

Health Letter

SIDNEY M. WOLFE, M.D., EDITOR

AUGUST 2001 ♦ VOL. 17, NO. 8

In Memory of Our Colleague Henry Bergman

*Including excerpts from his Health Letter articles and
Launching of the Henry Bergman Health Letter Writing Fund*

Last fall, Henry Bergman, one of our best researchers and writers, died. He had worked as a volunteer for the Health Research Group for 20 years and had contributed many articles to the *Health Letter* concerning serious problems with our health care system. Most *Health Letter* subscribers, despite reading and learning from what he wrote, were not familiar with him because, although his name appeared as a researcher in issues containing an article he had written, we do not usually have bylines. The topics he wrote about—excerpts of which are at the end of this article—included long-term care, financial outrages in health care billing, national health insurance, problems with Medicare, individual physicians who were found to be practicing medicine in a dangerous manner and HMOs. He was the author of many *Medicare Update* and some *Outrage of the Month* columns. He was also the keeper of the *Clippings* which you, our readers, faithfully sent in letting us know if Public Citizen was mentioned in your local papers or any health care issue you felt was important. Henry scrupulously read each of these, tracking down additional data because of some, and using them as the inspiration for many of his articles in *Health Letter*.

Henry was extremely wise, warm, funny, had extraordinary quantitative and economic skills, was quite familiar

with most aspects of the health care system, had a never-ending sense of outrage, and was an excellent writer whose work required little editing. In addition to issues concerning health, he and I also shared a passion for classical music.

Henry had spent much of his career at the Veterans' Administration working on issues related to the quality of health care and when he reached the retirement age of 65, he called to ask if he could volunteer a couple of days a week. After meeting him and seeing what he had done, we were delighted to have him join our staff.

When asked to describe her father, his daughter Ellen said: *My father was*

a champion of people. This was something I knew about him from my very earliest childhood. Whether it was his not allowing me to go to Glen Echo Amusement Park and Pool with my friends because of its discriminatory policies, or his coming home from work at the Veterans' Administration bubbling over about some way he'd figured out for veterans to get better care in the VA hospitals, or his commitment to the original not-for-profit Group Health concept and his vehement resistance as a member of the Group Health board, to the privatization and subsequent corruption of that organization, my father was principled, my father was consistent, and my father cared.

C O N T E N T S

Questionable Hospitals

Our latest report lists 527 hospital violations of the Emergency Medical Treatment and Labor (Patient Dumping) Act, many of which were serious actions turning away patients that really needed help. 6

Product Recalls

June 12—July 11, 2001

Aspirin, hydrocortisone, strollers and computer adapters are on our list this month. 8

Outrage of the Month

Darvon, Darvocet, Darvon Compound

Twenty years ago Public Citizen tried to get this drug banned or more controlled. Unfortunately it's still on the market and widely prescribed. 12

Ellen continued: *My father was an amazingly humble man. And yet, as he had faith in humankind, so you seemed to have faith in him. He was passionately committed to not letting you down. That he could no longer be of service was perhaps his greatest source of discouragement when he became incapacitated. And yet he still kept doing what Henry Bergman did, even from his hospital bed.*

One day, during one of my father's last hospital stays, a big balloon bouquet appeared in his room. No friends or relatives knew where the balloons had come from. As it turned out, the balloons were from the nurses on his floor—because, as they said, Henry Bergman was the one patient who most made them want to come to work, and the one patient who made it easiest for them to give the best care possible to all the patients in their charge. My dad never stopped.

The following are but a few excerpts from the many articles which Henry researched and wrote for the *Health Letter* from shortly after its inception until several years ago.

Medicare Update (November 1987)

Written in the context of another large increase in premiums for Medicare beneficiaries.

“...policy-makers once again intend to lay the cost of their failure at the feet of those the Medicare program is supposed to serve....Older Americans must be better protected from out-of-pocket costs under Medicare, and they are ill-served by yet another plan to hike these costs now amidst promises to contain them later. Even Representative Stark (D. Calif.) has recognized that ‘at some point, Medicare beneficiaries will revolt’ against high out-of-pocket costs and force reform. That point should be now.”

Catastrophic Coverage Act Costly for Seniors (November 1988)

Written early in the history of implementation of the flawed Catastrophic Health Insurance legislation.

“Almost all of the publicity sur-

rounding the new Medicare Catastrophic Coverage Act has directed attention to the additional benefits provided by the new law. But many Medicare enrollees will be surprised to find out how much this coverage is going to cost them. The cost will be especially shocking to those who discover that their current Medicare supplemental insurance already provides as much or even more benefit than that dictated by the new law.

We want our readers to be aware that this is the first time in the history of the Medicare program that the full cost burden of a benefit change is placed solely on the Medicare enrollee....”

How to Get the Most for Your Money—Carefully Choose Your Physician and Medigap Policy (July 1989)

Written, with the usual Henry Bergman prescience, before lack of control of doctor-overcharging—beyond the co-insurance and deductible—and trickery of Medigap policies finally forced government action on both.

“With respect to who paid the largest share of the elderly’s health care in 1988, it was a close race between the elderly themselves and the Medicare program....The solution to the overcharging problem is **mandatory assignment** legislation.” [At that time, only some states had gone this route and Henry was urging national legislation to accomplish this for all Medicare beneficiaries. In 1994, this legislation passed, ending such overcharging.]

