PUBLIC CITIZEN HEALTH RESEARCH GROUP

Health Letter

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Medical Errors, Not Lawsuits, are Real Cause of Rising Malpractice Insurance Premiums

Statement of Public Citizen President Joan Claybrook, January 9, 2003

Three years ago, the Institute of Medicine released its report on patient safety in the United States. The report's findings were shocking — that between 44,000 and 98,000 Americans die in hospitals each year as a result of preventable medical errors. The upper estimate is more than highway, breast cancer or AIDS deaths. The report made consumer advocates hopeful that policymakers would finally address what we know is a major public health problem.

Unfortunately, nothing has happened to make patients safer. Since then, the economy has soured, leading to investment losses and lower profits for malpractice insurers. To fill the financial void, insurers raised liability premiums for many insurance lines, including big hikes for doctors. In reaction to the steep increases, doctors and insurers have falsely blamed higher premiums on injured patients who exercise their right to seek remedy in the courtroom.

To divert attention from the real causes, physicians have declared war on the patients they took an oath to protect. That's a sorry statement about the ethics of today's medical profession. These tactics are deplorable. The first casualty in this debate has been the truth.

The fact is that there is no litigation crisis. There has been no sudden increase in claims. In fact, there was a four percent reduction between 1995 and 2000. But there is a health care crisis. The medical lobby should stop lying and look in the mirror rather than team up with the big insurance companies to deny injured patients the right to challenge malpractice doctors. According to a survey released in December in the *New England Journal of Medicine*, more than a third of the doctors surveyed said either they or members of their family had experienced medical errors, and most of those were serious.

Doctors and insurers claim that jury verdicts are skyrocketing, but they are not. They also claim that juries are out of control. Studies show they are not. Most people who are injured don't even sue, and of those who file suit, many drop their claims during litigation. The legal system itself has checks and balances. Judges and juries, who hear all the evidence and arguments of a case, should decide the award — not politicians in Washington. And jury awards are subject to review in at least two levels of appeal.

Malpractice premiums are rising as

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MALPRACTICE INSURANCE,
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a result of a business cycle wholly unrelated to tort claims. Liability insurance expenditures and victim compensation are barely keeping pace with overall increases in health care costs. Claims have not skyrocketed, nor have average award amounts.

Capping jury verdicts is not the answer. In California, which has done just that, insurance rates did not fall. Further, limits hurt those who have suffered the most harm — people who have experienced brain damage, spinal cord injuries, operations on the wrong part of the body and other life-altering conditions due to medical errors. It simply isn't right to tell these people they can't be fully compensated for their devastating injuries.

The economic costs of medical malpractice are between $17 and $29 billion annually. But we spend just $6.7 billion on the entire medical liability system. This includes all the litigation costs and court awards. That's about what we spend annually on dog food. It's unconscionable that doctors have walked out of hospitals. This is a classic case of blaming the victim. Instead, doctors should be calling on medical boards to better police their own and demanding reform of the insurance industry. But state medical boards have been asleep on the job.

Equally unconscionable has been the doctors' choice of battlegrounds. Doctors are first targeting the low-income, largely rural states like Nevada, Mississippi and West Virginia, which always are medically under-served. These states with fewer doctors provide the medical lobby with huge leverage, guaranteeing maximum national media exposure. It would be a travesty of justice for Congress and state legislatures to take away patients' legal rights in the name of protecting insurance company profits and doctors' income. This is a prescription for even more medical errors and more suffering, because the legal system is all patients have to ensure just compensation for injury and to force improvements in patient safety. It's clear that the current regulatory system is not up to the task.

* * * *

Our goal today is not just to refute the phony charges but to call on the medical establishment to do more to prevent malpractice and medical errors. Prevention is the cheapest remedy. That's what will make patients safer, reduce lawsuits and bring down insurance premiums.

It would be a travesty of justice for Congress and state legislatures to take away patients' legal rights in the name of protecting insurance company profits and doctors' income.

- First, state medical boards should do more to discipline negligent and incompetent doctors. Doctors who repeatedly injure patients because of preventable mistakes should lose their licenses to practice.

- Medical boards responsible for enforcement should sever links with state medical societies and be given more money and staff to investigate complaints.

