PUBLIC CITIZEN HEALTH RESEARCH GROUP

Health Letter

SIDNEY M. WOLFE, M.D., EDITOR

June 2003 ◆ VOL. 19, NO.6

Doctor, Advocate, Activist

The following article is similar to one appearing in the Spring, 2003 issue of Inside Out, *a publication of students from the University of North Carolina at Chapel Hill. The author, William Wood, is a fourth-year student in the School of Medicine.*

"Of all the forms of inequality, injustice in health care is the most shocking and inhumane."

— Rev. Martin Luther King, Jr.

At last spring's "Pearls" assembly for fourth-year medical students, presented by a small number of faculty elected by the students, UNC Attending physician Dr. Tim Weiner delivered this pearl of wisdom: "As a pediatric surgeon, I'll save more kids by telling them to not smoke and to wear bike helmets and seat belts, than I will by doing surgery on them."

As future healthcare providers, we all will have the opportunity, and I would argue the responsibility, to be public political activists for social change, as well as direct caregivers. We need to work for what Ralph Nader terms "wholesale change," in addition to the "retail" work we will do daily with our individual patients. As he also is fond of saying, "this country has more problems than it should tolerate, and more solutions than it uses." As civic and healthcare leaders, we can have an enormous impact on bringing more of those tabled solutions to fruition.

Physicians and other health professionals have often been at the forefront of constructive social change, but they have served as frequently as stalwart opponents of progress. The American Medical Student Association (AMSA) started life as the Student American Medical Association (SAMA), a part of the AMA, but broke from the parent organization when the AMA opposed the introduction of Medicare in the 1960's. Fortunately for everyone over age 65 in our society, the AMA lost that battle, and AMSA and other progressive healthcare provider organizations (with their many citizen-group allies) won.

Organized medicine in the U.S. doesn't have a national monopoly on regressive politics, of course. Saskatchewan's physicians went on strike to protest that Canadian province's introduction of a single-payer Medicare health insurance system for all citizens, in 1964, which led later to a national single-payer system. Now Canada's life expectancy is longer than ours, and infant mortality lower, while that country spends about half of what we do per capita on health care. The Canadian system isn't perfect, but it's far preferable to ours, from both a healthcare and social justice perspective.

Here in the U.S., AMSA and Physicians for a National Health Program (PNHP) are campaigning for Medicare for all. (National health *insurance*, by the way, does not equal a nationalized health system. Canadian physicians are in private practice; they are not government employees, but they only have to deal with one insurance company to get reimbursed.) This issue will continue to be one of the key ones facing our society, as we move through our training and into practice. As I write,

continued on page 2

CONTENTS

RESPONSIBILITY, *from page 1*
union workers at General Electric are preparing to strike over new hikes in required co-payments when they visit healthcare providers, under their GE-sponsored health plan.

One could write many pages about the issue of health care reform in the U.S., of course — we are the only industrialized democracy in the world without some form of universal coverage, with 40+ million Americans without health insurance, in the richest country in history. Suffice it here to say that each of us, as future healthcare providers, will have an opportunity to have enormous influence in this arena. Doing our part to get our local Congressperson to support universal health care, for example, will have far greater impact on the health of everyone in our community, I would argue, than all of the scrips we are likely to write, or procedures we are likely to perform, in our careers.

Stumbling Into Social Change

I had the great fortune, before medical school, to more or less stumble into full-time social change work with a network of savvy and committed progressive citizen organizations. This work opened up the world for me. It taught me that social structures and injustice exist because someone benefits from them, and that we can attack and change these inequities, if we organize and build power. Many of us, I know, come to medicine in answer to a calling to service. I think it is key to understand that, while we all must and will serve our fellows, we also owe it to them, and to ourselves, to make charity obsolete. Paraphrasing Ralph, if there is justice, we don't need charity.

"We have it in our power to begin the world over again," wrote Thomas Paine, on the eve of the American Revolution. Thanks to a relatively open system of government (although seriously flawed by our privately financed political campaigns), each of us has the power to help begin our own world and that of our patients over again also, if we accept the challenge. Social change happens most effectively through organizations, which can pool resources to hire full-time staff to work on campaigns. As Margaret Mead famously put it, "Never doubt that a small group of thoughtful, committed people can change the world...indeed it's the only thing that ever has."

At the very least, each of us, regardless of calling, will have far more disposable income than almost all of our patients. I urge each of us to commit to a pattern of giving, of both our money and time, to organizations whose work we support. For example, give 5 or 10% or more of your income, every year, toward groups working to solve the basic problems our patients will present with: domestic violence, increased morbidity and mortality secondary to poor educational opportunities and resulting stagnant socio-economic deprivation, gun violence, anti-tobacco efforts, etc. Perhaps even more importantly, use the imprimatur of those extra letters after your name: write your elected officials, publicly endorse campaign efforts, speak at local press conferences on child safety and environmental protection, etc.

