the 2008-10 ranking for all states. See Table 6 on page 5 for state rankings across the last eight three-year periods reviewed.

Annual Rate of Serious Disciplinary Actions by State Medical Boards, 2000-2010



10 worst states (lowest three-year rate of serious disciplinary actions)

As can be seen in Table 1, the list of the bottom 10 states, those with the lowest serious disciplinary action rates for 2008-10, includes not only small states such as New Hampshire and Vermont, but also large states such as Florida, Massachusetts and Minnesota.

Table 1 also shows that three of these 10 states (Minnesota, South Carolina and Wisconsin) have been consistently among the bottom 10 states for each of the last eight three-year periods. In addition, Connecticut has been in the bottom 10 states for each of the last five three-year cycles. Florida has now been in the bottom 10 boards for the last three three-year periods. For the first time since we have been reporting on state boards, Utah is among the bottom 10 boards.

This year we have again done further analyses to determine which states have had the largest decreases or increases in

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Table 1. 10 Worst States

State	Actions/ 1,000 Docs/ 2008-10	Times in Bottom 10 since 2001-03
Minnesota	1.29	8
South Carolina	1.31	8
Wisconsin	1.59	8
Connecticut	1.69	5
Massachu-setts	1.83	2
Rhode Island	1.92	3
Florida	1.94	3
New Hampshire	2.13	3
Utah	2.15	1
Vermont	2.18	2

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Table 2. States with Largest Decreases in Rank for the Rate of Serious Disciplinary Actions from Year of Highest Average Rank to 2008-10

State	Highest Rate and Rank (year)*	2008-10 Rank	Decrease in Rank	Decrease in Rate/ 1,000 Docs
Vermont	8 (2007)	42	34	2.65
Utah	10 (2003)	43	33	3.28
Georgia	15 (2003)	40	25	1.83
Montana	8 (2004)	32	24	3.60
Massachusetts	23 (2004)	47	24	1.58

*Year of highest rank also represents year of highest rate.

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their rankings compared to other states between the year of their highest rate and the 2008-10 period. All of the states with the greatest decrease or increase in rankings had considerable changes in the actual rates between their highest year and 2008-10.

As can be seen in Table 2, five states had decreases of at least 24 in their ranking of state disciplinary actions from the year of their highest rate until the latest (2008-10) rate.

Table 2 shows that Massachusetts fell 24 places in ranking from 2002-04 until 2008-10. If the rate of serious disciplinary actions in 2008-10 had been as high as in 2002-04 (1.58 more serious actions per 1,000 doctors per year), there would have been 56 more serious disciplinary actions taken against Massachusetts physicians in 2008-10 than actually occurred.

10 best states (highest three-year rates of serious disciplinary actions)

Table 3 shows the 10 states with the highest three-year rate of serious disciplinary actions and also shows that five of these 10 states (Alaska, Arizona, Colorado, Ohio and Oklahoma) have been in the top 10 for all eight of the three-year average periods covered in this report.

For North Carolina, the most populous of the states with largest increases in rank (see Table 4), the increase of 1.62 serious actions per 1,000 licensed physicians translates into an increase of 46 more physicians seriously disciplined than if the rate had stayed as it was in 2001-03 (1.62 multiplied by 28.3, the number of thousands of current physicians).

Table 3. 10 Best States

State	Actions/ 1,000 Docs/ 2008-10	Times in Top 10 since 2001-03
Louisiana	5.98	3
Alaska	5.47	8
Ohio	5.36	8
Oklahoma	5.23	8
Wyoming	5.14	6
North Dakota	5.05	6
New Mexico	4.99	2
Arizona	4.82	8
Nebraska	4.57	3
Colorado	4.51	8

For the state of Washington, the second most populous of those states with large increases in rank, the increase in 1.70 serious actions per 1,000 licensed physicians translates into 1.70 multiplied by 21.4 (the number of thousands of physicians) for an increase in 36 more physicians seriously disciplined than if the rate had stayed as it was in 2002-04.

Overall, between the 2001-03 and the 2008-10 periods, a total of 25 states had changes in the rate of serious disciplinary actions of more than one physician disciplined per 1,000 licensed in the state. However, partly reflecting how much tighter state budgets are now than they were then, those states decreasing their rates of serious disciplinary actions by at least one per 1,000 doctors outnumbered

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those increasing the rates 17-8. Other important issues in addition to budget considerations are discussed below in the "What makes the better boards 'better'?" section.

