PUBLIC CITIZEN HEALTH RESEARCH GROUP

Health Letter

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Public Citizen's Health Research Group Ranking of State Medical Board Disciplinary Actions in 2000

Based on data Public Citizen obtained from the Federation of State Medical Boards (FSMB) on the number of disciplinary actions taken in 2000 against doctors, Public Citizen's Health Research Group has calculated, for the 10th year in a row, the rate of serious disciplinary actions (revocations, surrenders, suspensions and probation/restrictions) per 1,000 doctors in each state and compiled a national report ranking state boards by number of serious disciplinary actions taken against doctors in the year 2000 (See Table 1, pg. 2).

Our calculation of rates of serious disciplinary actions (revocations, surrenders, suspensions and probations/restrictions) per 1,000 doctors by state is created by taking the number of such actions and dividing it by the American Medical Association data on nonfederal M.D.s as of December 1999 (adding to this the number of osteopathic physicians if the board is a combined M.D./D.O. board) then multiplying the result by 1,000 to get state disciplinary rates per 1,000 physicians.

Nationally, there were 2,746 serious disciplinary actions taken by state medical boards in 2000, up slightly from the 2,696 serious actions taken in 1999. However, there were more physicians practicing in 2000 and the rate, per 1,000 physicians, was essentially the same in the two years: 3.50 serious actions per 1,000 physicians in 1999 and 3.49 in 2000.

State rates ranged from 12.43 serious actions per 1,000 doctors (North Dakota) to 0.85 per 1,000 physicians (Idaho), a 14.6-fold difference between the best and worst states. *If all the boards did as good a job as the lowest of the top five boards, the lowest rate for #5, Oklahoma being 6.68 serious disciplinary actions per 1,000 physicians or 0.668 percent, this would amount to a total of 5,255 (0.668 percent of 786,685 nonfederal doctors) serious actions a year. This is 1.9 times as many (2,509 more serious actions) than the 2,746 that actually occurred in 2000.*

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

As can be seen in Table 1, the bottom 15 states, those with the lowest serious disciplinary rates in 2000, were, starting with the lowest: Idaho (0.85 per 1,000 physicians), South Dakota (1.24), Hawaii (1.33), Delaware (1.39), Minnesota (1.53), Massachusetts (1.58), Illinois (1.67), Washington (1.78), Montana (1.91), New Mexico (2.13), Maryland (2.21), Nebraska (2.39), Texas (2.42), Kansas (2.53), and West Virginia (2.54). Of the 15 states with the worst serious disciplinary records, eight of the states, Massachusetts, Illinois, Maryland, Washington, Minnesota, Kansas, Hawaii, and Delaware were also in the bottom 15 states in 1999 and 1998 (see Table 2, pg. 3). In 2000, the

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bottom 24 states all had rates of serious disciplinary action that were one-half or less than the rate of all of the top five states.

These data raise serious questions about the extent to which patients in many states with poorer records of serious doctor discipline are being protected from physicians who might well be barred from practice in states with boards that are doing a better job of disciplining physicians. It is likely that patients are being injured or killed more often in states with poor doctor disciplinary records than in states with consistent top performances.

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

Table 1 lists each state's ranking and rate in descending order. The top 10 states, or those with the highest rate of serious disciplinary actions per 1,000 physicians are (in order): North Dakota (12.43 per 1,000 physicians), Alaska (11.47), Kentucky (8.51), Wyoming (8.10), Oklahoma (6.68), Utah (6.27), Arizona (6.18), Ohio (5.89), Georgia (5.35), and New York (5.08). Four of these 10 states (Alaska, Oklahoma, Wyoming, and Ohio) were also in the top 10 in 1998 and 1999 and one state, Alaska, has been in the top 10 for 10 straight years. Oklahoma, 5th this year, has been in the top 10 states for 9 of the last 10 years. Wyoming, 4th this year, has been in the top 10 for 8 of the last 10 years and Ohio, 8th this year, has been in the top 10 for 6 of the last 10 years. (See Table 2)

It is clear that state-by-state performance is spotty. Only two of the nation's 15 largest states, Ohio, and New York, are represented among those 10 states with the highest disciplinary rates. Other large states such as Michigan and California (14th and 19th respectively in 2000) have shown improvement from 40th and 37th in 1991. But other large states such as Texas, Illinois, and Massachusetts (38th, 44th, and 45th in 2000) have not done very much doctor discipline for many of the last 10 years.

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Table 1

Ranking of Serious Doctor Disciplinary Actions By State Medical Licensing Boards — 2000