An Issue That Matters

Find an issue you care about deeply, and donate a chunk of your money, your time, and your prestige. Social change organizations with a healthcare membership base abound: Physicians for Human Rights, Physicians for Social Responsibility, PNHP, Committee of Interns and Residents, etc. Many provider professional groups also work for social change: the American Academy of Pediatrics works for access to health care for all children, for example, and the American College of Obstetricians and Gynecologists advocates to protect choice. And, speaking from experience, many broad-based public interest organizations would love to have more physicians lend their names and prestige to local, state, and national campaigns for consumer and environmental protection, campaign finance reform, and other issues that certainly affect public health.

I think the cost and difficulty of our medical education naturally reinforces our self-interested perception of being "owed" a substantial financial return for our arduous career trek. Certainly we need the resources to pay off our debts, and should be compensated for the hard work we will do. I fear it may become too easy, though, to let this feeling overshadow what we owe our society and fellow citizens, who have *invested* in *us*. In addition, of course, our hard-won knowledge is mostly the end-product of centuries of others' labor, conveniently packaged for us in a few years of intense education. As the nineteenth-century social philosopher Proudhon put it,

> "I say, first, that the doctor must be treated as favourably as any other producer, that he must not be placed below the level of others. I will not stop to prove this, but I add that he must not be lifted above that level either, because his talent is collective property for which he did not pay and for which he is forever in debt."

Somewhere in the first two years of medical school I remember one of our lecturers quoting Dr. Rudolf Virchow, the nineteenth-century father of pathology, who noted that "If medicine is to fulfill her great task, then she must enter political and social life;" and "Medicine is a social science, and politics is nothing else but medicine on a large scale." Speaking of scourges that still plague the majority of our fellow persons on the planet, like tuberculosis and childhood killer diseases, he asked, "Do we not always find the diseases of the populace traceable to defects in society?" He answered his rhetorical question, "Education, wealth and freedom are the only guarantee for the permanent health of a population." He also noted, similarly to Proudhon, that "Medical education does not exist to provide students with a way of making a living, but to ensure the health of the community."

Health Research Group Ranks Medical Boards

Based on data we obtained from the Federation of State Medical Boards (FSMB) on the number of disciplinary actions taken in 2002 against doctors, Public Citizen's Health Research Group has calculated the rate of serious disciplinary actions (revocations, surrenders, suspensions and probation/restrictions) per 1,000 doctors in each state and compiled a national report ranking state boards by the rate of serious disciplinary actions per 1,000 doctors in the year 2002 (See Table 1).

Our calculation of rates of serious disciplinary actions (revocations, surrenders, suspensions and probations/restrictions) per 1,000 doctors

continued on page 4

Table 1 — Ranking of Serious Doctor Disciplinary Actions By State Medical Licensing Boards — 2002

Rank 2002	State	Number of Serious Actions 2002	Total Number of Physicians 2000	Serious Actions Per 1,000 Doctors
1	Wyoming	12	1,011	11.87
2	North Dakota	14	1,599	8.76
3	Alaska	11	1,283	8.57
4	Kentucky	72	9,500	7.58
5	Oklahoma	48	6,353	7.56
6	Arizona	88	11,791	7.46
7	Ohio	247	33,138	7.45
8	Colorado	89	12,029	7.40
9	Montana	15	2,205	6.80
10	Utah	31	5,056	6.13
11	New Mexico	23	4,327	5.32
12	Alabama	52	9,954	5.22
13	West Virginia	22	4,296	5.12
14	Idaho	12	2,412	4.98
15	Iowa	33	6,784	4.86
16	Oregon	44	9,473	4.64
17	Georgia	84	18,995	4.42
18	Louisiana	50	12,068	4.14
19	Mississippi	22	5,346	4.12
20	New York	322	80,134	4.02
21	Massachusetts	107	28,851	3.71
22	Maine	13	3,528	3.68
23	New Jersey	109	29,757	3.66
24	California	329	95,038	3.46
25	Texas	163	47,994	3.40
26	District of Columbia	14	4,134	3.39
27	Nebraska	14	4,290	3.26
28	Virginia	64	19,673	3.25
29	Illinois	120	37,138	3.23
30/31	Indiana	44	13,929	3.16
30/31	New Hampshire	11	3,480	3.16
32	Vermont	7	2,280	3.07
33	Arkansas	17	5,738	2.96
34	Missouri	40	15,572	2.57
35	Rhode Island	10	3,919	2.55
36	Kansas	17	6,847	2.48
37	Michigan	60	24,901	2.41
38	Connecticut	32	13,312	2.40
39	South Dakota	4	1,672	2.39
40	Nevada	9	3,893	2.31
41	Washington	36	16,154	2.23
42	Minnesota	30	14,218	2.11
43	Pennsylvania	82	39,052	2.10
44	Florida	93	44,747	2.08
45	North Carolina	43	20,851	2.06
46	Maryland	39	21,883	1.78

continued on page 4

RESPONSIBILITY, *from page 2*

Many of us, sometimes including myself, shrink from political involvement because politics seems tinged, or even dirty, or at the least messy and unpleasant. But this only leaves the field to those who do not shrink from the arena, and more often than not, they will be promoting interests that harm the interests of us and our patients. As the founder of modern community organizing, Saul Alinsky, wrote, "Change means movement. Movement means friction. Only in the frictionless vacuum of a nonexistent abstract world can movement or change occur without that abrasive friction of conflict...life is there ahead of you and either one tests oneself in its challenges or huddles in the valleys in a dreamless day-to-day existence whose only purpose is the preservation of an illusory security and safety."