Discussion

These data demonstrate a remarkable variability in the rates of serious disciplinary actions taken by the state boards. Once again, only one of the nation's 15 most populous states, Ohio, is represented among those 10 states with the highest disciplinary rates. For the third year in a row, one of the largest states in the country, Florida, is among the 10 states with the lowest rates of serious disciplinary actions. 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 rapidly 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 2006, 67 percent of insurance fraud convictions and 36 percent of convictions related to controlled substances were associated with only nonsevere discipline by the board.[1]

In this report, we have concentrated on the most serious disciplinary actions. Although the FSMB does report less severe actions, such as fines and reprimands, it is not appropriate to provide such actions with the same 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 on the Internet the particulars of disciplinary actions they have taken. In October 2006, we published a report that ranked the states according to the quality of those postings.[2] 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 that year's disciplinary rate report. 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.

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.

Table 4. States with Largest Increases in Rank (20 or more) for the Rate of Serious Disciplinary Actions from Year of Lowest Average Rank* to 2008-10

State	Lowest Rate and Rank (year)	2008-10 Rank	Increase in Rank	Increase in Rate/ 1,000 Docs
Hawaii	51 (2003)	11	40	3.20
Delaware	50 (2003)	13	37	2.69
Maine	46 (2005)	19	27	1.68
Washington	45 (2006)	18	27	1.70
North Carolina	41 (2003)	16	25	1.62
Arkansas	45 (2004)	23	22	1.02

*See Table 6.

The 2010 rate of serious actions per 1,000 physicians is slightly lower than the rate in 2009 and continues to be significantly lower than the peak rate in 2004.

What makes the better boards 'better'?

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

see RANKING, page 6

Table 5. Ranking of Serious Doctor Disciplinary Action Rates by State Medical Licensing Boards, 2008-10 *(See endnotes on page 6)*

Rank 2008-10[1]	State/District	Number of Serious Actions, 2010	Number of Physicians, 2010[2,3]	Serious Actions per 1,000 Physicians, 2008-10[4]
1	Louisiana	98	13484	5.98
2	Alaska	6	1928	5.47
3	Ohio	210	39911	5.36
4	Oklahoma	28	7476	5.23
5	Wyoming	11	1321	5.14
6	North Dakota	5	1893	5.05
7	New Mexico	23	5688	4.99
8	Arizona	70	16608	4.82
9	Nebraska	32	5352	4.57
10	Colorado	58	16379	4.51
11	Hawaii	20	5029	4.38
12	Kentucky	29	11823	4.03
13	Delaware	22	2794	3.96
14	Iowa	30	7832	3.89
15	West Virginia	16	4894	3.88
16	North Carolina	103	28311	3.80
17	Oregon	52	13486	3.78
18	Washington	98	21337	3.76
19	Maine	11	4380	3.70
20	Illinois	140	43485	3.51
21	Virginia	71	26259	3.45
22	Kansas	20	8216	3.11
23	Arkansas	27	7035	3.08
24	New York	271	90014	3.03
25	Missouri	60	18601	2.91
26	Indiana	35	16727	2.78
27	Tennessee	55	18839	2.78
28	Pennsylvania	130	44336	2.76
29	Idaho	7	3434	2.72
30	Nevada	13	5829	2.70
31	Alabama	33	11928	2.69
32	Montana	8	2794	2.66
33	Mississippi	18	6422	2.62
34	Texas	181	63495	2.61
35	California	317	116489	2.61
36	South Dakota	5	2241	2.60
37	District of Columbia	6	5481	2.57
38	Michigan	85	29133	2.57
39	Maryland	79	27895	2.55
40	Georgia	60	25018	2.52
41	New Jersey	68	34111	2.28
42	Vermont	9	2750	2.18
43	Utah	18	6701	2.15
44	New Hampshire	18	4783	2.13
45	Florida	115	57066	1.94
46	Rhode Island	6	4768	1.92
47	Massachusetts	71	35359	1.83
48	Connecticut	23	15634	1.69
49	Wisconsin	30	17938	1.59
50	South Carolina	18	12423	1.31
51	Minnesota	28	18310	1.29

Table 6. Ranks Based Upon Average Doctor Disciplinary Rates Over the Preceding Three Years[5,6] *(See endnotes on page 6)*