- States should require hospitals and other health care providers to institute meaningful risk prevention programs.

- Doctors should be recertified based on a written exam and audit of their patients' medical records.

- The National Practitioner Data Bank should be open to the public, not be a secret docket that patients cannot use to check out their doctors.

- Also, hospitals should implement measures to cut down on errors — such as using computers to order and track prescriptions, requiring proper hand-washing to reduce infections, addressing the nursing shortage, and reducing the long hours of medical residents.

For too long, doctors and hospitals have been able to shift the costs of their carelessness onto victims, most of whom never file a claim for their losses. This "compensation gap" has allowed the medical community to cover up the problem of medical errors.

It is time for Congress and state legislators to assume leadership in reducing malpractice. It is time for state medical boards to wake up and protect patients rather than bad doctors. It is time for doctors to demand better policing of their own profession.

If lawmakers are serious about addressing malpractice premiums, they should stop blaming the victims and enact measures to reduce medical errors, because that's where the problem begins. If they don't, we will again be facing drastic malpractice insurance rate increases.

Inadequate Doctor Discipline By State Medical Boards

Statement by Sidney M. Wolfe, MD, Director, Public Citizen's Health Research Group
January 9, 2003

• Better regulation of doctors by greatly increased doctor discipline coupled with disclosure to patients of much more information about doctors would greatly diminish, and thereby prevent, a large proportion of negligently caused injury and death of patients and the malpractice litigation and expenses that occur.

• Most state medical boards are doing a dangerously lax job in enforcing their state medical practice acts and adequately disciplining physicians. Every year we have calculated the state medical board disciplinary rates (serious actions per 1,000 doctors). The states doing the most discipline are disciplining between 10 and 15 times more doctors each year (per 1,000 doctors) than the states doing the worst job. Last year, for example, Arizona, the state with the highest rate of discipline in the country, had a rate of 10.52 physicians per 1,000 doctors in the state, 14.4 times higher than the rate of 0.73 in the District of Columbia. I am not aware that the doctors and doctor organizations who are marching on state capitals demanding tort reform are similarly demanding doctor discipline reform to increase the amount of discipline their state medical boards are doing and thereby helping to prevent medical malpractice.

• Although data about specific, named doctors in the federally funded National Practitioner Data Bank (NPDB) is kept secret from patients and doctors, overall statistics show that since the data bank started in September 1990, 5.1 percent of the doctors in the U.S. account for 54.2 percent of the number of malpractice payouts. These are physicians against whom two or more malpractice payouts have been made. In other words, most repeat offenders are still practicing, usually without ever having had any disciplinary actions taken against them by state medical boards.

• Only 7.6 percent (one out of 13) of those doctors who have had two or more malpractice payouts against them have been disciplined in the last 12 years. Even those doctors with five malpractice payouts against them have rarely been disciplined with only 13.3 percent (fewer than one in seven) of the 1,192 U.S. physicians with five malpractice payouts having disciplinary actions. For the smaller number of physicians with 10 or more malpractice payouts against them, fewer than one out of three (32.1 percent) have had any disciplinary action taken against them.

• The secrecy of the NPDB, the result of successful lobbying by the American Medical Association (AMA) in 1986 when the law setting it up was passed, prevents patients (and doctors) from learning, for example, the identity of those doctors who have had malpractice payouts against them and from possibly deciding not to use them as their physician. Similarly, the identity of the 10,553 physicians in the NPDB who have either lost or had restrictions placed on their hospital admitting privileges is kept secret, depriving patients and doctors alike of this valuable information.

• It is unethical for doctors to strike or refuse to give medical care to patients. Just as placing limits on financial recovery for patients, as advocated in tort reform, punishes patients, so too does refusing to give them medical care. Punishing patients, instead of protecting them is a poor strategy to solve this problem.

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.

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

Government Publishes Adult Immunization Schedule

For decades, the U.S. government has provided clear guidelines for pediatric immunizations, saving millions of young lives worldwide in the process. Not so in the case of adults. At times, to be sure, the government has recommended certain immunizations for adults and different medical organizations have put forth differing vaccination schedules. Now, for the first time, the Centers for Disease Control and Prevention (CDC) has put together a set of consensus recommendations on adult immunization. It has also put together useful graphics that explain when and for whom the immunizations are indicated.