Long-Term Care Insurance (October and December 1991)

“The health insurance industry has found long-term care (LTC) insurance to be a fertile field for growth. The number of companies selling LTC insurance has proliferated from a handful to about 140 and the number of people who have policies has almost doubled—to nearly three million—in only three years. They [LTC policies] range from bad to better-than-average (which isn’t very good) with much room left for improvement. It continues to be a ‘buyer beware’ and ‘get it

in writing’ marketplace (and by ‘get it in writing,’ we mean from an officer of the company, not the agent).”

[After carefully delineating principles for evaluating LTC policies, Henry included some other warnings in the second of these articles.]

“We strongly object to companies that also ask you to authorize contact with persons other than your doctor in order to ask questions about you or your lifestyle.”

The High Cost of Health Care is Higher Than You Think (December 1994)

“Between 1947 and 1991 the purchasing power of the dollar decreased by a factor of six. In other words, what cost \$1 to buy in 1947 would have cost \$6 in 1991 because of inflation. The hospital bill is for a six-day hospitalization in a New York hospital in 1947 for a woman and her newborn infant. At \$12 per day for the mother’s room, \$42 for the use of the delivery room, and other charges, the six-day bill was \$110.95. If the cost of a hospital stay had risen at the same rate as costs in the rest of the economy (six-fold), this hospital stay would have cost \$666 in 1991.

In fact, the hospital cost for a vaginal delivery, usually a two to three day stay, averaged about \$3,100 in 1991. For a longer six day stay, the cost now would be approximately \$5,000, an amount seven-and-one-half times higher (\$4,334 more) than can be accounted for by inflation alone. A small amount of this increase might be justified—such as now having an electronic fetal monitor for mothers who are at high risk. But, for example, the routine use of fetal monitoring on all mothers in most hospitals not only adds precious dollars to the bill but also increases the risk of an unnecessary cesarean section as a result of the frequently false signals of fetal distress of the monitor. So although there has clearly been some progress since 1947, it is clearly not as much as \$4,000+ per delivery and some of the “progress,” as noted above, is backward.

Health Care Costs: Executive Compensation (April 1996)

"Recently, a National Education Association publication noted that between 1980 and 1993 Chief Executive Officer (CEO) pay shot up 514 percent and corporate profits soared 166 percent, while workers' wages grew by only 68 percent. This disparity was reflected in data for 1992, when the average CEO compensation was 157 times what the average factory worker made. The cover story on executive pay in the April 26, 1993 issue of *Business Week* translated these data into more concrete terms. Noting that total pay for CEOs had gone up 56 percent in just the one year, from 1991 to 1992, it reported that for 1992 annual average compensation was \$3,842,247 for CEOs, \$24,411 for workers, \$34,098 for teachers, and \$58,240 for engineers.

Obviously, the top executives of health care corporations whom we identified in previous issues of the *Health Letter* as receiving incomes in the eight-digit bracket were above average. Even so, they didn't make the top 10 in *Business Week's* list of highest paid chief executives for 1992. Topping the list was Thomas F. Frist Jr. He stood out above the rest—way way out!

Mr. Frist (actually Dr. Frist—he was for many years a family physician), who was then Chairman and CEO of the Hospital Corporation of America (HCA), was compensated to the tune of \$127,000,002, over \$125,000,000 of

which was from his exercise of long-term stock options. (Two years later, in 1994, HCA was merged with Columbia Healthcare Corporation to form Columbia/HCA Healthcare Corporation, which including its overseas holdings, is the world's largest health care conglomerate.)

Just how much is \$127,000,000? At an average cost of \$5,000 for an episode of inpatient hospitalization, it would pay the full hospital bills of 25,400 patients...."

Budget Balancing Medicare Savings, Medicaid Savings, and Other Shenanigans (October 1997)

"Two other Medicare-gutting provisions have received some media attention: Medical Savings Accounts (MSAs) have for some time been a pet project of insurance companies and of employers who want to reduce their costs for employees' health insurance. A program, limited to about 390,000 participants, is already underway and was incorporated into the balanced budget law as an alternative to Medicare participation. Tax breaks have made the program attractive to the healthy and the affluent, but must inevitably raise the costs for those who don't participate. Opponents of Medicare, emboldened by the inclusion of MSAs, added a provision to the law that permits a doctor/patient arrangement under which the patient pays the doctor more than Medicare permits. This discrimination based on monetary differential is highly disturbing. We hope

very few patients and doctors will take the bait."

Managed Care: Doctors' Perspectives (November 1997)

In this article, Henry, using data, as he was so skilled in doing, brought readers the view from doctors about the dangers of managed care. He pointed out that the following percentages of Tucson doctors said managed care had negatively affected these aspects of their practices.

Your professional independence:
93.1% negative

Your relationships with patients:
81.5% negative

The quality of care you give patients:
71.7% negative

Henry's Last Article for *Health Letter* Access to Health Care: Some Nibbles and a Bite (March 1998)

On a note of optimism, we print this in its entirety—Henry deserves as much.