Rank 2000	State	Number of Serious Actions 2000	Total Number of Physicians 1999	Serious Actions Per 1,000 Doctors
1	North Dakota	20	1,609	12.43
2	Alaska	14	1,221	11.47
3	Kentucky	80	9,401	8.51
4	Wyoming	8	988	8.10
5	Oklahoma	42	6,285	6.68
6	Utah	30	4,787	6.27
7	Arizona	71	11,487	6.18
8	Ohio	193	32,751	5.89
9	Georgia	99	18,497	5.35
10	New York	404	79,601	5.08
11	Iowa	33	6,693	4.93
12	Alabama	46	9,765	4.71
13	Mississippi	23	5,191	4.43
14	Michigan	102	24,551	4.15
15	Arkansas	21	5,638	3.72
16	Vermont	8	2,148	3.72
17	Oregon	34	9,234	3.68
18	Virginia	69	18,922	3.65
19	California	337	92,985	3.62
20	Louisiana	43	11,897	3.61
21	Nevada	13	3,611	3.60
22	Maine	12	3,356	3.58
23	New Hampshire	12	3,388	3.54
24	Indiana	47	13,647	3.44
25	Missouri	53	15,470	3.43
26	New Jersey	100	29,208	3.42
27	South Carolina	27	9,315	2.90
28	Connecticut	37	13,237	2.80
29	Pennsylvania	106	38,524	2.75
30	Wisconsin	37	13,933	2.66
31	Colorado	31	11,814	2.62
32	North Carolina	53	20,344	2.61
33	Rhode Island	10	3,854	2.59
34	Florida	113	43,835	2.58
35	Tennessee	38	14,774	2.57
36	West Virginia	11	4,323	2.54
37	Kansas	17	6,724	2.53
38	Texas	114	47,108	2.42
39	Nebraska	10	4,181	2.39
40	Maryland	48	21,715	2.21
41	New Mexico	9	4,231	2.13
42	Montana	4	2,094	1.91
43	Washington	28	15,688	1.78
44	Illinois	61	36,618	1.67
45	Massachusetts	45	28,456	1.58
46	Minnesota	21	13,713	1.53
47	Delaware	3	2,160	1.39
48	Hawaii	5	3,747	1.33
49	South Dakota	2	1,612	1.24
50	Idaho	2	2,354	0.85
	United States	2,746	786,685	3.49

Table 2

Ranking for Last 10 Years

Rank 2000	Rank 1999	Rank 1998	Rank 1997	Rank 1996	Rank 1995	Rank 1994	Rank 1993	Rank 1992	Rank 1991	State
1	2	11	9	2	34	10	3	5	13	North Dakota
2	1	1	2	6	8	2	8	7	6	Alaska
3	6	14	7/8	14	14	4	4	16	5	Kentucky
4	3	7	3	31	3	1	21	4	9	Wyoming
5	5	2	5	7	12	5	2	1	2	Oklahoma
6	33	20	25/26	16	38	46	39	43	18	Utah
7	21	38	19/20	5	10	17	16	22	22	Arizona
8	7	10	7/8	8	9	24	22/23	19	23	Ohio
9	15	12	23/24	19	4	8	10	9	4	Georgia
10	14	16	16	18	17	29	34	39	49	New York
11	11	23	4	3	2	7	5	2	3	Iowa
12	13	17	23/24	38	30	43/44	29	30	31	Alabama
13	8	3	1	1	1	9	9	6	6	Mississippi
14	19	13	15	28	21	34/35	35	40	40	Michigan
15	12	4	13	15	23	28	26	18	29	Arkansas
16	9	6	25/26	10	6	39	17	15	10	Vermont
17	30	31	28/29	29	16	20	22/23	24	14	Oregon
18	22	40	34/35	50	41/42	32	30	37	32	Virginia
19	20	27	18	27	20	34/35	32	42	37	California
20	23	15	34/35	44	13	18	11	12	7	Louisiana
21	25	26	32	9	11	31	20	25	26	Nevada
22	24	9	22	17	32	33	41	44	46	Maine
23	18	30	46	51	49	49	47	47	44	New Hampshire
24	16	21	19/20	33	28	16	7	14	15	Indiana
25	31	48	17	30	37	13	12	13	12	Missouri
26	28	35	42	20	25	19	18	28	20	New Jersey
27	29	22	40	45	44	14	15	11	11	South Carolina
28	46	32	31	37	27	42	36	35	30	Connecticut
29	36	45	27	32	43	47	48	48	47	Pennsylvania
30	42	46	39	34	47	41	27	26	34/35	Wisconsin
31	10	18	6	4	5	12	6	8	17	Colorado
32	26	43	33	48/49	35	36	40	34	42/43	North Carolina
33	35	24	10	25	26	26	42	41	50/51	Rhode Island
34	38	49	36	22	22	25	25	21	27	Florida
35	49	51	48	48/49	31	38	44	49	38	Tennessee
36	17	5	12	11	7	6	1	3	8	West Virginia
37	45	44	41	12	46	22	37/38	20	25	Kansas
38	34	28/29	37	35	19	23	28	29	21	Texas
39	50	28/29	43	24	41/42	15	50	38	39	Nebraska
40	40	36/37	38	41	29	21	19	27	42/43	Maryland
41	27	8	50	23	15	43/44	49	33	33	New Mexico
42	32	34	11	13	18	3	14	10	19	Montana
43	37	36/37	28/29	40	24	27	24	17	24	Washington
44	43	41	21	46	45	40	31	36	36	Illinois
45	39	47	45	43	40	37	45	46	48	Massachusetts
46	48	42	51	47	39	45	33	31	28	Minnesota
47	51	50	47	26	48	48	43	51	16	Delaware
48	47	39	49	39	51	50	46	50	41	Hawaii
49	44	19	14	42	33	11	13	32	50/51	South Dakota
50	4	25	30	21	36	30	37/38	23	34/35	Idaho
	41	33	44	36	50	51	51	45	45	District of Columbia

How to Reduce the Risk of Mad Cow Disease in the United States

Adapted from the Testimony of Peter Lurie, MD, MPH, Deputy Director, Public Citizen's Health Research Group, Before the Consumer Affairs, Foreign Commerce and Tourism Subcommittee, Senate Commerce, Science and Transportation Committee, April 4, 2001.