In this issue of the *Health Letter*, we reprint those graphics in their entirety, along with some rather technical footnotes that accompany the charts. You should show this information to your doctor, in case he or she hasn't seen it. Figure 1 is the recommended immunization schedule for adults without particular medical conditions. Regardless of the circumstances, the CDC recommends everyone should have a tetanus booster every ten years, everyone 50 and over should receive an influenza vaccination (this recommendation may vary from year to year) and everyone 65 and over should receive a pneumococcal vaccine if they have not done so already. You should note, however, that there is no evidence that 50- to 64-year-olds benefit from influenza vaccination if they do not have an underlying medical condition such as heart or lung disease. Other vaccines (e.g., hepatitis A, hepatitis B, chicken pox) are recommended under the conditions described in Figure 1. Figure 2 describes adult recommendations for those with particular medical conditions such as diabetes, heart disease, kidney failure and cancer.

The failure to undergo adult immunization is a missed opportunity to prevent needless suffering. For example, only 60 percent of adults 65 and older received the influenza vaccination in 2000 and only 45 percent have ever received the pneumococcal vaccine. We urge you to follow these recommendations. Should you experience an adverse event that you suspect may be due to vaccination, you should report it to the Vaccine Adverse Event Reporting System (phone: 800-822-7967). Reporting forms are also available on the web at http://www.vaers.org.

FIGURE 1. Recommended adult immunization schedule — United States, 2002-2003

Vaccine	Age group (yrs)		
	19-49	50-64	≥65
Tetanaus, diphtheria (Td)*	1 dose booster every 10 years†		
Influenza	1 dose annually for persons with medical or occupational indications or household contacts of persons with indications§	1 annual dose	
Pneumococcal (polysaccharide)	1 dose for persons with medical or other indications (1 dose revaccination for immunosuppressive conditions)¶**		1 dose for unvaccinated persons¶ 1 dose revaccination**
Hepatitis B*	3 doses (0, 1-2, 4-6 months) for persons with medical, behavioral, occupational,or other indications††		
Hepatitis A	2 dose (0, 6-12 months) for persons with medical, behavioral, occupational, or other indications§§		
Measles, mumps, rubella (MMR)*	1 dose if MMR vaccination history is unreliable; 2 doses for persons with occupational, geographic, or other indications¶¶		
Varicella*	2 doses (0, 4-8 weeks) for persons who are susceptible***		
Meningococcal (polysaccharide)	1 dose for persons with medical or other indications		

☐ For all persons in this age group ▨ For persons with medical exposure indications ■ Catch-up on childhood vaccinations

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*Covered by the Vaccine Injury Compensation Program.

† Tetanus and diphtheria (Td): A primary series for adults is 3 doses: the first 2 doses given at least 4 weeks apart and the 3rd dose, 6-12 months after the second. Administer 1 dose if the person had received the primary series and the last vaccination was 10 years ago or longer. MMWR 1991; 40 (RR-10): 1-21. The ACP Task Force on Adult Immunization supports a second option: a single Td booster at age 50 years for persons who have completed the full pediatric series, including the teenage/young adult booster.

§ Influenza vaccination: Medical indications: chronic disorders of the cardiovascular or pulmonary systems including asthma; chronic metabolic diseases including diabetes mellitus, renal dysfunction, hemoglobinopathies, immunosuppression (including immunosuppression caused by medications or by human immunodeficiency virus [HIV]), requiring regular medical follow-up or hospitalization during the preceding year; women who will be in the second or third trimester of pregnancy during the influenza season. Occupational indications: health care workers. Other indications: residents of nursing homes and other long-term care facilities; persons likely to transmit influenza to persons at high-risk (in-home care givers to persons with medical indications, household contacts and out-of-home caregivers of children birth to 23 months of age, or children with asthma or other indicator conditions for influenza vaccination, household members and care givers of elderly and adults with high-risk conditions); and anyone who wishes to be vaccinated

¶ chronic disorders of the pulmonary system (excluding asthma), cardiovascular diseases, diabetes mellitus, chronic liver diseases including liver disease as a result of alcohol abuse (e.g., cirrhosis), chronic renal failure or nephrotic syndrome, functional or anatomic asplenia (e.g., sickle cell disease or splenectomy), immunosuppressive conditions (e.g., congenital immunodeficiency, HIV infection, leukemia, lymphoma, multiple myeloma, Hodgkins disease, generalized malignancy, organ or bone marrow transplantation), chemotherapy with alkylating agents, anti-metabolites, or long-term systemic corticosteroids. Geographic/other indications: Alaskan Natives and certain American Indian populations. Other indications: residents of nursing homes and other long-term care facilities.