"There's one thing that can be said about Ronald Reagan. In the 1980s he made people feel good even though they had little to feel good about. He railed against big government and big spenders while his policies ballooned the national debt to almost \$300 billion—with hardly a peep from the opposition. Fewer than 15 percent of the people owned more than 80 per-

Editor Sidney M. Wolfe
Managing Editor Phyllis McCarthy
Staff Researchers Katja Blalock
Benita Marcus Adler
Contributing Editor William Hines
Production Mgr. Kristy I. Jackson
Proofreader Benita Marcus Adler

President Joan Claybrook
Founder Ralph Nader

THE PUBLIC CITIZEN HEALTH RESEARCH GROUP

Health Letter

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

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Annual subscription price is \$18.00 (12 issues). Mail subscriptions and address changes to *Health Letter*, Circulation Department, 1600 20th St., NW, Washington, D.C., 20009.

Our Web site address is www.citizen.org/hrg

cent of the country's wealth and there were about 30 million people (half of them employed and 40 percent children) who had no health insurance at all.

Now, a decade later, we get monthly federal reports about huge numbers of people being added to the work force. President Clinton has submitted a balanced budget for fiscal year 1999—three years ahead of schedule—and many states are pondering what to do with bloated treasuries. The incumbent's approval rating—sexual scandals notwithstanding—holds pretty steady at about 66 percent.

Unfortunately, as in the 1980s, there are highly disturbing down sides to the picture of the 1990s. The disparity between rich and poor has grown. There are continuing reports of massive layoffs from downsizing and mergers to increase profits. As a consequence, for example, the December 1997 report of increased employment was accompanied by a report of increased unemployment, which evoked an explanation (in response to a media inquiry) to the effect that the contradictory sets of data came from separate studies. We noted, incidentally, that the employment rise was presented in whole numbers, while unemployment was given as a percentage of the workforce. Also, the simple numbers tell us nothing about the quality of jobs filled and lost.

On the health care front, employers who wanted to reduce their costs for employees' health insurance negotiated contracts with managed care organizations, thereby contributing to the phenomenal growth of these entities in the 1990s. Some of the largest managed care companies were found to be guilty of rampant fraud, paid hundreds of millions of dollars in fines, and some even changed their names. By 1997 the ranks of the health care uninsured had grown by almost half, to 42 million, or about one American in every six.

But all is not bleak on the health care front, we are delighted to report. There have been some nibbles at the problem, and at least one bite:

- President Clinton has proposed expansion of Medicare eligibility to 55-64 year olds, who would be permitted to buy into entitlement at an out-of-pocket cost of \$3,600 to \$5,000 a year, plus liability for additional Medicare Part B premiums (which pay for doctor bills) when they turn 65. Although promulgated as "cost-neutral," it may fall victim to more adverse selection than is built into the proposed premiums. We're for the concept if it can be changed so it does not discriminate against low-income people, because we think it's a move in the right direction toward universal health care. But we call it a nibble because only about 10 percent of the 3.8 million people in this age group who meet the eligibility criteria are expected to participate.

- The federal government and some states have taken steps to improve access to health care (primarily preventive, e.g. immunizations) to millions of otherwise uninsured people, mostly young children.

- A faithful "Clippings" contributor brought our attention to a new Oklahoma law that, when fully in force next December, will extend Medicaid eligibility to about 100,000 children and 4,000 pregnant women who were part of the 500,000 adults and 200,000 children in the state who were otherwise medically uninsured.

- For the "bite," we must look overseas, to Holland and Germany across the Atlantic and to Japan across the Pacific. The following is from the December 1997 issue of the British medical journal *The Lancet*:

Insurance for long-term care planned in Japan

Legislation was passed on Dec. 9 for a new public long-term care insurance scheme—Kaigo Hoken—to be fully operational from 2000. This makes Japan only the third country, after Holland and Germany, to provide such insurance.

These proposals are epoch making, because they depart radically from the Japanese tradition that

families are primarily responsible for long-term care. Eligibility criteria will no longer take into account the extent of informal care available to patients; and ultimate responsibility for care will lie with the state rather than with families.

The scheme will pay for institutional and home-based care not only for those aged 65 or more, but also for people over 40 years old with age-related diseases such as dementia. Each municipal government is deemed a provider, and the level of services will be decided by the patients' impairment. Half of the funding will come from monthly premiums levied on people over 40. There will also be a 10 percent copayment at the point of service provision. Rates will be altered for those on low income. The rest of the funding will come from general taxation.

Will this scheme be effective? There are two potential drawbacks. First, health and social-services professionals in each municipal government will have to assess eligibility and decide on care plans—skills that have long been neglected in Japan. Second, the mechanism of quality assurance has not been clearly defined. The scheme marks a new departure in Japanese social policy, but these obstacles will need to be overcome quickly if clients and caregivers are to receive the intended benefits.

What a sharp contrast that is with the plight of more than half the nursing home residents in the richest country in the world, who depend on Medicaid—if they have no assets or have "spent down" to get rid of the assets they had—to pay for their care."

We love you, Henry

Henry Bergman *Health Letter* Writing Fund

We are pleased to announce the beginning of the Henry Bergman *Health Letter* Writing Fund. Contributions to the fund are tax-deductible and will be used to solicit and support articles for *Health Letter* in the spirit of the many contributions Henry made during the years he was on our staff, researching and writing for this publication. Although his contribution is irreplaceable, we hope to encourage journalists to provide articles for *Health Letter* that continue the tradition Henry started. All contributors will be sent, in appreciation of their donation—and in appreciation of Henry—a compilation of many of the articles he was responsible for while on our staff.