While the U.S., to the best of our knowledge, remains free of both Bovine Spongiform Encephalopathy (BSE), otherwise known as "Mad Cow Disease," as well as its human counterpart, variant Creutzfeldt-Jacob Disease (vCJD), the experiences of European countries that grew complacent and now are suffering from epidemics of BSE and, in some cases, vCJD should make us more vigilant than we are at present. The agent that causes BSE has often found a way to pierce small chinks in the public health armor. For this reason, it is critical not only to maintain our defenses but also to strengthen them in the several areas I will highlight in this testimony.

I will address four areas: 1. How the agent that causes BSE might enter the country; 2. How the agent, if it entered the country or arose spontaneously within the country, could spread; 3. Whether the U.S. is doing enough testing to detect the disease; and 4. Whether there are medical practices that might spread the disease.

How Could the BSE Agent Enter the Country?

We have serious concerns about the ability of customs inspectors to adequately police the borders. With the dramatic increase in global trade, the workload of these inspectors is only likely to grow. Transhipments between countries can make determining the origin of meat and bone meal quite difficult. This is, of course, an issue that extends well beyond BSE to encompass broader issues of food safety.

An issue of particular concern is that of dietary supplements. In 1994, the government, unwisely, essentially deregulated the dietary supplement industry. Whereas, prior to the Dietary Supplement, Health and Education Act (DSHEA), the industry had the burden of demonstrating the safety of its products, now the Food and Drug Administration (FDA) must demonstrate that a particular dietary supplement is unsafe before it can take action. Moreover, this now-$17 billion industry is not required to prove the efficacy of its products and the FDA has still failed to issue Good Manufacturing Practice (GMP) regulations for dietary supplements four years after the agency commenced rulemaking on this issue and seven years after DSHEA. Manufacturers are not required to register with the FDA and the agency only inspects approximately 1 percent of imported items subject to its jurisdiction, a fraction that may be still lower for dietary supplements. The agency has issued an Import Alert for materials sourced from BSE countries, but compliance is voluntary.

For BSE, this means that an unscrupulous manufacturer could literally take a British cow brain, crush it, dry it out, formulate it into a dietary supplement and export it to the U.S. Indeed, a letter by Dr. Scott Norton in the *New England Journal of Medicine* mentions a product available in the U.S. with 17 cow organs including brain, pituitary, and pineal gland. Due to DSHEA, the FDA is limited in what it can do. Instead of claiming that its regulatory authority over dietary supplements is adequate, as it often does publicly, the agency should be coming back to the Congress to undo the damage done by DSHEA. The best option would be to simply repeal DSHEA. In the alternative, we recommend a variety of im-

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RANKINGS, *from page 2*

What Makes a Difference?

Boards are likely to be able to do a better job in disciplining physicians if most if not all of the following conditions are true:

* Adequate funding (all money from license fees going to fund board activities instead of going into the state treasury for general purposes);

* Adequate staffing;

* Proactive investigations rather than only following complaints;

* The use of all available/reliable data from other sources such as Medicare and Medicaid sanctions, hospital sanctions;

* Excellent leadership;

* Independence from state medical societies and other parts of the state government;

* A reasonable statutory framework for disciplining doctors (preponderance of the evidence rather than beyond reasonable doubt or clear and convincing evidence).

Given the importance of medical boards in protecting patients in a state from doctors who are not practicing medicine in the best manner and are thus endangering the lives and health of residents of those states, most states are not living up to this obligation. Serious attention must be given to finding out which of the above variables are deficient in each state and taking action, legislatively and through pressure on the medical boards, to increase the amount of discipline and, thus, the amount of patient protection. See page 10 to order Public Citizen's report on Questionable Doctors.

provements, including a mandatory adverse event reporting requirement for all dietary supplement manufacturers, mandatory risk warnings, requirements for company and product registration, and identification of the raw ingredients and the source (by country) for each of the ingredients in each product. This is, of course, a problem that goes well beyond the risk of vCJD; over 100 people have been killed by ephedra, and the agency seems essentially powerless to act.

Releasing the GMP regulations for dietary supplements is necessary, but will not suffice to adequately protect American consumers from vCJD that might be caused by these products.

If the BSE Agent Entered the Country, How Might It Spread?

A. Feeding practices

Since 1997, the FDA has had a ban on the feeding of mammalian parts to ruminants (animals that chew the cud, e.g., cows, goats, sheep), the main route by which the BSE epidemic occurred in Britain and would be amplified in the U.S. This ban requires that manufacturers take action to prevent the commingling of two types of feed: those intended for ruminants, and those intended for non-ruminants (e.g., pigs, fish, chickens which can be fed material from mammals).

FDA inspections to date provide evidence that this commingling is possible. The March 2001 FDA inspection report findings, while improved from the January 2001 findings, still show that 14 percent of renderers and 13 percent of FDA-licensed feed mills do not have adequate procedures to prevent mammalian parts from entering ruminant feed: i.e., cows could still be recycled and fed to other cows. (This is precisely what happened in a Purina Mills plant in Texas in which, purely through the voluntary admission of the company, the FDA learned that cow parts had entered cow feed. One thousand, two hundred and twenty-two cows had to be removed from the food chain.) Moreover, 23 percent of renderers and 63 percent of FDA-licensed feed mills have still not been inspected for compliance with the feed restrictions and some 6,000 to 8,000 feed mills are not even required to register with the FDA. Of the 1,829 non-FDA licensed feed mills that handle material prohibited from use in ruminant feed, 18 percent do not have adequate procedures to prevent the recycling of mammalian parts as feed for ruminants. Considering the possibility of trans-species transmission and the possibility for commingling both at the plant and farm levels, a mammal-to-mammal ban is the safer public health course at present.