To be a good doctor, I argue, requires us to join in the broader battles of society, and accept the difficulty of fighting the inevitable friction and inertia. We need to work to make the world better by changing the root causes of illness and unhappiness, not just addressing the daily damage. Be a good doctor: be an activist.

MEDICAL BOARDS, *from page 3*
by state is created by taking the number of such actions (columns A and B from the FSMB data) and dividing it by the American Medical Association data on nonfederal M.D.s as of December 2000 (adding to this the number of osteopathic physicians if the board is a combined M.D./D.O. board), then multiplying the result by 1,000 to get state disciplinary rates per 1,000 physicians.

Nationally, there were 2,864 serious disciplinary actions taken by state medical boards in 2002, up 5.8% from the 2,708 serious actions taken in 2001. The latest published data on the number of doctors is from 2000; thus some of this increase may be attributable to the fact that there were certainly more doctors in 2002 than in 2000. State rates ranged from 1.07 serious actions per 1,000 doctors (Hawaii) to 11.87 actions per 1,000 physicians (Wyoming) an 11.1-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 rate for #5, Oklahoma, being 7.56 serious disciplinary actions per 1,000 physicians or 0.756 percent, this would have amounted to a total of 6,089 (0.756 percent of 805,372 non-federal doctors) serious actions a year. This would be 3,225 more serious actions than the 2,864 that actually occurred in 2002.**

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 2002, were, starting with the lowest: Hawaii (1.07 per 1,000 physicians), Delaware (1.35), Wisconsin (1.40), Tennessee (1.47), South Carolina (1.77), Maryland (1.78), North Carolina (2.06), Florida (2.08), Pennsylvania (2.10), Minnesota (2.11), Washington (2.23), Nevada (2.31), South Dakota (2.39), Connecticut (2.40) and Michigan (2.41).

Of these 15 states with the worst serious disciplinary records, six — Maryland, Hawaii, Delaware, South Dakota, Minnesota, and Washington — were also in the bottom 15 states in 2001 and 2000 (see Table 2). In 2002, the bottom 16 states all had rates of serious disciplinary action that were one-third or less than the rate of all of the top six states.

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

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

Table 1 lists each state's ranking and rate in descending order. The top 10 states, or those with the highest rate of serious disciplinary actions per 1,000 physicians are (in order): Wyoming (11.87 per 1,000 physicians), North Dakota (8.76), Alaska (8.57), Kentucky (7.58), Oklahoma (7.56), Arizona (7.46), Ohio (7.45), Colorado (7.40), Montana (6.80) and Utah (6.13). Five of these 10 states (North Dakota, Alaska, Kentucky, Oklahoma and Ohio) were also in the top 10 in 2001, 2000 and 1999 and one state, Alaska, has been in the top 10 for more than 10 straight years. Kentucky, 4th this year and Oklahoma, 5th this year, have been in the top 10 states for seven and nine of the last ten years, respectively. Arizona, 6th this year, has been in the top 10 states for 4 of the last 10 years. Ohio, 7th this year, has been in the top 10 for the last eight years in a row. And Colorado, 8th this year, returns to the top 10 for the 6th time in the last 10 years. (See Table 2).

It is clear that state-by-state performance is spotty. Only one of the nation's 15 largest states, Ohio, is represented among those 10 states with the highest disciplinary rates. Other large states such as New York, California and Michigan ranked 20th, 24th and 37th respectively in 2002. Michigan dropped from 29th in 2001 to 37th in 2002, New York from 14th in 2001 to 20th in 2002. Another large state, Massachusetts, improved from 45th in 2000 to 21st in 2002.

Table 1 — Ranking of Serious Doctor Disciplinary Actions By State Medical Licensing Boards — 2002 *continued*

Rank 2002	State	Number of Serious Actions 2002	Total Number of Physicians 2000	Serious Actions Per 1,000 Doctors
47	South Carolina	17	9,607	1.77
48	Tennessee	22	14,954	1.47
49	Wisconsin	20	14,241	1.40
50	Delaware	3	2,219	1.35
51	Hawaii	4	3,746	1.07
United States		**2,864**	**805,372**	**3.56**