State/District	2003	2004	2005	2006	2007	2008	2009	2010
Alabama[7]	13	17	22	26	34	36	37	31
Alaska[7]	6	4	2	1	1	1	1	2
Arizona	2	7	6	9	4	4	5	8
Arkansas[7]	29	45	39	23	16	18	32	23
California	22	22	23	27	36	43	41	35
Colorado[7]	8	9	8	8	6	9	7	10
Connecticut[7]	38	38	38	42	45	47	47	48
Delaware[7]	50	50	50	44	29	23	35	13
District of Columbia[7]	42	31	36	37	22	17	16	37
Florida	36	37	32	35	31	44	44	45
Georgia[7]	15	18	20	25	33	42	36	40
Hawaii[7]	51	51	42	33	21	13	10	11
Idaho[7]	14	21	25	24	25	26	28	29
Illinois[7]	35	25	18	12	12	15	15	20
Indiana[7]	27	27	24	28	27	30	24	26
Iowa[7]	12	12	15	7	11	8	13	14
Kansas[7]	32	30	31	36	41	34	27	22
Kentucky[7]	1	2	1	2	2	2	3	12
Louisiana[7]	17	14	13	11	14	7	8	1
Maine	34	35	46	34	24	10	14	19
Maryland[7]	48	47	44	43	43	45	43	39
Massachusetts[7]	23	23	28	30	35	39	46	47
Michigan	40	39	40	39	40	37	39	38
Minnesota[7]	47	48	49	49	50	51	51	51
Mississippi[7]	20	41	51	51	49	48	45	33
Missouri[7]	31	11	10	6	30	27	34	25
Montana[7]	9	8	12	18	20	20	22	32
Nebraska[7]	28	24	16	10	5	11	11	9
Nevada	33	46	47	47	46	32	29	30
New Hampshire[7]	25	26	21	21	26	46	48	44
New Jersey[7]	24	29	35	40	42	41	40	41
New Mexico	21	19	29	22	37	24	9	7
New York[7]	18	16	17	17	19	19	21	24
North Carolina[7]	41	34	26	16	15	14	12	16
North Dakota[7]	3	3	7	19	13	6	2	6
Ohio[7]	7	6	4	4	3	3	4	3
Oklahoma	5	5	5	5	9	5	6	4
Oregon[7]	16	20	19	20	17	16	17	17
Pennsylvania	45	36	33	32	38	31	31	28
Rhode Island[7]	46	44	37	38	23	29	30	46
South Carolina[7]	43	43	45	50	51	50	50	50
South Dakota[7]	37	33	43	48	47	35	26	36
Tennessee	44	40	30	29	28	40	33	27
Texas[7]	26	28	27	31	32	33	38	34
Utah	10	13	14	15	10	21	25	43
Vermont	19	15	11	13	8	22	42	42
Virginia[7]	30	32	34	41	39	28	19	21
Washington	39	42	41	45	44	38	23	18
West Virginia	11	10	9	14	18	25	18	15
Wisconsin[7]	49	49	48	46	48	49	49	49
Wyoming[7]	4	1	3	3	7	12	20	5

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doctors who are practicing medicine in a substandard manner. Serious attention must be given to finding out which of the bulleted variables on page 3 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.

Methods

We have calculated the rate of serious disciplinary actions per 1,000 doctors in each state. Using state-by-state data just released by the FSMB on the number of disciplinary actions taken against doctors in 2010,[3] combined with data from earlier FSMB reports covering 2008 and 2009, we have compiled a national report ranking state boards by the rate of serious disciplinary actions per 1,000 doctors for the years 2008-10 (see Table 5) and for earlier three-year intervals (see Table 6).

The 2008-10 average state disciplinary rates ranged from 1.29 serious actions per 1,000 physicians (Minnesota) to 5.98 actions per 1,000 physicians (Louisiana).

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 (and the rank) in such states 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 2008, 2009 and 2010.

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 (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 2010[4] in that state. We add to this denominator the number of osteopathic physicians[5] 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 (see Table 5). We then repeated these calculations for each of the seven previous three-year intervals (2001-03, 2002-04, 2003-05, 2004-06, 2005-07, 2006-08 and 2007-09 — see Table 6).

This report is available online at http://www.citizen.org/hrg1949. ✦

RANKING report references

[1] Jung P, Lurie P, Wolfe SM. U.S. Physicians Disciplined For Criminal Activity. Health Matrix 2006; 16:335-50.
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[4] Physician Characteristics and Distribution in the U.S. American Medical Association, 2011 Edition.
[5] Fact Sheet: American Osteopathic Association. Statistics as of August 2004, available at http://www.osteopathic.org/index.cfm?PageID=aoa_ompreport_us#50.