Please make contributions payable to Public Citizen Foundation, and mail with the form below to the Health Research Group, *Health Letter* Writing Fund, 1600 20th Street, NW, Washington, DC 20009.

☐ Yes, I would like to contribute to the Henry Bergman *Health Letter* Writing Fund.

☐ \$10

☐ \$35

☐ \$100

☐ \$20

☐ \$50

☐ Other \$ _____

Name _____

Address _____

City _____

State _____ Zip _____

Phone (____) _____

☐ Contribution enclosed (check or money order payable to "Public Citizen Foundation")

☐ Charge to credit card ☐ VISA ☐ MasterCard ☐ American Express ☐ Discover

Note charge(s) will appear on your statement as "Public Citizen."

Credit Card # _____ Expiration Date _____

Signature _____



Health Research Group

Hospital Emergency Rooms And "Patient Dumping"

Since 1991, Public Citizen's Health Research Group has published a series of reports tracking the Department of Health and Human Services' (DHHS) enforcement of the federal Emergency Medical Treatment and Active Labor Act (EMTALA), popularly known as the "patient dumping" law. As its nickname suggests, the measure was passed (in 1986) in response to growing public dissatisfaction with denial of treatment by hospitals and doctors to urgently ill or injured individuals. Five such reports were published in the last decade, and now a sixth has been released, mostly covering EMTALA violations in 1997, 1998 and 1999. (For information on the previous reports, see the accompanying box.)

The latest report, released in July, names 527 hospitals with confirmed violations of the law, as well as 164 hospitals and 13 physicians who paid fines to settle charges growing from official investigations into alleged dumping violations. This brings to 1,288 (22.9 percent of all U.S. hospitals) the total number of violators we have documented since the law's enactment. Of these, 117 (9 percent) have been listed with confirmed violations in more than one Public Citizen report. Excluding the repeat violators and using the total number of non-federal hospitals accepted for registration by the American Hospital Association in 1998, our numbers demonstrate that more than 1 in 10 acute care hospitals have violated the statute since its enactment. For-profit hospitals were significantly (1.7 times) more likely to violate the law than not-for-profit hospitals.

Most violations listed in this report were confirmed by the Health Care Financing Administration (HCFA) in calendar years 1997, 1998 and 1999. The number of hospitals listed averages 168 violators per year, a number similar to that in Public Citizen's last report (170 per year). Sixty-eight (12.9 percent) of the violating hospitals in the current report had previous violations. Of the 527 violating hospitals listed, 475 (90.3 percent) violated

screening, stabilizing treatment, or transfer provisions. These usually involve direct patient care (or the lack of it) and tend to be the most serious types of violations. Still, not all such violations confirmed by HCFA constitute serious risks to patients. For example, transfer violations may involve

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only simple documentation omissions, a "screening violation" may cover an incident in which the patient voluntarily left the emergency room (ER) prior to receiving an exam. But other violations involve denial of basic services to individuals with potentially life-threatening conditions, and these are truly serious.

Of hospitals violating the Act, 72.5

percent were not-for-profit hospitals (382 hospitals out of 527) and 19.7 percent were for-profit hospitals (104 out of 527). The profit status of 41 hospitals (8 percent) was unknown. In 1998, 13.7 percent of non-federal hospitals accepted for registration by the American Hospital Association were for-profit entities (771 hospitals). Our data demonstrates a statistically significant increased risk of violation by for-profit hospitals. (Relative risk = 1.70, confidence interval = 1.39 < 1.70 < 2.30)

For the second time, the report includes patient-specific clinical information culled from HCFA Forms 2567, the reports of state agency inspectors who investigate dumping complaints. Examples of violations from these inspection reports include:

- A motor vehicle accident victim was brought to an ER unconscious, with multiple facial fractures and brain injury. Because the hospital lacked the capacity to treat neurological patients, the ER physician sought to transfer the patient to a facility where he could receive such specialized care. Memorial Medical Center of East Texas (Lufkin, TX) was contacted. A neurologist there agreed to examine the patient. Transfer arrangements were initiated but apparently curtailed when a hospital administrator at Memorial refused to accept him.

Earlier "Patient Dumping" Reports

Earlier Public Citizen Health Research Group reports on EMTALA ("patient dumping") violations can be found in the following issues of the *Health Letter*:

140 Hospitals Named for Patient Dumping Violations — May 1991

Patient Dumping Continues in Hospital Emergency Rooms — June 1993

Update on Patient Violations — November 1994

Patient Dumping in Hospital Emergency Rooms — April 1996

Hospital Violations of the Emergency Medical Treatment and Labor Act:
A Detailed Look at "Patient Dumping." — January 1998

- A hospital security officer at Harbor Hospital Center in Baltimore, MD requested ER assistance for an individual found lying in the parking lot. ER staff refused to provide assistance. After emergency medical technicians manning a nearby private ambulance determined that the individual had no pulse and was not breathing, the security officer made a second request for assistance, this time informing the ER that the individual had no pulse and was not breathing. This request was also refused. An ER physician was brought out to assist by the security officer and the patient was eventually taken to the ER by ambulance. Shortly thereafter he was pronounced dead.