** Revaccination with pneumococcal polysaccharide vaccine: one time revaccination after 5 years for persons with chronic renal failure or nephrotic syndrome, functional or anatomic asplenia (e.g., sickle cell disease or splenectomy), immunosuppressive conditions (e.g., congenital immunodeficiency, HIV infection, leukemia, lymphoma, multiple myeloma, Hodgkins disease, generalized malignancy, organ or bone marrow transplantation), chemotherapy with alkylating agents, anti-metabolites, or long-term systemic corticosteroids. For persons 65 and older, one-time revaccination if they were vaccinated 5 or more years previously and were aged less than 65 years at the time of primary vaccination

†† Hepatitis B vaccination: Medical indications: hemodialysis patients, patients who receive clotting-factor concentrates. Occupational indications: health-care workers and public-safety workers who have exposure to blood in the workplace, persons in training in schools of medicine, dentistry, nursing, laboratory technology, and other allied health professions. Behavioral indications: injecting drug users, persons with more than one sex partner in the previous 6 months, persons with a recently acquired sexually-transmitted disease (STD), all clients in STD clinics, men who have sex with men. Other indications: household contacts and sex partners of persons with chronic HBV infection, clients and staff of institutions for the developmentally disabled, international travelers who will be in countries with high or intermediate prevalence of chronic HBV infection for more than 6 months, inmates of correctional facilities

§§ Hepatitis A vaccination: For the combined Hep A-Hep B vaccine use 3 doses at 0, 1, 6 months. Medical indications: persons with clotting-factor disorders or chronic liver disease. Behavioral indications: men who have sex with men, users of injecting and noninjecting illegal drugs. Occupational indications: persons working with HAV-infected primates or with HAV in a research laboratory setting. Other indications: persons traveling to or working in countries that have high or intermediate endemicity of hepatitis A.

¶¶ Measles, Mumps, Rubella Vaccination (MMR): Measles component: Adults born before 1957 may be considered immune to measles. Adults born in or after 1957 should receive at least one dose of MMR unless they have a medical contraindication, documentation of at least one dose or other acceptable evidence of immunity. A second dose of MMR is recommended for adults who:

- are recently exposed to measles or in an outbreak setting
- were previously vaccinated with killed measles vaccine
- were vaccinated with an unknown vaccine between 1963 and 1967
- are students in post-secondary educational institutions
- work in health care facilities
- plan to travel internationally

Mumps component: 1 dose of MMR should be adequate for protection.