Tables 5 & 6 notes

[1] Rank is calculated based upon an average of the disciplinary rates for 2008, 2009 and 2010.
[2] Includes osteopathic physicians for boards with jurisdiction over both physicians and osteopaths.
[3] In previous reports we used nonfederal 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/nonfederal status.
[4] Disciplinary rate for the period is calculated by averaging the disciplinary rates over the 2008-10 three-year period.
[5] Rank for each year is calculated based on an average of the disciplinary rates from that year and the preceding two years.
[6] Whereas in previous reports we used data on nonfederal physicians, in this report we used data for total physicians because the American Medical Association no longer provides physician data broken down by federal/nonfederal status. The data in this table are based on total physician data for all years, including those in previous reports. Differences in rank from previous reports are minor (see text).
[7] These states have a combined state medical and osteopathy board.

How Does the Medical Industry Influence Patient Care?

A version of the following article, by Charles Ornstein and Tracy Weber, originally appeared as a co-publication of ProPublica and USA Today *on May 5, 2011. It has been reprinted with permission from propublica.org.*

From the time they arrived to the moment they laid their heads on hotel pillows, the thousands of cardiologists attending this week's Heart Rhythm Society conference have been bombarded with pitches for drugs and medical devices.

St. Jude Medical adorns every hotel key card. Medtronic ads are splashed on buses, banners and the stairs underfoot. Logos splay across shuttle bus headrests, carpets and cellphone-charging stations.

At night, a drug firm gets the last word: A promo for the heart drug Multaq stood on each doctor's nightstand Wednesday.

Who arranged this commercial barrage? The society itself, which sold access to its members and their purchasing power.

Last year's four-day event brought in more than $5 million, including money for exhibit booths the size of mansions and company-sponsored events. This year, there are even more "promotional opportunities," as the society describes them.

Concerns about the influence of industry money have prompted universities such as Stanford and the University of Colorado-Denver to ban drug sales representatives from the halls of their hospitals and bar doctors from paid promotional speaking.

Yet, one area of medicine still welcomes the largesse: societies that represent specialists. It's a relationship largely hidden from public view, said David Rothman, who studies conflicts of interest in medicine as director of the Center on Medicine as a Profession at Columbia University.

Concerns about the influence of industry money have prompted universities such as Stanford and the University of Colorado-Denver to ban drug sales representatives from the halls of their hospitals and bar doctors from paid promotional speaking.

Professional groups such as the Heart Rhythm Society are a logical target for the makers of drugs and medical devices. They set national guidelines for patient treatments, lobby Congress about Medicare reimbursement issues, research funding and disease awareness, and are important sources of treatment information for the public.

Dozens of such groups nationwide encompass every medical specialty from orthopedics to hypertension.

"What you're exploring here is the subtle ways in which the companies and professional societies become partners and — wittingly or unwittingly — physicians become agents on behalf of the interests of the sponsoring company," said Dr. Steven Nissen, chair of cardiovascular medicine at the Cleveland Clinic.

"It has a not very subtle effect on medicine," said Nissen, an expert on the impact of industry money.

'This is our business'

Nearly half the $16 million the heart society collected in 2010 came from makers of drugs, catheters and defibrillators used to control abnormal heart rhythms, the group's website disclosed.

Officials of the Heart Rhythm Society say industry money does not buy influence and is essential to developing new treatments. Still, on Thursday the group unveiled a formal policy that, among other things, requires more detailed disclosure of board members' industry ties.

"This is our business," said Dr. Bruce Wilkoff, the incoming society president. "We either get out of the business or we manage these relationships. That's what we've chosen to do."

The society is one of a handful of groups that make public details about their finances. Most don't. As non-profits, they must disclose their tax returns but not their specific sources of funding.

Sen. Charles Grassley, R-Iowa, requested the information from the Heart Rhythm Society and 32 other professional associations and groups that promote disease awareness and research.

Their responses and reporting by ProPublica showed wide disparities in money the groups accept from medical companies, what they disclose and how they manage potential conflicts of interest.

With billions of dollars at stake, companies can court entire specialties by helping to bankroll doctors' groups. The Heart Rhythm Society's 5,100 members represent a particularly lucrative market.

One implantable cardioverter defibrillator — a device that jolts the heart back to a normal beat — can cost more than $30,000. A single electrophysiologist, a physician specializing in heart-rhythm disorders, can implant dozens a year. World sales of the devices totaled $6.7 billion last year, according to JPMorgan.

All the defibrillator manufacturers are at this week's conference, including

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market leaders Medtronic, Boston Scientific and St. Jude Medical, which together gave the society $4 million last year.

These companies and others not only provided financial support to Heart Rhythm but paid many of its board members: Twelve of 18 directors are paid speakers or consultants for the companies, one holds stock, and the outgoing president disclosed research ties, according to the society's website, which does not specify how much they receive.