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 and malpractice payouts
- Excellent leadership
- Independence from state medical societies and other parts of the state government

continued on page 6

Table 2: Ranking for Last 10 Years

Rank 2002	Rank 2001	Rank 2000	Rank 1999	Rank 1998	Rank 1997	Rank 1996	Rank 1995	Rank 1994	Rank 1993	State
1	38/39	4	3	7	3	31	3	1	21	Wyoming
2	6	1	2	11	9	2	34	10	3	North Dakota
3	3	2	1	1	2	6	8	2	8	Alaska
4	5	3	6	14	7/8	14	14	4	4	Kentucky
5	2	5	5	2	5	7	12	5	2	Oklahoma
6	1	7	21	38	19/20	5	10	17	16	Arizona
7	8	8	7	10	7/8	8	9	24	22/23	Ohio
8	17	31	10	18	6	4	5	12	6	Colorado
9	19	42	32	34	11	13	18	3	14	Montana
10	9	6	33	20	25/26	16	38	46	39	Utah
11	30/31/32	41	27	8	50	23	15	43/44	49	New Mexico
12	12	12	13	17	23/24	38	30	43/44	29	Alabama
13	11	36	17	5	12	11	7	6	1	West Virginia
14	7	50	4	25	30	21	36	30	37/38	Idaho
15	4	11	11	23	4	3	2	7	5	Iowa
16	15	17	30	31	28/29	29	16	20	22/23	Oregon
17	10	9	15	12	23/24	19	4	8	10	Georgia
18	24	20	23	15	34/35	44	13	18	11	Louisiana
19	13	13	8	3	1	1	1	9	9	Mississippi
20	14	10	14	16	16	18	17	29	34	New York
21	27/28	45	39	47	45	43	40	37	45	Massachusetts
22	38/39	22	24	9	22	17	32	33	41	Maine
23	23	26	28	35	42	20	25	19	18	New Jersey
24	25	19	20	27	18	27	20	34/35	32	California
25	30/31/32	38	34	28/29	37	35	19	23	28	Texas
26	51		41	33	44	36	50	51	51	District of Columbia
27	34	39	50	28/29	43	24	41/42	15	50	Nebraska
28	22	18	22	40	34/35	50	41/42	32	30	Virginia
29	45	44	43	41	21	46	45	40	31	Illinois
30/31	41	24	16	21	19/20	33	28	16	7	Indiana
30/31	21	23	18	30	46	51	49	49	47	New Hampshire
32	35	16	9	6	25/26	10	6	39	17	Vermont
33	16	15	12	4	13	15	23	28	26	Arkansas
34	27/28	25	31	48	17	30	37	13	12	Missouri
35	42	33	35	24	10	25	26	26	42	Rhode Island
36	20	37	45	44	41	12	46	22	37/38	Kansas
37	29	14	19	13	15	28	21	34/35	35	Michigan
38	40	28	46	32	31	37	27	42	36	Connecticut
39	48	49	44	19	14	42	33	11	13	South Dakota
40	18	21	25	26	32	9	11	31	20	Nevada
41	37	43	37	36/37	28/29	40	24	27	24	Washington
42	44	46	48	42	51	47	39	45	33	Minnesota
43	36	29	36	45	27	32	43	47	48	Pennsylvania
44	26	34	38	49	36	22	22	25	25	Florida
45	30/31/32	32	26	43	33	48/49	35	36	40	North Carolina
46	43	40	40	36/37	38	41	29	21	19	Maryland
47	47	27	29	22	40	45	44	14	15	South Carolina
48	33	35	49	51	48	48/49	31	38	44	Tennessee
49	46	30	42	46	39	34	47	41	27	Wisconsin
50	49	47	51	50	47	26	48	48	43	Delaware
51	50	48	47	39	49	39	51	50	46	Hawaii

Product Recalls

April 17, 2003 — May 12, 2003

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

DRUGS AND DIETARY SUPPLEMENTS

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

Name of Drug or Supplement; Class of Recall; Problem	*Lot #; Quantity and Distribution; Manufacturer*
Allegra Tablets, 60/120mg, 60 count bottles, Rx only; Class III; Mislabeled (by repacker) bottle labeled to contain Allegra actually contains Allegra-D (fexofenadine/pseudoephedrine HCl)	Lot # 3B1250BA EXP 5/2004 Lot # 3B1250BB EXP 5/2004; 56 bottles distributed nationwide; Aventis Pharmaceuticals, Kansas City, Missouri
Ancom tablets, Anti-hypertensive Compound Tablets, 100 count bottle. Each tablet contains: Reserpine 0.032 mg, Potassium Chloride 30 mg, Hydrochlorothiazide 3.1 mg, Vitamin B1 1 mg, Diazepam 1 mg, Promethiazine HCL 2.1 mg, Dihydralazine Sulphate 4.2 mg, Calcium pantothenate 1 mg, Magnesium Trisilicate 30 mg, Vitamin B6, labeled in English and Chinese; Class II; Unapproved new drug containing several prescription ingredients	All lot codes; 591 bottles distributed nationwide; Shanghai Pharmaceutical Industry Corp. Shanghai, China. Recalled by Best Life International, Incorporated, Mayaguez, Puerto Rico

MEDICAL BOARDS, *from page 4*

• 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.