In addition, the FDA feed ban contains an exemption that should be ended. Despite U.S. Department of Agriculture (USDA) objections, the FDA permits the feeding of so-called plate waste (leftover food that has been prepared and/or served to humans) in feed for ruminants. The European Union, Canada and Mexico have banned such practices and so should we.

Finally, there is the issue of Chronic Wasting Disease (CWD), a Transmissible Spongiform Encephalopathy (TSE) of wild and captive elk and deer. While there exists no evidence that humans have become infected from eating deer or elk, current USDA procedures permit deer and elk from a herd with a proven case of CWD to enter the food chain. The problem is that deer and elk are exempt from the USDA's Meat Inspection Act, under which the packer has the burden of demonstrating the safety of his or her product. Instead, deer and elk would have to be restricted under the FDA's Food, Drug and Cosmetic Act, which places the burden upon the agency to demonstrate potential harm and provides no funds to compensate farmers if their herd is seized. This creates an incentive for farmers not to be forthcoming about CWD in their herds. This could be addressed either by a specific regulation excluding CWD-affected herds from the food chain and providing for compensation for the rancher or by bringing deer and elk under the Meat Inspection Act, which does provide for compensation.

B. Meat processing

The processes of slaughtering and processing are not, by their nature, extremely precise ones. Infectious material from the most infectious parts of the cow, the brain and spinal cord, may spread to other parts of the animal. Pneumatic stunning devices, which stun the animal prior to slaughter by injecting a bolt and compressed air into the head, have been shown to spread potentially infectious brain tissue to other parts of the body. Although the

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industry appears to be reducing its use of pneumatic stunning devices, this should be given the force of federal regulation and banned. These devices are now banned for use in cattle in Europe.

European countries require that the brain and spinal cord be removed early in the slaughtering process. However, in the United States, processes vary widely and are not effectively regulated. We therefore support a regulation that would require the removal of the brain and spinal cord before further processing, since these organs contain the highest levels of infectious material.

Two other meat processing methods have also come under scrutiny. In one, mechanically separated product (MSP), bones with attached muscle are crushed and pushed through an extruder to create a paste. Bone fragments are removed by a sieve-like mechanism. Both spinal cord and dorsal root ganglia (nerve tissue next to the vertebrae), which have demonstrable BSE infectivity, can enter MSP. In the other processing method, advanced meat recovery (AMR), muscle fragments are also removed from bone; this material can become part of ground beef. Early AMR machines used a belt to shave meat off bones, but later AMR machines use a "bone press" that differs from MSP only in degree. MSP must be labeled as such, but AMR product can legally be labeled as meat. While MSP inherently involves the crushing of bones and is thus more likely to introduce nerve tissue into the product than AMR, 1997 USDA inspection records obtained by the Government Accountability Project through the Freedom of Information Act clearly demonstrate that spinal cord can also be part of the material generated by AMR. Four of 34 AMR samples sent by USDA inspectors to a USDA laboratory because they were suspected of containing spinal cord tissue turned out to actually contain central nervous system tissue. To prevent vCJD, we therefore support a ban on the production of MSP from vertebrae or the use of any process that could permit the inclusion of spinal cord. However, other concerns, including truth-in-labeling issues and the low nutritional content of meat recovered through both of these processes, makes banning them both the preferable public health approach overall.

Is the U.S. Doing Enough Testing to Detect the Disease?

To date, the U.S. surveillance efforts for BSE have been quite inadequate. Only 11,954 cow brains had been examined by the USDA in the ten-year span ending in 2000. (Some 40 million cattle are slaughtered annually in the U.S.) By comparison, France, a country which, importantly, has a proven BSE epidemic, is now testing about 20,000 brains per week.

Under current USDA procedures, all cows with neurological symptoms are supposed to be tested for BSE and, regardless of the result, excluded from the food chain. Cows that are unable to ambulate, so-called downer cows, are only occasionally tested. The USDA did not begin testing downer cows until 1993 but has now increased such testing to about 1,900 in 2000. This represents about 1 percent of all downer cows brought to slaughter in the U.S. The USDA has promised to increase such testing to 5,000 per year in 2001, a move we fully support. Testing of healthy cows does not seem justified in the U.S. at present as the prevalence of disease would almost certainly be lower than in downer cows or those with neurological symptoms. Moreover, even in countries with clear BSE epidemics, BSE-positive normal animals have only been detected extremely rarely, if ever, even as the disease is detected in downer cows and those with neurological symptoms.

Testing for the presence of BSE in cow brain can be very time-consuming. However, while three rapid tests for BSE are on the market in Europe, none are on the market in the U.S. It is imperative that these tests be evaluated by the FDA and that test performance characteristics be made public.