Board members at other medical societies have similar arrangements. The American Society of Hypertension does not post disclosures on its website, but records provided to Grassley show that 12 of its 14 board members had financial ties to medical companies.

Grassley, the top Republican on the Senate Judiciary Committee, said these groups commonly say the money doesn't affect what they do, but he has doubts. "I don't think it's believable," he said. "There are a lot of incestuous relationships that really bother me."

Big booths boost devices

As competition among cardiac-device makers has intensified, so have questions about whether their products are being used and marketed appropriately.

In January, a study in the *Journal of the American Medical Association* found that more than one in five patients who received cardiac defibrillators did not meet science-based criteria for getting them.

Weeks later, the Heart Rhythm Society disclosed it was assisting a U.S. Justice Department investigation of the issue.

Two of the society's biggest funders — Boston Scientific and St. Jude Medical — have paid millions since 2009 to settle federal allegations that they improperly paid kickbacks to unidentified physicians to use their cardiac devices. Neither company admitted wrongdoing.

Top sponsor Medtronic also has disclosed to shareholders that the Department of Justice is investigating the advice it gave purchasers on how to bill Medicare for defibrillators and payments it made to buyers of the devices.

In January, a study in the *Journal of the American Medical Association* found that more than one in five patients who received cardiac defibrillators did not meet science-based criteria for getting them.

In a statement, Medtronic said societies play an important role in educating physicians about their devices. Boston Scientific declined to comment, and St. Jude did not respond to questions.

At this week's conference, Medtronic is front and center with a 12,000-square-foot booth to demonstrate its products and allow physicians to examine them.

Medtronic spent $543,000 at last year's meeting on a similar exhibit, part of $1.6 million it paid to prominently display its name around the conference and fund educational grants. The Minnesota device maker also paid unspecified speaking or consulting fees to eight of the society's 18 board members.

The spending befits the company's dominance of the world market for implantable defibrillators. It sold more than $3 billion worth last year.

Next booth down is the 8,100-square-foot spread of rival Boston Scientific, with $1.6 billion in defibrillator sales last year. The company spent $1.5 million on the society in 2010 and paid speaking or consulting fees to seven board members.

Physicians must traverse these and other booths to reach "Poster Town," where the latest research findings, a big draw of the gathering, are displayed. "It's very hard to get through there without being accosted," said Dr. Paul D. Varosy, director of cardiac electrophysiology at the Department of Veterans Affairs' Eastern Colorado Health Care System.

'Tag and release'

Through the years, groups such as the Heart Rhythm Society have expanded the range of sponsorships they offer to drug and device makers. Companies can now fund Wii game rooms or put their names on conference massage stations and on the shirts of the masseuses.

Some deals give companies more than name exposure. Last month, the American College of Cardiology attached tracking devices to doctors' conference ID badges. Many physicians were unaware that exhibitors had paid to receive real-time data about who visited their booths, including names, job titles and how much time they spent.

Dr. Westby Fisher, an Evanston, Ill., electrophysiologist, called the practice "Tag and release." College officials say they'll do a better job of notifying doctors next year.

Attendees at the Heart Rhythm Society conference also have tracking badges. Society officials say exhibitors are not getting doctors' personal information.

Two years ago, the American Society of Hypertension (ASH) teamed with its biggest donor, Daiichi Sankyo, to create a training program for drug company sales reps. The society says about 1,200 Daiichi reps have graduated — at a cost of $1,990 each — allowing them to put the "ASH Accreditation symbol" on business cards.

In fiscal 2009, Daiichi gave the society more than $3.3 million — more than 70 percent of its total industry funding — according to financial records it provided Grassley. Daiichi makes four hypertension drugs.

"I think it's an obscenity," said former ASH president Michael Alderman, professor emeritus at Albert Einstein College of Medicine in New York City. "I can see how it would play out in the doctor's office: 'I'm a Daiichi sales rep.

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But let me tell you something: The American Society of Hypertension is backing me.'"

Alderman and some other prominent members of the group quit after a dispute in 2006 about industry influence.

Current ASH President George Bakris said the training program is science-based and doesn't focus on specific drugs. The reps "ought to know what they are talking about," he said.

The 1,900-member group has revised its policies since 2006, he said. Financial conflicts disclosed by board members, however, are available only to members, who must request them in writing and explain why they want them, according to the group's conflict of interest policy.

A question of influence

Bakris and leaders of several other professional groups say industry funding is essential for much of what they do. It reduces conference registration fees, subsidizes the cost of continuing medical education courses and provides money for disease awareness.