- A kidney failure patient's screening exam at Colquitt Regional Medical Center in Moultrie, GA demonstrated fluid volume overload and probable heart failure (indications that the patient likely needed a dialysis treatment), as well as EKG abnormalities, poor oxygenation and possible pneumonia. A nephrologist (kidney specialist) contacted by the ER physician refused to admit the patient or give a dialysis treatment until the following day. The patient died at home approximately seven hours after she was discharged.

EMTALA (a part of the Social Security Act) was passed in response to just such outrageous and unethical conduct. It lays out directives governing the provision of emergency medical services by hospitals participating in the Medicare program of health care for the elderly and certain disabled persons regardless of age. EMTALA goes further, covering all individuals, not just those eligible for Medicare benefits. As a result, when a hospital emergency department denies medical screening, or a stabilizing treatment that it is capable of providing, and/or inappropriately transfers an individual with an unstabilized emergency condition, this is called "dumping," and is illegal.

Why are patients dumped? A number of factors may be involved: race,

gender, politics, personal prejudice, and—of course—money. The Centers for Disease Control and Prevention's 1998 National Hospital Ambulatory Care Survey found that the expected primary source of payment for 15.1 percent of ER visits in 1998 was self-payment. Another 17.9 percent of visits cited Medicaid (a federal-state collaborative program for low-income individuals) as the primary expected source of payment. Even privately insured patients can be financial liabilities for hospital ERs, since managed care organizations may deny or reduce payment for medical screening exams if the individual is found not to have an emergency medical condition. Thus,

fiscal motives for patient dumping remain significant.

As a deterrent, EMTALA provides a number of penalties for violation. Since October of 1994, HCFA regional offices are required to send all cases of confirmed dumping violations to the Department of Health and Human Services' Office of Inspector General—Office of Civil Fraud and Administrative Adjudication (OIG) in Washington. The OIG can impose monetary penalties (fines) for some violations. To date, 975 cases against hospitals and physicians have been referred to the OIG. Of these, 237 violating hospitals and physicians (24.3 percent) have

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HCFA Regional Offices To Send Complaints

Region 1 (serves Connecticut, Maine, Massachusetts, New Hampshire, Rhode Island and Vermont)
John F. Kennedy Federal Building
Room 2325
Boston, MA 02203-0003
(617) 565-1232

Region 2 (serves New Jersey, New York, Puerto Rico, the Virgin Islands)
26 Federal Plaza
Room 3811
New York, NY 10278-0063
(212) 264-3657

Region 3 (serves Delaware, District of Columbia, Maryland, Pennsylvania, Virginia, West Virginia)
Suite 216, The Public Ledger Building
150 South Independence Mall
Philadelphia, PA 19106
(215) 861-4140

Region 4 (serves Alabama, North Carolina, South Carolina, Florida, Georgia, Kentucky, Mississippi, Tennessee)
Atlanta Federal Center
Suite 4T20
Atlanta, GA 30303-8909
(404) 562-7500

Region 5 (serves Illinois, Indiana, Michigan, Minnesota, Ohio, Wisconsin)
233 North Michigan Avenue
Suite 600
Chicago, IL 60601
(312) 886-6432

Region 6 (serves Arkansas, Louisiana, New Mexico, Oklahoma, Texas)
1301 Young Street
8th Floor
Dallas, TX 75202
(214) 767-6423

Region 7 (serves Iowa, Kansas, Missouri, Nebraska)
Richard Bolling Federal Building
601 East 12th Street
Room 235
Kansas City, MO 64106-2808
(816) 426-2866

Region 8 (serves Colorado, Montana, North Dakota, South Dakota, Utah, Wyoming)
Federal Office Building
Room 522
1961 Stout Street
Denver, CO 80294-3538
(303) 844-4024

Region 9 (serves American Samoa, Arizona, California, Commonwealth of Northern Marianas Islands, Guam, Hawaii, Nevada)
75 Hawthorne Street,
4th and 5th Floors
San Francisco CA 94105-3903
(415) 744-3501

Region 10 (serves Alaska, Idaho, Oregon, Washington)
2201 Sixth Avenue
MS/RX-40
Seattle, WA 98121-2500
(206) 615-2354

Product Recalls

June 12—July 11, 2001

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

DRUGS & 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 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 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.

Class I Recall

Name of Drug or Supplement; Class of Recall; Problem

Oxygen, Liquid, 196 Liter Dewars (Tanks); Oxygen was misbranded with non-permanent fittings involved in deaths

Lot #: Quantity and Distribution; Manufacturer

Lot #: 333F001, 333F002, 333F003 EXP 11/28/01, 334F001, 334F002, 34F003 EXP 11/29/01, 340H001, 340H002, EXP 12/05/01, 341F001, 341F002, 341F003 EXP 12/06/01; 12 cylinders distributed in Ohio; BOC Gases, Dayton, Ohio

Name of Drug or Supplement; Class of Recall; Problem

Aspirin Tablets, Film Coated, 325 mg. (5 gr); OTC analgesic, packaged in Robot Ready blister packages of 25 and unit dose blister packages of 100, 200 and 500; Class III; Failed dissolution specifications