Surveillance for human CJD and vCJD is coordinated through the Centers for Disease Control and the National Prion Disease Pathology Surveillance Center at Case Western Reserve University. The Center has examined the brains of about 300 patients with CJD in the past four years. This represents an estimated 39 percent of patients with CJD in 2000, whereas in Germany and Britain the brains of almost all patients with CJD are examined by pathologists. Canada has recently revamped its surveillance system and provides much more funding for such efforts than does the U.S.

The U.S. government also needs to do more to increase the overall hospital autopsy rate in this country, which has declined from over 40 percent after World War II to under 10 percent at present, as well as to increase the rate of examination of brain material specifically. Currently, hospitals and families bear the costs of autopsies, including transportation costs; they should be reimbursed for these costs. The government should also consider creating a network of regional pathology centers to do brain examinations for CJD and needs to do more to contact all neurologists to inform them of the current surveillance system.

Are There Medical Practices That Might Transmit BSE and vCJD?

While there has never been a documented case of CJD or vCJD transmitted by blood transfusion, the agent is present in white blood cells (inevitably present to some extent in even red blood cell transfusions) and, in an experiment, a sheep was recently infected by transfusion from a cow with BSE. In 1999, the FDA's TSE Advisory Committee recommended a ban on blood donations from potential donors who had spent more than a total of six months in Britain between 1980 and 1996. The Committee determined that the impact on the blood supply would be manageable and data collected since the restriction on British donors confirm that the supply of blood remained stable after the ban was enacted. In January 2001, with cases of vCJD in France and of BSE in Europe mounting, the Committee extended this recommendation to include France, Portugal and Ireland, although with a 10-year cumulative residency require-

Product Recalls

March 13—April 11, 2001

DRUGS & DIETARY SUPPLEMENTS

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.

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

Class I Recall

There has been a Class I recall of all lots from the following "All Green Kingdom Herbs" because the products contain aristolochic acid, a potent carcinogen and nephrotoxin. They are listed with their Latin name of botanical: Akebia Extract (akebia trifoliata), Stephania Extract (stephania tetrandra), Clematis (Chinese) Extract (clematis chinensis), Virginia Snake Root Extract (aristolochia serpentaria), Witch Hazel Formula (containing Virginia Snake Root Extract, aristolochia serpentaria), PFC—custom made formula (containing Virginia Snake Root Extract, aristolochia serpentaria), HPX—custom made formula (containing Virginia Snake Root Extract, aristolochia serpentaria), Ligusticum & Green Tea Formula I (containing asarum), Ligusticum & Green Tea Formula II (containing asarum), Ligusticum & Green Tea Formula III (containing asarum), Ligusticum & Green Tea Formula IV (containing asarum), Ligusticum & Green Tea Formula V (containing asarum), Minor Blue Dragon Combination (containing asarum). There were 55 bottles (from 1—12 ounces) and over 50 gallons of product in larger containers distributed in Michigan, Texas, Georgia, Indiana, Illinois, New York and California by Green Kingdom Herbs of Bay City, Michigan.

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MAD COW DISEASE, *from page 6*

ment, since BSE and vCJD case rates are lower in those countries than in Britain. The FDA should adopt the Committee's recommendation.

Similar travel restrictions should be placed on cadaveric cornea donors, especially because as many as three cases of CJD due to corneal transplantation have been documented. Due to the existing shortages of other transplantable organs such as heart and bone marrow, and the failure to document CJD transmission associated with their transplantation, a travel restriction on such organ donors is not justified. On the other hand, because the U.S. is a net exporter of cornea, we are not concerned that there would be a shortage of cornea were a travel restriction to be implemented.

Finally, there is the issue of vaccines. In 1993, the FDA wrote to the manufacturers of FDA-regulated products and in a voluntary Guidance instructed manufacturers to no longer source materials for their products from BSE-affected countries. It repeated the admonition in 1996. Nonetheless, at least six manufacturers simply ignored the Guidance, which does not have the force of a regulation, and continued to source bovine materials for the production of vaccines from BSE-affected countries. The FDA only learned that its recommendation had been disregarded in early 2000. By then, millions of doses of vaccines such as polio and diphtheria, tetanus, and pertussis (DTP) were injected into Americans, including small children. At a TSE Advisory Committee meeting in July 2000, Committee members agreed that the risk of disease transmission through these vaccines is extremely small and that there is no evidence that vCJD has been spread through this route. Nonetheless, this event was a reminder of the dangers presented by agencies that fail to regulate and industries that act in arrogant disregard of the government.

The lesson of the vaccine debacle applies more broadly to our efforts to reduce the risks of BSE and vCJD: for the public to be adequately protected, government will have to take forceful action—regulations, not guidelines—and not simply depend upon voluntary actions by industry.