Dr. Jack Lewin, chief executive of the American College of Cardiology, said the money is helping build registries of cardiac procedures that track side effects and flag whether physicians are using devices in the right patients.

Bakris [American Society of Hypertension president] and leaders of several other professional groups say industry funding is essential for much of what they do. It reduces conference registration fees, subsidizes the cost of continuing medical education courses and provides money for disease awareness.

The "circus element" of the exhibit booths doesn't unduly influence attendees, Lewin said. "I don't buy a soft drink just because of the advertising…I buy it because I like it."

Researchers say companies are not spending millions solely for altruistic reasons. "If it weren't influencing the doctors, they wouldn't be doing it," said Dr. Gordon Guyatt, a health policy expert at McMaster University in Ontario.

There are fledgling efforts to push medical societies toward stricter limits on industry funding: 34 groups have signed a voluntary code of conduct calling for public disclosure of funding and limits on how many people on guideline-writing panels have industry ties.

"The general feeling is that the societies need to be independent of the influence of companies," said Dr. Norman B. Kahn Jr., chief executive of the Council of Medical Specialty Societies, which helped draft the code.

Grassley, too, is continuing his efforts to make the groups publicly accountable. In initial responses to his December 2009 request for information, some said they planned to post financial information on their websites. This week, the senator followed up with letters to some groups, asking why they hadn't done so.

He hopes the political pressure succeeds: "You might conclude that maybe they don't want to give the information out because it might be embarrassing." ✦

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and 23-mg doses. In the fourth test, the improvement over the 10-mg dose was only two points on a 100-point scale, which is not clinically important.

Increased adverse effects of the 23-mg dose of donepezil compared to the 10-mg dose include a slowed pulse rate, nausea, vomiting, diarrhea, urinary incontinence, fatigue, dizziness, agitation, confusion and loss of appetite. Vomiting — which occurred more than 3.5 times as often in patients taking the 23-mg dose than in those taking the 10-mg dose — is a particularly dangerous side effect for patients with Alzheimer's disease because it can lead to pneumonia, massive gastrointestinal bleeding, esophageal rupture and even death. Overall, patients taking the 23-mg dose stopped taking the drug because of adverse effects more than twice as often as those taking the 10-mg dose. Additionally, because of the drug's very long half-life, it can stay in patients' systems for about two weeks after they stop taking the drug. So those who suffer adverse effects may not have immediate relief after they stop treatment.

Vomiting is a particularly dangerous side effect for patients with Alzheimer's disease because it can lead to pneumonia, massive gastrointestinal bleeding, esophageal rupture and even death.

With no evidence of an added advantage in benefit to patients, the clear increase in risk should have been more than adequate grounds for denying approval, a conclusion reached by both the FDA medical officer and statistician. It is inexcusable that the FDA approved this higher dose. Its prompt removal would belatedly fulfill the agency's mission to allow the marketing of only those drugs whose benefits outweigh their risks. ✦

Emails Show Drug Company Used Third-Party Medical Groups to Influence Regulators, Undercut Rivals

The following article, by Marian Wang, originally appeared on the website of ProPublica. It has been reprinted with permission from propublica.org.

Brand-name drug manufacturers have long used controversial tactics to keep their generic competitors off the market, but a new report by the U.S. Senate Finance Committee sheds light on how one firm leveraged hidden financial ties with reputable medical groups to undermine its generic rivals.

Facing what it called "an imminent threat" to its brand-name blood thinner Lovenox, pharmaceutical company Sanofi-Aventis launched an advocacy campaign to influence the U.S. Food and Drug Administration (FDA) to delay generic competitors, according to the report. It did so by contacting medical societies and researchers, urging them to write in to the FDA — or in one case, to write an advertorial for *The Wall Street Journal* — to raise safety concerns about generics.

The medical groups — the Society of Hospital Medicine and the North American Thrombosis Forum — each received more than $2.3 million from Sanofi between 2007 and 2010. A Duke University researcher who wrote the FDA received more than $260,000. None of the letters mentioned financial ties to Sanofi. (The *Journal*, first reported on the two groups' letters to the FDA last year, sparking the Senate investigation.)

ProPublica has reported on the ways that drug and device makers have sought to influence professional medical societies and health advocacy groups through millions in donations and advertising revenue at conferences. And while we've repeatedly raised questions about how the corporate cash influences these groups, there are limits to what reporters can expose about all that happens behind the scenes.