Editor.....*Sidney M. Wolfe, MD*
Managing Editor.....*Lynn Miller*
Staff Researchers.....*Larry Sasich, PharmD, MPH*, *Paul Stolley, MD*
Information Specialist.....*John Paul Fawcett*
Production Mgr......*Kristy I. Jackson*

President.....*Joan Claybrook*
Founder.....*Ralph Nader*

THE PUBLIC CITIZEN HEALTH RESEARCH GROUP
Health Letter

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

Material in the *Health Letter* may not be re-printed without permission from the Editor. Send letters and requests to HEALTH LETTER, Editor, 1600 20th St., NW, Washington, D.C., 20009.

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

DRUGS AND DIETARY SUPPLEMENTS *cont.*

Name of Drug or Supplement; Class of Recall; Problem	*Lot #; Quantity and Distribution; Manufacturer*
Carisoprodol Tablets, 350mg, 500 and 1000 tablet bottles; Class III; Incorrect tablet imprinting. Some tablets bear the incorrect identification "A265" rather than "A266"	Lots 210049A , 210050A , 210051A , 210052A exp. 9/04; 210053A exp 10/04; 7,731 bottles distributed nationwide; Able Laboratories, Inc., South Plainfield, New Jersey
Necon 0.5/35 Tablets (norethindrone 0.5mg and ethinyl estradiol 35mcg), 6 tablet dispensers, 28 tablets each, Rx only; Class III; Impurities — product exceeds total impurities specification (stability)	Lot 50701D00, Exp April 2003; 6,366 cartons distributed nationwide; Watson Diagnostics, Inc., Corona, California
Premarin Tablets (Conjugated Estrogens Tablets) 1.25 mg, 100 count bottles, Rx Only; Class III; Dissolution failure	Lot 1D00076, Exp. 08/03; 449 bottles distributed nationwide; Ayerst Laboratories Inc., Philadelphia, Pennsylvania. Recalled by Amerisource Health Services, Corp., Columbus, Ohio
Zyvox oral suspension (linezolid for oral suspension), 100 mg/5 ml, 150 ml (when constituted), Rx only; Class II; Superpotent	Lots 11HKU, 97HAH, 82HHW, 16HXK, 61JBC, 94JAM, 08HDC, 10HHM, 22HFC, 63HJD, 64HJD, 11HMC, 12HMC, 34HMC, 75HKU, 86HMJ, 14JAH, 15JAH, 18HXP, 19HXP, 21HXP, 22HXP, 31JAK, 53JAY, 59JBC, 76HXP, 77HXK, 91HYT,and 96HWY; 21,127 units distributed nationwide and internationally; Pharmacia Corporation, Kalamazoo, Michigan

MEDICAL DEVICES

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

Name of Device; Class of Recall; Problem	*Lot #; Quantity and Distribution; Manufacturer*
a) **Accu-Chek Comfort Curve glucose test strips**, part numbers 2030420, 2030365, 2030373, 2030381, 3000133 and 3000141 and b) **Accu-Chek Advantage glucose test strips**, part numbers 336, 556, 787 and 966; Class II; Crack in the bottom of the test strip vial will cause erroneously low or high blood glucose readings	All lots; 10,600,000 vials distributed nationwide and internationally; Roche Diagnostics, Corp., Indianapolis, Indiana

CONSUMER PRODUCTS

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

Name of Product; Problem	*Lot #; Quantity and Distribution; Manufacturer*
Bicycles; Stems on these bicycles can loosen during use, causing riders to lose control and fall	BMX Next Voltage and Vertical Street Blade models; 52,900 sold at Wal-Mart and Pamida stores nationwide from April 2002 through May 2003; Dynacraft Industries Inc., San Rafael, California (800) 288-1560 at www.dynacraftbike.com
Chainsaws; Saws can operate while the engine is at the "idle" setting, posing a risk of serious lacerations to the operator and bystanders	Model UT10946 with manufacture dates of 11-02 or 12-02; 6,900 sold nationwide from December 2002 through February 2003; Homelite Consumer Products, Inc., Anderson, South Carolina (800) 776-5191 www.homelite.com