DRUGS & DIETARY SUPPLEMENTS *cont.*

Name of Drug or Supplement; Class of Recall; Problem	*Lot #; Quantity and Distribution; Manufacturer*
Aldroxicon II Double Strength Antacid/Anti-gas liquid, OTC (Aluminum Hydroxide 400 mg, Magnesium Hydroxide 400 mg, Simethicone 40 mg), 30 mL screw cap tubes in units of 10 per box; Class II; Product exceeded the microbial limits for release	Lot No. 10056; 11,680 tubes distributed nationwide; York Pharmaceuticals, Kansas City, Kansas. Recalled by Textilease Medlique, Wood Dale, Illinois
Anti-gas, Fast-Acting Antacid, Original Flavor, Pharmacy's Prescription Brand 12 fl oz; Class II; Microbial contamination (Bacillus licheniformis)	Lot No. C-1188; 10,498 units distributed in Kentucky, California, Tennessee, New York; Aaron Industries, Inc., Lynwood, California
Leukeran® Tablets (Chlorambucil), 2 mg, 50 count; Class III; Impurity specification failure (stability)	Lot No. 0E2036; 25,808 bottles and 7,200 (bulk) tablets distributed nationwide and in Canada; GlaxoSmithKline, Inc., Research Triangle Park, North Carolina
Liqui-Doss® Liquid for constipation (Mineral Oil 13.5mL/15mL), 2 and 16 fl. oz. bottles; Class II; Possible yeast contamination	Lots 57-142, 57-144, 57-145, 57-152, 58-055, 58-057, 58-058, and 58-063; 28,564 bottles distributed nationwide; Ferndale Laboratories, Inc., Ferndale, Michigan
Maximum Strength Sinus Tablets (Acetaminophen 500 mg, Pseudoephedrine HCL 30mg, Chlorpheniramine Maleate 2 mg) 24 counts, OTC; Class III; Subpotency and dissolution failures at 12 months of expiry	Lot RM0260; 798,580 units distributed in Arkansas and Ohio; Contract Pharmacal Corp., Hauppauge, New York. Recalled by Leiner Health Products, Inc., Carson, California
Methyldopa Tablets, 250 mg, 100 count bottles; Class III; Tablet Discoloration	Lot No. 465-916, EXP 6/02, Batch #1404; 14,402 bottles distributed nationwide; Wyeth-Ayerst/Lederle, Pearl River, New York. Recalled by ESI Lederle, Philadelphia, Pennsylvania
Prax ® Lotion, (Pramoxine HCL 1%), 15 mL, physician samples; Class III; Subpotency at 12 month stability	Lot Nos. 57-209A, 58-007, 58-203; unknown quantity distributed nationwide; Ferndale Laboratories, Inc., Ferndale, Michigan
Toothpaste; Class III; Microbial contamination (Bacillus licheniformis)	SKU 74004, SKU 74003, SKU 72600 EXP 11/03/02; 7375 cases distributed nationwide; Colgate Palmolive, Jeffersonville, Indiana
Trecator®-SC Sugar-Coated Tablets (Ethionamide), 250mg, 100 count; Class III; Dissolution failure	Lot No. 3990893, EXP 11/04; 2,005 bottles distributed nationwide, and in Sweden, New Zealand, and the Czech Republic; Wyeth-Ayerst Laboratories, Rouses Point, New York

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 1-800-638-2772. The CPSC web site is *http://www.cpsc.gov.*

Name of Product; Problem	*Lot #; Quantity and Distribution; Manufacturer*
Air Conditioners; Can short circuit, posing a risk of fires, and shock and burn injuries to consumers	Frigidaire FAH096J2T1, White-Westinghouse WAH09EH2T1 and WAH096H2T1, Kenmore 253.79093990 and 253.70093000; 17,000 sold nationwide from November 1998 through November 2000; White Consolidated Industries Inc., Cleveland, Ohio (866) 897-5612
Backpack Blowers; Fuel hose on the carburetor can be dislodged and leak fuel, presenting fire and burn hazards	Model number BR 420C with a serial number in the ranges: 47988257 through 47989256 and 49014561 through 49015560; 890 sold in California from November 2000 through January 2001; STIHL Inc., Virginia Beach, Virginia (800) 711-7959