Lot #: Quantity and Distribution; Manufacturer

Lots 0H624, 0P219, 1C014, 0H616, 0K043, 0P237, 1C991, 1C044, 0F530, 0K971, 1C982, 0F524, 0K963, 1C974; 16,196,325 tablets sold nationwide; LNK International, Inc., Hauppauge, New York. Recalled by UDL Laboratories, Inc., Rockford, Illinois

Capzasin-HP Lotion, 2 fl. oz. (59.1 mL), containing the active ingredient-Capsaicin, 0.075%; Class III; Subpotency

Lot 00D403 EXP 04/02; 11,064 units sold nationwide; Chattem, Inc., Chattanooga, Tennessee

Enteric Coated Aspirin Tablets, 325 mg. under the Pharmacist Formula and Hannaford labels in 100 tablet bottles; Class III; Dissolution failure

Lot 0A01453; 18,888 bottles distributed in Florida, Illinois, Maryland, Maine, Vermont and Virginia; LNK International, Hauppauge, New York

Hydrocortisone and Acetic Acid OTIC Solution, USP, 1%/2%, 10 mL bottle; Class III; Degradants out of specification results during stability testing

Numerous lots; 328,022 units distributed nationwide; Morton Grove Pharmaceuticals, Inc., Morton Grove, Illinois

Indapamide Tablets, 2.5 mg., in bottles of 100 and 1000 tablets; Class III; Illegible monograph on tablets

Lot Number 4259-710 EXP 10/02; 13,936 bottles distributed nationwide; Zenith Laboratories Caribe, Inc., Cidra, Puerto Rico

Lotrimin/AE AF Spray Liquid, 4 oz. (113 gram) aerosol can, The product is an OTC, topically applied antifungal aerosol and the active ingredient is 2% Miconazole Nitrate; Class III; Misbranding—Lotrimin AF Liquid Spray was incorrectly labeled as Lotrimin AF Deodorant Powder

Lot Numbers 1A05CC, 1A05CCC EXP 01/04; 96,500 units distributed nationwide; CCL Custom Manufacturing, Inc., Cumberland, Rhode Island

DRUGS & DIETARY SUPPLEMENTS *cont.*

Name of Drug or Supplement; Class of Recall; Problem

Methocarbamol and Aspirin Tablets 400mg/325mg, Rx; Class III; Super potency

Pharmacist FormulaE Maximum Strength Non-Aspirin Sinus Caplets, (Acetaminophen 500mg/Pseudoephedrine HCL 30mg), units of 24; Class III; Misbranding: blister strips incorrectly list chlorpheniramine maleate as an ingredient

Phenytoin Sodium 100mg, Prompt Release Capsules, 100 count bottles; Class II; Dissolution failure

Scot-Tussin Allergy Relief Formula Clear Sugar Free, OTC antihistamine, packaged in 4 fl oz bottles and **Scot-Tussin Senior Clear Sugar Free**, OTC Expectorant, Cough Suppressant, Packaged in 4 fl. oz. bottles; Class III; Allergy Relief is subpotent, Senior Clear is superpotent

Scot-Tussin Original Clear Five-Action Cold and Allergy Formula Sugar Free, 4 fl.oz. and 16 fl.oz. bottles; Class III; Stability failure for sodium salicylate component

Z-52 Nighttime Sleep Aid (Diphenhydramine HCl) 50 mg. tablets; Class III; Misbranded— product is labeled with an expiration date having no supporting stability data

Lot #: Quantity and Distribution; Manufacturer

Lot Numbers: 2813-098 EXP 6/01, 2813-99V EXP 5/02, 2813-100V EXP 6/02; 9,235 100 tablet bottles distributed nationwide; Zenith Goldline Pharmaceuticals, Northvale, New Jersey

Lot Number OPB1174; 6,432 units distributed in Ohio; Leiner Health Products, Inc., Carson, California

Product code is #2057, Lot Number 268 EXP 2/01; 18,963 bottles distributed nationwide; Zenith Goldline Pharmaceuticals, Northvale, New Jersey

Lot Numbers 980102, 990121 EXP 1/03, 970113 EXP 01/02; 15,084 bottles distributed nationwide; Scott-Tussin Pharmaco Co., Inc., Cranston, Rhode Island

Lot Number 201027 EXP 10/02; 3,311 units distributed nationwide; Scot-Tussin Pharmaco Co., Inc., Cranston, Rhode Island

Lot 6072 EXP 1/02; 144 bottles distributed nationwide; Nittany Pharmaceuticals, Inc., Milroy, Pennsylvania

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

AC Adapter with a two-pin connector that came with Apple Macintosh PowerBooks G3s or that were sold separately; Adapters could overheat, posing a fire hazard

Baby Boy Bodysuits; The wheel-shaped zipper pull can twist off and become a choking hazard to young children

Backpack Blowers; Fuel tanks on these blowers can leak, posing a fire hazard and risk of burn injuries to consumers

Lot #: Quantity and Distribution; Manufacturer

Model Number: M4402; 570,000 sold worldwide from May 1998 through March 2000; Apple, Cupertino, California (866) 277-2096 www.apple.com/adaptorexchange/

One-piece outfits for toddlers sizes 0-3T. The bodysuits come in green and red, and have a wheel-shaped zipper pull; 5,500 sold nationwide at Gymboree website and stores from March through May 2001; The Gymboree Corp. (Gymboree®), of Burlingame, California, (800) 222-7758 www.gymboree.com