But Senate investigators have subpoena power, and they've produced a report drawing on Sanofi documents and emails between the drugmaker and these supposedly independent medical groups. It's worth reading in full. Here's some of the email correspondence between Sanofi and the CEO of the Society of Hospital Medicine after the drug company encouraged the group to contact the FDA. From the report (emphasis ours):

> SHM has no history of making similar comments to the FDA or any government agency of this kind. While the Ec [Executive Committee] might be supportive they may feel this is *not something that SHM has the expertise or knowledge to say much about. ... That being said when something is important to any of our partners (like Sanofi) that we have a long term relationship with we want to give any issue that is important to our partner careful consideration.*

The Society of Hospital Medicine did end up sending a letter to the FDA. The group's CEO sent Sanofi a draft of the letter, and he even asked for the name and address of the intended recipient at the FDA.

A senior manager at Sanofi, in an internal email, later listed the letter as a "key accomplishment" for Sanofi's public relations team.

Emails also show Sanofi representatives worrying about keeping the appearance of these groups' independence for fear that Sanofi's involvement — if reported — could tarnish the groups' credibility.

After the North American Thrombosis Forum wrote an advertorial for Lovenox that ran in the *Journal*, a public relations firm hired by Sanofi emailed the piece to some reporters. That set off some alarm bells for one Sanofi spokeswoman, who worried that Sanofi's involvement might be too obvious: "I'm a little concerned about how this activity by an agency of ours can be perceived by the media, in terms of any s-a [Sanofi-Aventis] involvement in this activity," she wrote. (A reporter inquiring about the ad asked about the financial ties between Sanofi and the NATF. She was told to ask the NATF.)

The Society of Hospital Medicine told the *Journal* that the group has new transparency policies, and "if we were writing the FDA now, we would be very clear about our relationship with any partner, including financial support." The North American Thrombosis Forum told the *Journal* that Sanofi's funding was not intended "to shape public policy."

As for the Duke University doctor, Dr. Victor Tapson, the Project on Government Oversight (POGO) posted one of his letters to the FDA. Worth noting, as POGO did, that it's on Duke University letterhead. Tapson told the *Journal* that parts of the Senate report were "very incorrect," but didn't explain further.

As for Sanofi, it maintains that the comments from the experts "brought legitimate and important patient safety facts and considerations to the attention of the FDA," the *Journal* reported.

The FDA approved the first generic version of Lovenox in July of last year.

Keeping generics off the market costs consumers and the government billions in potential savings every year, according to the Federal Trade Commission. The agency has strongly opposed the industry practice known as "pay for delay," whereby drug companies intent on protecting their monopoly on a particular drug pay off generics companies to get them to drop their patent challenges.

Drug companies have argued that the practice of reaching these settlements doesn't prevent competition once the patents expire — something happening for several major brand-name drugs over the next few years. The FTC, however, has said the practice costs consumers and the government more than $3 billion annually. ✦

Product Recalls

May 12, 2011 – May 25, 2011

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

Recalls and Field Corrections: Drugs – Class I

Indicates a problem that may cause serious injury or death

Celerite Slimming Capsules, 30-count boxes. Volume of product in commerce: approximately 5,040 boxes of 30. Product was collected and sampled by FDA and found to contain undeclared sibutramine. It was marketed without an approved NDA/ANDA. Lot #s: all codes/lots distributed up to and including product distributed through Jan. 24, 2011. Shaping Beauty Inc.

Fruta Planta/Reduce Weight Fruta Planta (all weight loss formulas) Dietary Supplement Capsules, 100% Pure Nature. Volume of product in commerce: 5,300 boxes – estimate. Marketed without an approved NDA/ANDA: Product was found to contain undeclared sibutramine based on FDA's sampling and analysis. Lot #s: all lots and all codes. Prock Marketing LLC.

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 CPSC, call its hotline at (800) 638-2772. The CPSC website is www.cpsc.gov. Visit www.recalls.gov for information about FDA recalls and recalls issued by other government agencies.

Name of Product; Problem; Recall Information

Full-Size Cribs. The drop-side rail hardware can break or fail, allowing the drop side to detach from the crib. When the drop-side rail partially detaches, it creates a space between the drop side and the crib mattress. An infant or toddler's body can become entrapped in the space, which can lead to strangulation and/or suffocation. A child can also fall out of the crib. Dream on Me Inc., at (877) 201-4317 or www.dreamonme.com.

Gas-Powered STIHL Trimmers, Brushcutters, KombiMotors, Hedge Trimmers, Edgers, Clearing Saws, Pole Pruners, and Backpack Blowers That Utilize a Toolless Fuel Cap. The level of ethanol and other fuel additives can distort the toolless fuel cap, allowing fuel to spill, posing a fire and burn hazard. STIHL Inc., at (800) 233-4729 or www.stihlusa.com.