continued on page 8

CONSUMER PRODUCTS *cont.*

Name of Product; Problem	*Lot #; Quantity and Distribution; Manufacturer*
Cordless Electric Lawnmowers; Lawnmowers lack a safety guard and do not comply with the mandatory federal safety standard for lawnmowers under the Consumer Product Safety Act	Model EM 4.1; 2,800 sold nationwide from January through March 2003; Country Home Products Inc., Vergennes, Vermont (800) 673-1225 www.neutonowners.com
Cordless Power Tool Battery Packs; Packs can detach from the power tool unexpectedly and strike the operator or bystander, resulting in injuries	EY9230, EY9136, EY9231, EY9200, EY9106 and EY9201; 64,000 manufactured between May 1, 2001 and Nov. 20, 2002 and sold nationwide; Panasonic Consumer Electronics, Secaucus, New Jersey (800) 833-9626 www.Panasonic.com/cordlesstools
Cribs, wooden convertible. Recall to repair; Hinges along fold-down drop gate can crack or break and allow babies to have their fingers pinched. In addition, an unknown number of cribs made between 1996 and 2002 may have latches that do not fit securely into the strike plate, which can allow the drop gate to open if a child leans on it, and the child could fall out	Always Crib, Crib 4 Life, Legendary Crib, Set 4 Life, and Crib-2-College; 4,600 manufactured from January to August 2001; Baby's Dream Furniture Inc., Buena Vista, Georgia (800) TEL CRIB (835-2742) www.babysdream.com
Dry fire sprinklers; Sprinklers are defective and are likely to fail to operate in a fire, thereby exposing consumers to the risk of death or serious injury	Star ME-1; 60,000 sold nationwide from 1977 through 1982; American Household Inc. (AHI), formerly known as Sunbeam Corporation, Boca Raton, Florida (888) 551-5014 www.starme1recall.com
Electric blankets; Heating element can overheat, causing the element and blanket to melt, posing the risk of thermal burns to consumers	Vellux(r) Fahrenheit; 11,000 sold nationwide from July 2002 through April 2003; WestPoint Stevens Inc., West Point, Georgia (888) 439-4794 www.westpointstevens.com
Exerciser; Some of the exercise units contain two faulty handlebar welds under the seat that could fail, allowing consumers to fall to the ground	Ab Swing exercise units; 9,500 sold by Home Shopping Network in September 2002; DCD Incorporated of Malibu, California (866) 473-0164
Fabric Lanterns; Fabric is not flame retardant and can be ignited by the lantern's votive candle, posing a fire hazard	Cylinder-shaped lanterns 7 1/2-inches high and 6 inches wide; 64,000 sold at Wal-Mart stores nationwide from December 2002 through March 2003; Wal-Mart Stores Inc., Bentonville, Arkansas (800) 925-6278 www.walmartstores.com
Home Entertainment Amplifiers; Amplifier can overheat due to a lack of ventilation, which can cause melting of the plastic front cover and pose a shock hazard to consumers	Model numbers RT2600, RT2600DVD and RT2600DVD5 and serial numbers beginning with 220 through 230; 50,000 sold nationwide from May 2002 through March 2003; Thomson Inc., Indianapolis, Indiana (800) 613-0897 www.rca.com/recall
Lighters; Lighters lack child-resistant mechanisms that meet federal safety standards. Young children could operate these lighters, which poses a fire hazard	Shaped like matchsticks; 2,400 sold from July 2002 through January 2003; Amen Wardy Home, Las Vegas, Nevada (877) 349-5330
Little People(r) Animal Sounds Farms; Two small metal screws that hold "stall doors" in place can come off, posing an aspiration or choking hazard to young children	Model 77973 or 77746 with six-character manufacturing date code beginning with 168 through 212, followed by the number 2 as the fourth digit; 67,000 manufactured from July through December 2002; Fisher-Price, East Aurora, New York (866) 259-7873 www.service.mattel.com
Oil lamps; Glass wick holder can shatter when lit, posing a fire hazard	Vintage Rose and Love Potion models; 37,200 sold nationwide from December 2002 through February 2003; DesignPac Inc., Northlake, Illinois (800) 440-0680 www.target.com
Toy Drumsticks; End piece of drumstick handle can break off, posing a choking hazard to young children. Additionally, the screw at the end of the drumstick can loosen and detach, posing a choking hazard	Sold with the Parents Bee Bop Band drum sets; 300,000 sold nationwide from November 2001 through March 2003; Battat Incorporated, Plattsburgh, New York (866) 617-9137

Resisting Antibiotic-Resistant Bacteria

The Food and Drug Administration (FDA) announced new regulations on February 5, 2003 to encourage physicians to prescribe antibiotics correctly. The plan will require antibiotic manufacturers to include information in the professional product labeling, or "package insert," for all antibiotics on the appropriate prescribing of these drugs to reduce the development of drug-resistant bacteria.

Unquestionably, when prescribed and used appropriately, antibiotics can be lifesaving. Unfortunately, the inappropriate prescribing and use of antibiotics in recent years has contributed to a dramatic increase in the prevalence of antibiotic-resistant bacterial infections. Antibiotic resistance is a serious and growing public health problem in the U.S. and worldwide. Many bacteria, including the ones that cause pneumonia and other respiratory tract infections, meningitis (infection of the lining of the brain), and sexually transmitted diseases, are becoming increasingly resistant to the antibiotics used to treat them. Some bacteria are now resistant to every antibiotic on the market. This severely limits treatment, and what were once relatively routine infections to treat are now, in some cases, life-threatening.

The extent of the inappropriate prescribing of antibiotics is staggering. The Centers for Disease Control and Prevention (CDC) and the American Academy of Pediatrics estimated in a report published in the journal Pediatrics in 1998 that half of the 100 million antibiotic prescriptions a year written in physicians' offices in the U.S. are unnecessary because they are prescribed for the common cold and other viral infections, against which antibiotics are ineffective.

In addition to the negative health consequences of inappropriate antibiotic prescribing, there is an economic downside for individual patients and the healthcare system at large. In 2001, 13 of the top 200 selling brand name drugs in the U.S. were antibiotics and accounted for almost $7 billion in drug sales. Appropriate prescribing of just this one family of drugs, antibiotics, would save about $3.5 billion a year. This assumes these 13 are a typical cross-section of mis-prescribed antibiotics. Better prescribing of all drugs would go a long way in paying for a sustainable prescription drug benefit for senior citizens.