Husqvarna 155BT and 155BF, sold from June 1998 through June 2001, (800) 438-7297 www.husqvarna.com. John Deere UT 26113, UT08093 and UT08104, sold from January 1998 through April 2001, (800) 537-8233 www.johndeere.com. Makita RBL500, sold from March 1997 through January 2001, (800) 625-4828 www.makita.com. Carswell FL500, sold from December 1996 through June 2001, (800) 929-1948 www.carswelldist.com. Tilton TB50, sold from August 2000 through May 2001, (800) 447-1152 www.tiltonequipment.com; 50,500 sold nationwide; Contact the manufacturer for additional information

Name of Product; Problem

Beanbag Cushions; Infant pillows and cushions have been banned under the Federal Hazardous Substances Act since 1992 because they pose a suffocation hazard to infants. In addition, two 8- to 9-inch cords, which attach toys to the cushions, pose strangulation hazards

Chain Saws; A missing screw can cause the chain brake to fail to operate, presenting a laceration hazard to consumers

Child Table Seats; Seats were sold without a seat belt, posing a risk to children who climb out of the seat

Electronic Light N' Learn Activity Gyms; Five detachable hanging rattle toys have small round pegs at the top of the toys that can break off, posing a choking hazard to young children

Multi-Use Strollers; Strollers can unexpectedly collapse or the car seat/carrier adapter can unexpectedly detach. When this happens, an infant or young child inside the stroller or an attached car seat/carrier can fall to the ground and suffer serious injuries

Preschool Toys; Some of the larger-sized ball halves can become stuck on a young child's face, covering the nose and mouth, and causing suffocation

Remote Controlled Toy Race Cars; Problems with the circuits are rendering some of the Remote Controlled Race Cars inoperable. These cars can overheat and emit smoke and may pose a potential burn hazard

Tea Light Lamps; Plastic shade that covers the tea light candle can melt, posing a fire hazard

Lot #: Quantity and Distribution; Manufacturer

Airplane-shaped cushions, measuring approximately 27 inches long by 21 inches wide, are covered in various solid-colored cloth panels, and are filled with plastic foam pellets. They have a "smiley face" on the front with a propeller that spins and makes clicking sounds, and a plush nose; 1,500 sold at Target stores nationwide from September 2000 through May 2001; Battat Incorporated, Plattsburgh, New York (800) 247-6144 www.battat-toys.com or the Target web site www.target.com

Model number 019T with serial numbers 249129398 through 249956311; 1,000 sold nationwide from December 2000 through May 5, 2001; Stihl Inc., Virginia Beach, Virginia (800) 467-8445 www.stihlusa.com

Chairs come in blue and yellow and have the name "Inglesina" printed on the arms and the back of the seat; 780 sold nationwide from June 2000 through May 2001; Inglesina USA Inc., Montclair, N.J. (877) 486-5112

Rattles in the shape of a bear, snail, star, half-moon and horse hang from the bottom of the console. A label under the handle on the gyms' main console reads in part "ELECTRONIC LIGHT N' LEARN ACTIVITY GYM MODEL: 8735, MADE IN CHINA;" 115,000 sold nationwide from September 2000 through January 2001; KB Toys, Pittsfield, Massachusetts (800) 279-5066 <http://www3.kbkids.com>

"Take 2," "Travel Solutions," "Pioneer," "Travelite," and "Pro Sport" 4-in-1 strollers; 650,000 sold nationwide from December 1996 through March 2001; Century Products Co., Macedonia, Ohio (800) 766-9998 www.centuryproducts.com

Five balls in the toy set range in size from about 2-inches to 4-inches in diameter. One-half of the balls are white, green, blue, red or yellow, and the other half are clear. "chicco" is written inside the balls. The balls are packaged in a box labeled "chicco," "Build-a-Ball," "Cod. 66167," and "Made in China." ; 6,000 sold nationwide from January 1999 through April 2001; Chicco USA Inc., Bound Brook, New Jersey (866) 242-0643 www.chiccousa.com.

Black with the number 28 printed in red on the doors and roof and the Texaco logo printed on the hood of the car; 4,300 sold at Texaco gas stations nationwide from May through June 2001; Equity Marketing Inc., Los Angeles, California (888) 747-4355 www.equity-marketing.com

12 inch high lamp with dark brown curved S-shaped support wire that is decorated with leaves supports the lampshade; 1,300 sold nationwide at Hallmark Creations stores from January through May 2001; Hallmark Specialty Retail Marketing Group Inc., Kansas City, Missouri (800) 425-5627

OUTRAGE, from page 12

propoxyphene for longer than several weeks have become addicted to the drug without knowing it. Thousands of these people have died, some through accidental overdoses. *Do not stop taking your drug suddenly.* With the help of your doctor, work out a schedule for slowly lowering the amount of the drug you take by about 5 to 10 percent each day. Keep a written record of the dosage reduction

schedule with you. These steps will make it much easier to become drug free without developing distressing symptoms of drug withdrawal.

There have been a number of case reports of liver damage involving a possible drug interaction between isoniazid, a medication used to prevent and treat tuberculosis, and acetaminophen, an over-the-counter painkiller and an active ingredient in Darvocet-N and Wygesic. Each drug alone is known to cause liver damage. Acetaminophen,

alone in large doses or probably in combination with alcohol, also increases the risk of liver damage. The combination of acetaminophen with isoniazid may also be dangerous.