CONSUMER PRODUCTS *cont.*

Name of Product; Problem	*Lot #; Quantity and Distribution; Manufacturer*
Baseball Video Games. (Recall to replace bats); Bats can separate during a swing. Broken pieces can hit a bystander and cause injury	RADICA PLAY TV Baseball; 140,000 sold nationwide from June 2000 through January 2001; Radica USA Ltd., Dallas, Texas (800) 803-9611 www.radicagames.com
Bungee Baby Jumper; Metal clasps can detach from the cord, causing the unit to fall to the floor	Model numbers 04-461 and 04-468. Three yellow cords connect seat to blue plastic strap holder, which says "Cosco"; 171,000 sold nationwide from May 1996 through March 2001; Cosco, Inc., Columbus, Indiana (800) 314-9327 www.coscoinc.com
Candles; When candle burns, the pooling of wax can ignite the paint on the duck, posing fire and burn hazards to consumers	3 1/2 inches tall in the shape of a yellow duck. Label on the bottom has the UPC code 7 3849 38819 8 and says, "Made in China;" 2,000 sold nationwide from September 2000 through January 2001; Midwest of Cannon Falls, Cannon Falls, Minnesota (800) 776-2075 www.midwestofcannonfalls.com
Cigarette Lighters; Lighters have child-resistant mechanisms that do not work	Blue, orange, red or clear oval tube shaped with a roll and press type ignition mechanism; 950,000 sold nationwide in the southeast U.S. from June 2000 through February 2001; Fleetwood EXIM Inc., Grenada, Mississippi (888) 251-5252
Fleece Pants; Cord locks can break off, posing a choking hazard to young children	Blue, gray, red, or green pant legs, with stitching around the knees, gray elastic waistband with black elastic drawcord secured in place with two plastic cord locks in sizes 0-3T; 125,000 sold through Gymboree's website and stores nationwide from September 2000 through February 2001; The Gymboree Corp. (Gymboree®), Burlingame, California (800) 222-7758 www.gymboree.com
Gas Ranges; Igniters are too far from the burners, which can cause a delayed ignition of gas. The large amount of gas released can cause fire to escape from the oven, putting consumers at risk of burn injuries and house fires	Dynasty model numbers DGRSC and DGR(c), with serial numbers from 050198-A through 280200-Z; 3,300 sold nationwide from January 1998 through February 2000; Jade Products Inc., Los Angeles, California (888) 607-5694
Gas Ranges; Vent flue insulation can be out of position on these ranges. Using the broil or self-clean functions can cause scorching or burning of the cabinetry around the range, posing a fire hazard	Magic Chef model numbers CGS1230, CGS1740, CGS3760, MGS5770, MGS5870 with serial numbers ending in WU, WW, WY, WZ, YB, YF or YH; 14,800 sold nationwide from September 1999 through April 2000; Maytag Corp., Newton, Iowa (800) 544-2538 www.maytag.com
Hairdryers; Not equipped with an appliance leakage current interrupter plug (ALCI plug) to cut off electrical current in case of contact with water. If dropped in water, the hairdryers pose an electrocution hazard to consumers	Model Remington Vortex Ultra V-1030 1600 watts; 3,000 sold nationwide from July 2000 through January 2001; Remington Products Co., LLC, Bridgeport, Connecticut (800) 992-9686 www.remington-products.com
Lawn Mowers; Piece attaching blade to mower can crack and break off. Broken piece or blade can be propelled from underneath the mower, possibly injuring the consumer	Walk-behind mowers sold under the Ariens, Scotts, and Husqvarna brand; 40,000 sold nationwide from December 1999 through October 2000; Ariens Co., Brillion, Wisconsin (877) 740-7060 www.ariens.com/lawn_safety_recall/ or www.husqvarna.com/news/shl_news.htm
Light and Glitter Wands; Batteries can short-circuit, causing handles to become very hot and melt the plastic, posing a risk of burn injuries	"All That Glitters" wand with pink liquid and glitter; 5,000 sold in Meijer stores in Illinois, Indiana, Kentucky, Michigan and Ohio from January 2000 through January 2001; Meijer Inc., Grand Rapids, Michigan (800) 543-3704 www.meijer.com/qa

Name of Product; Problem	*Lot #; Quantity and Distribution; Manufacturer*
Propane Regulators; Can leak propane, which can result in a fire or explosion	Model 6000 of "0196," indicating January 1996, through "1099," indicating October 1999; 20,000 sold nationwide from June 1996 through October 1999; Hurricane Products, Valencia, California (877) 673-3278
Toys (Recall to repair); Two red knobs can break off, creating small parts that can pose a choking hazard for young children	Model 77148 Intelli-Table plastic activity table with removable top; 20,000 sold nationwide from October 2000 through March 2001; Fisher-Price, East Aurora, New York (800) 220-7137 www.fisher-price.com
Water Bottles; Drinking valve on cap can detach, presenting a potential choking hazard	Included with Mongoose Heart Breaker Girls' Bikes; 42,000 sold at Wal-Mart stores and Wal-Mart website nationwide from July 2000 through January 2001; Pacific Cycle LLC, McFarland, Wisconsin (800) 626-2811 www.mongoose.com
Wipe Warmers; Cracks in interior basin can allow moisture to contact the electrical components creating a potential electrical shock to consumers	Model 26133; 100,600 sold nationwide from December 1999 through March 2001; Safety 1st, Canton, Massachusetts (800) 964-8489 www.safety1st.com
Zapper Toys; Balloon tongues and cylinders holding the tongues can detach, posing a choking and aspiration hazard to young children	Vinyl 2 to 3 inch toy in animal, globe and smiley face styles; 835,000 sold and distributed at toy stores, doctor and dentist offices, and carnivals and circuses nationwide from October 1998 through March 2001; Distributed by eight different manufacturers. Call CPSC for more information (800) 638-2772

OUTRAGE, *from page 12*
than the 3,000 reported to the FDA. The number of AAPCC reports would be even higher if it included those commercial herbal supplements currently categorized as botanicals/plants. Nor does it capture the non-emergent hospitalizations due to adverse reactions that are more chronic than acute.

Ephedra

The close chemical structures of PPA, ephedrine and amphetamine are quite similar.

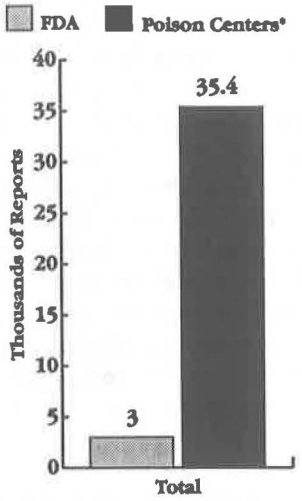
The well-documented concerns about the cardiac (arrhythmias) toxicity and brain toxicity of ephedrine (also associated with a large number of strokes due to bleeding in the brain), the known brain toxicity of amphetamine and the use of amphetamine as an appetite suppressant confirm that there are pharmacological as well as chemical similarities between all of these compounds.