We have listed three of these 13 top-selling antibiotics, amounting to almost $500 million in sales in 2001, as Do Not Use drugs. Nitrofurantoin (MACROBID) has been on the Do Not Use list since the publication of the first edition of *Worst Pills, Best Pills* in 1988. The fluoroquinolone antibiotic moxifloxacin (AVELOX) was listed as a Do Not Use drug in the February 2000 issue of *Worst Pills, Best Pills News* and gatifloxacin (TEQUIN), also a fluoroquinolone antibiotic, was added to the list of Do Not Use drugs in the July 2002 newsletter.

Under the new regulations that are due to take effect in February 2004, statements about antibiotic resistance would be in four locations on the labeling so that physicians would not miss the message.

The context and wording of each of the four statements is different. The statement that will appear under the antibiotic's name emphasizes that the goal of reducing the development of drug-resistant bacteria and maintaining the effectiveness of antibiotics can be accomplished by using antibiotics only to treat infections that are proven or strongly suspected to be caused by bacteria. The statement in the Precautions section of the labeling warns that prescribing antibiotics other than to treat a proven or strongly suspected bacterial infection is unlikely to provide benefit to the patient. The Indications and Usage section is where the physician looks to find the FDA-approved uses for the antibiotic. It is the most frequently consulted portion of the labeling. The statement in this section advises physicians to consider culture and susceptibility information and local epidemiology and susceptibility patterns when prescribing antibiotics.

The last section of the labeling that will contain the new information is the Information for Patients section. The name of this section is ironic as patients almost never receive this information. The FDA mandated this section of the professional labeling in the hope that physicians would actually tell their patients about the drugs they are being prescribed.

This section will state that patients should be counseled that antibiotics, including the antibiotic prescribed, should only be used to treat bacterial infections and that they do not treat viral infections, such as the common cold. This section must state that when an antibiotic is prescribed to treat a bacterial infection, patients should be told that, although it is common to feel better early in the course of therapy, the medication should be taken exactly as directed. The labeling must also advise physicians to counsel patients that skipping doses or not completing the full course of therapy may 1) decrease the effectiveness of the immediate treatment, and 2) increase the likelihood that bacteria will develop resistance and will not be treatable by the antibacterial drug product or other antibacterial drugs in the future.

The new FDA regulations embody the principles we wrote about 14 years ago in the first edition of *Worst Pills, Best Pills* on how you can avoid the unnecessary use of antibiotics:

1. Establish that an antibiotic is necessary. This means that your infection has to be the type that can

continued on page 10

ANTIBIOTIC-RESISTANT BACTERIA, *from page 9*

be effectively treated by an antibiotic. Antibiotics are used specifically to treat bacterial infections. Antibiotics do not treat viral infections, such as the common cold.

2. Choose the correct antibiotic. It must be effective against the most likely organisms that can cause your infection.

3. Take a culture before using an antibiotic. A culture should be taken from where you have an infection, such as your throat, urine or blood, and then grown to determine the specific organism that is causing your infection and whether it is susceptible to the preferred antibiotic. For example, if you have a urinary tract infection, the doctor should take a urine specimen and send it for culture before treating your infection. This does not mean that your infection cannot be treated right away, only that a culture is sent before you start antibiotics. In this way, if your infection persists, your doctor can determine which alternative antibiotic can be used against the bacteria. Your doctor may find out that you do not have an infection and do not require antibiotics.

4. Consider the cost of the antibiotic. This should be done when everything else is equal. If several antibiotics are equally effective, their cost should be taken into consideration when selecting a drug to use. Newer drugs on patent are much more expensive than older antibiotics that are often just as effective and have been on the market for some time.

A final crucial point that we covered in the first *Worst Pills, Best Pills* and with each succeeding edition is the importance, in general, of completing a full course of therapy. It is important with any antibiotic to take the entire amount of the drug that your doctor prescribes. Often, after the first few days of taking antibiotics, you will begin to feel better. Perhaps you think that you do not have to finish your course of treatment since you are, after all, feeling healthy. This is not the case. The length of the regimen that your doctor prescribes for you is designed to eliminate all of the bacteria that are causing your illness. If you do not take all of your medication, the bacteria will not be completely eliminated and can quickly multiply, causing another infection. This infection may then be resistant to the original antibiotic.

What You Should Do

You should only be taking an antibiotic if there is a likelihood that the infection is caused by a bacterium. Antibiotics are ineffective against viral infections such as the common cold.

OUTRAGE, *from page 12*

unsuccessful, to implement recommendations from the 1999 report on medical errors published by the Institute of Medicine (IOM) (*To Err Is Human: Building a Safer Health System*), which estimated that as many as 98,000 patients die each year as a result of errors in hospitals.