General Electric Food Processors. The safety interlock system on the recalled food processor can fail, allowing operation without the lid secured, which poses a laceration hazard. In addition, the product can emit smoke or catch fire, posing a fire hazard. Walmart Stores Inc., at (877) 207-0923 or www.walmartstores.com/recalls.

Katie Brown 12-Piece Tea Light Candle Sets. The clear plastic candleholder can ignite, posing a serious burn and fire hazard to consumers. Meijer Inc., at (800) 927-8699 or www.meijer.com.

Maclaren Strollers (sold prior to November 2009). The stroller's hinge mechanism poses a fingertip amputation and laceration hazard to the child when the consumer is unfolding/opening the stroller. Maclaren USA Inc., at (877) 688-2326 or hingecovers@maclaren-usa.com.

MDX Pool and Spa Drain Covers. The recalled drain covers were incorrectly rated to handle the flow of water through the cover, which could pose a possible entrapment hazard to swimmers and bathers. Paramount Pool & Spa Systems, at (800) 621-5886.

Pool and Spa Drain Covers. The recalled drain covers were incorrectly rated to handle the flow of water through the cover, which could pose a possible entrapment hazard to swimmers and bathers. A&A Manufacturing, AquaStar Pool Products Inc., Color Match Pool Fittings, Custom Molded Products, Hayward Pool Products, Pentair Water Pool and Spa, Rising Dragon USA, and Waterway Plastics, at (866) 478-3521 or www.apsp.org/draincoverrecall.

Pool Drain Covers. The recalled drain covers were incorrectly rated to handle the flow of water through the cover, which could pose a possible entrapment hazard to swimmers and bathers. Lawson Aquatics, at (800) 897-6160.

Pool Drain Covers. The recalled drain covers were incorrectly rated to handle the flow of water through the cover, which could pose a possible entrapment hazard to swimmers and bathers. Waterway Plastics, at (866) 719-6044 or www.waterwayplastics.com.

Portable Drop-Side Cribs. The drop-side rail hardware can break or fail, allowing the drop side to detach from the crib or fall unexpectedly. In addition, the portable crib mattress support hardware and the drop-side release latch can break easily, and the slats can loosen or break and detach from the crib. Children can also cut themselves on exposed hardware inside the cribs. Dream on Me Inc., at (877) 201-4317 or www.dreamonme.com.

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PUBLICCITIZEN **Health Letter**

Outrage of the Month!

Remove Dangerous Alzheimer's Drug — Aricept 23 — from the Market Immediately

A drug used to treat moderate or severe cases of Alzheimer's disease should be removed from the market immediately because of its risk of serious adverse effects and its lack of effectiveness, Public Citizen and an eminent geriatrician from Johns Hopkins said in a recent petition filed with the Food and Drug Administration (FDA).

Donepezil, also known as Aricept, has been approved by the FDA in a dose of 5 to 10 milligrams (mg) for patients with mild to moderate cases of Alzheimer's disease and in a dose of 10 or 23 mg for patients with moderate to severe Alzheimer's.

Data show that the 23-mg dose of donepezil, known as Aricept 23 and approved last July, is significantly more toxic than the 10-mg dose. Combined with its lack of improved clinical benefits, this leads to only one conclusion: that the 23-mg dose should be immediately withdrawn from the market.

We are also asking the FDA to warn doctors and patients against taking 20 mg of the drug (two 10-mg pills) a day, even if Aricept 23 is removed from pharmacy shelves.

Dr. Thomas Finucane, professor of medicine in the Division of Gerontology and Geriatric Medicine at the Johns Hopkins University School of Medicine and staff physician at the Johns Hopkins Bayview Medical Center, stated that "Cholinesterase inhibitors such as Aricept have gained multibillion-dollar success due primarily to two factors: the understandable desperation of those who care for patients with Alzheimer's disease, and a relentless promotional campaign by drug companies." Finucane is a co-petitioner with Public Citizen to ban Aricept 23.

"When clinicians consider whether to initiate a therapeutic trial of a largely ineffective drug, the risk of harm should be a prominent consideration," Finucane said. "The clearly increased risk of harm from Aricept 23-mg compared to Aricept 10-mg is so great, coupled with the lack of any evidence of improved benefit, that I believe it should not have been approved for sale to the families and caregivers of Alzheimer patients."

The only clinical trial of donepezil submitted to the FDA for approval of the 23-mg dose compared it to the 10-mg dose and failed to prove that the higher dose was more effective. In three of four tests, on either a cognitive or functional level, there was no significant difference between the 10-

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