Randy Sasich, M.D., the son of my colleague Larry Sasich, Pharm D., MPH, is in his third year of internal medicine residency at Barnes-Jewish, the main teaching hospital of Washington University in St. Louis. Within just a seven-month period during his residency, he took care of two patients admitted to the coronary care unit because of ephedra (Metabolife) -induced life-threatening cardiac arrhythmias. He is aware of a third patient who used Metabolife and experienced an arrhythmia but was not hospitalized.

Two reviews of 140 adverse reaction cases reported to the FDA involving the use of ephedra alkaloids confirmed the cardiac toxicity of ephedra. The first study found that 47 percent of cases involved the cardiovascular system (17 cases of hypertension, 13 with palpitations or fast heartbeat, 10 strokes). There were also 7 reports of seizures. The second study found that of the 104 reports in which causation by ephedra was very likely, there were 10 cases of sudden death, 9 cardiac arrhythmias, another 23 possible arrhythmic events, 3 heart attacks, 10 cases of chest pain and 15 severe strokes.

The FDA ban on PPA was based on a much smaller number of serious adverse reaction reports in their files than now exists, even with the extraordinary underreporting discussed above, for ephedra.

Adverse Reaction Reports for Dietary Supplements: FDA and National Poison Control Centers 1994-1999



*from Annual Poison Control Center Reports Data compiled by Public Citizen Health Research Group

Bleeding Risks of Herbals

Some supplements can increase the anti-coagulant effects of coumadin thereby increasing the risk of bleeding in such patients. These include Japonicum, ginseng, ginkgo biloba, Papaw, Red Clover and Horse Chestnut and therefore should not be used in patients on either anticoagulant or antiplatelet therapy. In addition, the standard text on drug interactions, *Evaluation of Drug Interactions*, lists several supplements, including ginkgo, ginseng, dong quai, vitamin C, and green tea as having interactions with coumadin.

Herbal Risks During Surgery

A recent news article in the *Journal of the American Medical Association*, entitled Herbs and Anesthesia, quoted the President of the American Society of Anesthesiology, Dr. John B Neeld, Jr., who said that because of changes in heart rate or blood pressure in people using herbals such as St. John's Wort, ginkgo biloba and ginseng, patients should stop taking herbal medicines at least two to three weeks before surgery. He pointed out that "It is very troubling to see our patients use products that they believe will provide a health benefit but, in fact, may jeopardize their lives during surgery if they don't tell us what they are taking."

Short-term and Long-term Remedies

Right now, legislation could be introduced—combined with the right signals during the FDA appropriation process and a strong version of the GMP regulations—to rapidly lessen the damage being done by this dietary supplement industry wish list masquerading as, and having the force of, a Federal Law, DSHEA. These improvements include a mandatory adverse event reporting requirement for all dietary supplement manufacturers, mandatory warnings for risks, requirements for company and product registration, and identification of the raw ingredients and the source (by country) for each of the ingredients in each product. This latter requirement is necessary to ensure that BSE-contaminated recycled cow organs do not appear on the shelves in this country as dietary supplements. In addition, mandated funds are necessary to implement and enforce the Good Manufacturing Practices regulation that will hopefully be finalized soon. In addition, the FDA should be appropriated the funds to purchase the entire dietary supplement database of the AAPCC. At present, only the ephedra alkaloid cases have been contracted for by the FDA.

When the first member of this committee or of Congress or their families, has a stroke, a fatal cardiac arrhythmia, or some other life-threatening adverse reaction to dietary supplements, perhaps there will be a belated reconsideration of the damage done by DSHEA. The law will then either be significantly modified or repealed so that pre-marketing safety and efficacy testing become the preferable alternative to post-marketing human experimentation. Until then, trust the snake oil companies. Their only concern is your health.

Dietary Supplements: The FDA Should Do More

The following is adapted from testimony of Sidney M. Wolfe, M.D. Editor of the Health Letter *to the House of Representatives Committee on Government Reform Hearing on Dietary Supplements on March 20, 2001.*

A former college roommate, now an investment advisor, told me two years ago that herbal/dietary supplement companies were a hot investment item because they do not have to spend money for the research to show that the products are safe and effective. In contrast to the $100 million (some companies claim more) it takes to get a pharmaceutical through the Food and Drug Administration (FDA) drug review process, several people in the industry have estimated to me that it takes a mere $3 to 5 million to get a supplement to the market. The legal cover for this profitable investment strategy comes from the Dietary Supplement Health and Education Act (DSHEA). I thank you for the opportunity to review the increasing evidence that this 1994 law is dangerous for people in this country.

The American Association of Poison Control Centers (AAPCC) correctly categorizes herbals/dietary supplements as pharmaceutical products since they do have pharmacologic activity. For drugs, the FDA has two opportunities to collect data on safety: legally mandated pre-market safety studies and post-marketing adverse reports. For dietary supplements, neither of these is required of the industry.

Scope of the Problem

The FDA has estimated that about 10 percent of adverse reactions to prescription drugs are reported to the agency, most of which come from the pharmaceutical companies who are required, by law, to report such reactions. For dietary supplements, it is likely that less than 1 percent of such reactions are reported to the FDA, one reason being that the manufacturers have no legal obligation to report. Based on data collected by the national network of Poison Control Centers, mostly located in hospitals throughout the country, the AAPCC publishes an annual report, in the *American Journal of Emergency Medicine*, which tabulates the number of adverse reactions reported by its toxic exposure surveillance system.

For 1994 through 1999, the total of such reports for AAPCC is 35,400 for that period, more than 10 times higher

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