Referring to Justice Louis Brandeis's famous statement that "Publicity is justly commended as a remedy for social and industrial diseases. Sunlight is said to be the best of disinfectants," Graham discusses the potential power of publicity, especially adverse publicity, and argues that "such disclosure systems supplement well-developed regulatory institutions that aim to reduce health and safety risks by means of rules and financial incentives." In her book, Graham recounts how the final forms of both the Toxics Release Inventory and the Nutritional Labeling and Education Act were seriously compromised by enormous political pressures, usually emanating from the regulated industries (or professions). For the Toxics Release Inventory, the disclosed data did not include many chemicals, failed to include information about the extent of human exposure and risks, was often based on approximations that underestimated the amounts of the toxic substances, and was issued to the public long after the chemicals had been released into the environment. In the case of the Nutritional Labeling and Education Act, pressure from the fast-food industry succeeded in exempting fast foods — among the most nutritionally dangerous foods — from the requirement for nutritional labels, and restaurants were similarly exempted. Further pressure prevented requirements that nutritional labels identify health risks. Last-minute lobbying resulted in the separation of dietary supplements from other foods regulated by the act, and consequently lower standards were instituted for health claims for dietary supplements.

Despite these unfortunate, though predictable, industry-induced flaws and Graham's admonition that "disclosure systems have been systematically oversold," the Toxics Release Inventory and the Nutritional Labeling and Education Act at least got off the ground. This standardized, government-mandated information is important in the transfer of power in these two examples of democracy by disclosure. Not so for the third example, the implementation of the IOM's recommendations concerning preventable errors that injure and kill patients. The recommendations were prefaced by the statement that "the goal of this report is to break this cycle of inaction. The status quo is not acceptable and cannot be tolerated any longer. . . . It is simply not acceptable for patients to be harmed by the same health-care system that is supposed to offer healing and comfort."

To achieve their proposed goal of a 50 percent reduction in errors by 2005, the IOM recommended that

there be a nationwide mandatory reporting system for serious errors — those that result in death or serious harm — for hospitals, other institutional providers, and ambulatory care systems, and that some of the data collected should be made publicly available. The IOM argued that such a system ensures a response to reports of serious harm, holds organizations and providers accountable for maintaining safety, responds to the public's right to know, and provides incentives to health care organizations to implement safety systems that reduce the likelihood that such events will occur. Opposition from the American Medical Association (AMA) and the American Hospital Association, among others, has succeeded in thwarting efforts to implement this critical IOM recommendation.

Other examples in the healthcare sphere of failed efforts at public disclosure of standardized, government-mandated information include patient-information leaflets approved by the Food and Drug Administration, which were about to be required in 1981 for many prescriptions dispensed, and the important information concerning doctors who have been disciplined by medical boards and hospitals and payouts in malpractice suits against doctors, which is found in the federal National Practitioner Data Bank. Months before the patient-information leaflets were to become required, strong opposition from pharmacists, physicians, and the pharmaceutical industry killed the program. Last-minute lobbying by the AMA in 1986 forced Congress to insert a secrecy clause into the operation of the National Practitioner Data Bank so that neither patients nor physicians — only medical boards, hospitals, and health maintenance organizations — have access. Despite this federal prohibition on disclosure, an increasing number of state medical boards are starting to make some of this information public.

Graham states that "disclosure systems could mimic problems endemic to more conventional forms of regulation" and that disclosure is "a useful variation on regulation but not an escape from its challenges." To provide the greatest possible protection for the public, we need a resurgence in traditional regulation and — aided by the Internet and Graham's suggestions, including the matching of disclosure to risk and the designing of accurate metrics and reporting — a more substantial implementation of democracy by disclosure.

Democracy By Disclosure: The Rise of Technopopulism

This book review by Sidney Wolfe, M.D. appeared in the New England Journal of Medicine, *May 8, 2003.*

By Mary Graham. 201 pp. Washington, D.C., Brookings Institution Press and the Governance Institute, 2002. $24.95. ISBN 0-8157-3234-1.

In the United States, there are three ways to achieve a transfer of power from the producers of goods or services to the public in order to improve health and safety. The first is traditional federal or state regulation, wherein laws enable governmental regulatory agencies, acting on behalf of the public, to hold industries accountable by means of standards, approval processes, and penalties and other sanctions for noncompliance. The second involves civil litigation, through which injured people can seek financial redress from producers of goods and services that have harmed them. The third is the power of accurate information to influence choices made by members of the public individually and collectively. The proper functioning of all three, often working together, is important in a democracy.

In her thoroughly researched and well-written book, *Democracy by Disclosure*, Mary Graham uses three case studies to illustrate both the promises and serious problems inherent in government-mandated public disclosure of standardized information as one strategy for helping people to reduce health and safety risks. The first case involves the Emergency Planning and Community Right-to-Know Act, which went into effect in 1986 as part of the Environmental Protection Agency's legal responsibilities. The act created the Toxics Release Inventory, a nationwide compendium from manufacturers of annual releases of toxic chemicals into the environment. The second, the Nutritional Labeling and Education Act of 1990, which requires standardized nutritional content labeling on processed food products, became fully effective in 1994. The third is the effort, as yet

continued on page 10