If you are taking isoniazid for tuberculosis or have a positive TB skin test and are using the drug, consult your physician before using acetaminophen or any combination product containing acetaminophen. Discuss alternatives to acetaminophen with your physician.

QUESTIONABLE HOSPITALS, from page 7

agreed to pay civil monetary penalties to resolve OIG's investigation into alleged violations.

HCFA is also authorized to terminate hospitals' participation in Medicare, but this is rarely done. Since EMTALA's enactment in 1986 through the end of Fiscal Year 1999, only six hospitals have been terminated for EMTALA violations. Termination is a severe penalty, as most hospitals rely on Medicare funds for a significant part of their revenue. The effect of termination on a community's access to health care is another concern that likely contributes to its rare occurrence. Hospitals are not terminated if they imple-

ment plans of correction and on resurvey are found to be in compliance with the Act. A community's concerns regarding access to health care should certainly be the most important consideration in terminating a hospital. Even so, in the case of hospitals that violate the Act repeatedly, implementation of a plan of correction doesn't seem to ensure long-term compliance and a harsher penalty may be required.

Finally, EMTALA provides for "civil enforcement." Any individual who suffers harm, or any medical facility that

suffers a financial loss as a direct result of a hospital's violation of the Act may bring an action in federal court against the violating hospital. Pursuant to this provision, plaintiffs may seek damages available under the law of the state in which the hospital is located. The use of EMTALA's civil enforcement provision could help increase compliance with the Act.

If you or someone you know suspect that you have been the victim of patient dumping, contact your HCFA regional office to lodge a complaint.

Visit www.citizen.org/questionablehospitals
to find the details on all 527 hospitals that violated the law.

C O N S U M E R P R O D U C T S cont.

Name of Product; Problem

Toy Baking Sets; Sets include a hand mixer with a knob that can break off, posing a choking hazard to young children

Weather Thermometers; Thermometers contain a liquid that is flammable and a hazardous substance that could be harmful or fatal if swallowed

Wood Strippers and Cleaners; Some of these bottles can leak at the cap, allowing the contents to come into contact with consumers. These strippers and cleaners can cause burns to the skin and eyes

Lot #; Quantity and Distribution; Manufacturer

Model number 31798 or 31795, yellow, blue and red hand mixers are 5.5 inches long, and are sold along with toy utensils, rolling pin, mixing bowl, and baking molds; 6,450 sold nationwide from March 1999 through April 2001; BRIO(r) Corp., Germantown, Wisconsin (888) 274-6869 www.briotoy.com

Galileo thermometers—cylinder-shaped measuring about 17-inches high. Inside the cylinder are floating small glass spheres filled with various colors of liquid; 28,000 sold at The Christmas Tree Shops Inc. in Massachusetts, Maine, New Hampshire, Rhode Island, Connecticut, and Albany, New York from June through December 2000; Nantucket Distributing Co. Inc., South Yarmouth, Massachusetts (800) 876-9677 www.christmastreesshops.com

Flood StainStrip and Stripper/Cleaner; 18,000 gallon bottles sold nationwide from March through June 2001; The Flood Co., Hudson, Ohio, (800) 321-3444 www.FloodCo.com

Darvon, Darvocet, Darvon Compound

The following article was published in Health Letter 12 years ago and then updated in 1999. Unfortunately the drug is still around and overused and the dangers still as great.

The death of former National Football League player John Matouszak due to Darvon, as reported recently in the *New York Times* and other papers, refocuses attention on this group of narcotics. Darvon, Darvocet, Darvon Compound and other medications containing propoxyphene are still widely used for the relief of pain because many doctors still believe that they are just as effective as codeine, non-addicting, and relatively safe. These impressions, all clearly wrong, are the remnants of Lilly's misleading marketing campaign, mounted when the drugs first came onto the market in the 1950s.

More than 10 years ago, the Public Citizen Health Research Group asked the federal government to either ban all Darvon-containing drugs or, in the alternative, to put them into Schedule II of the Controlled Substance Act which would mean that there could be no refills without seeing the doctor. Under great pressure from Lilly, our petition was rejected but then FDA Commissioner Jere Goyan advised doctors to write "No Refill" on all Darvon prescriptions. Reprinted below, from *Worst Pills, Best Pills*, (1999 edition) is the section on Darvon.

Do Not Use

Alternative treatment:
See Aspirin or Codeine

Propoxyphene
DARVON, DARVON-N (Lilly)
Propoxyphene and
Acetaminophen (combined)

DARVOCET-N (Lilly) **WYGESIC** (Wyeth)
Propoxyphene, Aspirin, and
Caffeine (combined)
DARVON COMPOUND, DARVON
COMPOUND-65 (Lilly)

Family: Narcotics

Propoxyphene (proe *pox* i feen) is a narcotic that relieves mild to moderate pain. We recommend that you do not use it because it is no more effective than aspirin or codeine and it is much more dangerous than aspirin. If you have taken aspirin for your pain and it has not worked, propoxyphene will probably not do any better. In fact, some studies say that propoxyphene by itself is no more effective than a sugar pill (placebo). Most studies show that propoxyphene is less effective than aspirin and that it has a potential for addiction and overdose.

Many people who have taken

continued on page 11

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