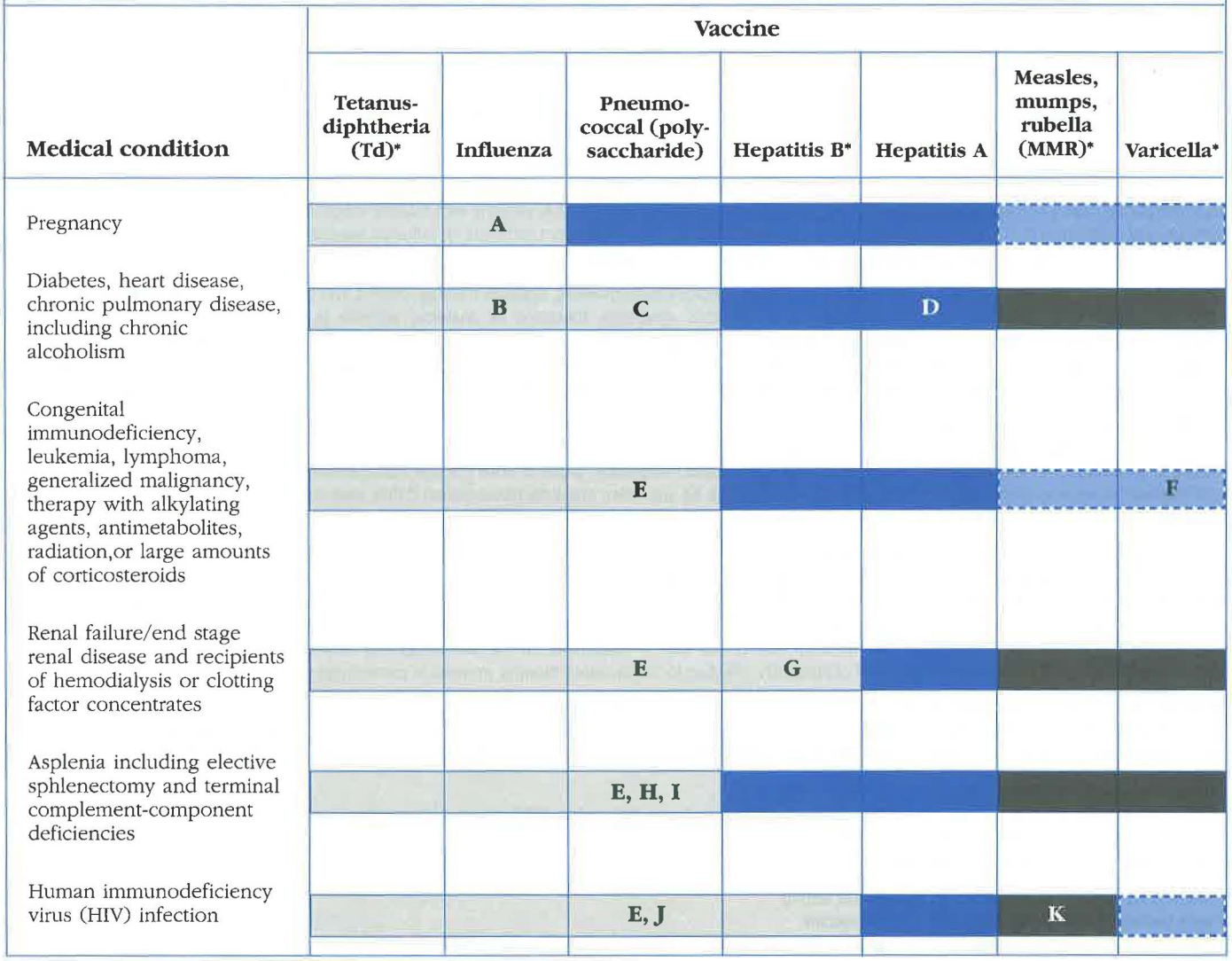
Rubella component: Give 1 dose of MMR to women whose rubella vaccination history is unreliable and counsel women to avoid becoming pregnant for 4 weeks after vaccination. For women of child-bearing age, regardless of birth year, routinely determine rubella immunity and counsel women regarding congenital rubella syndrome. Do not vaccinate pregnant women or those planning to become pregnant in the next 4 weeks. If pregnant and susceptible, vaccinate as early in postpartum period as possible.

*** Varicella vaccination: Recommended for all persons who do not have reliable clinical history of varicella infection, or serological evidence of varicella zoster virus (VZV) infection; health-care workers and family contacts of immunocompromised persons, those who live or work in environments where transmission is likely (e.g., teachers of young children, day care employees, and residents and staff members in institutional settings), persons who live or work in environments where VZV transmission can occur (e.g., college students, inmates and staff members of correctional institutions, and military personnel), adolescents and adults living in households with children, women who are not pregnant but who may become pregnant in the future, international travelers who are not immune to infection. Note: Greater than 90% of U.S. born adults are immune to VZV. Do not vaccinate pregnant women or those planning to become pregnant in the next 4 weeks. If pregnant and susceptible, vaccinate as early in postpartum period as possible.

††† Meningococcal vaccine (quadrivalent polysaccharide for serogroups A, C, Y, and W-135). Consider vaccination for persons with medical indications: adults with terminal complement component deficiencies, with anatomic or functional asplenia. Other indications: travelers to countries in which disease is hyperendemic or epidemic ("meningitis belt" of sub-Saharan Africa, Mecca, Saudi Arabia for Hajj). Revaccination at 3-5 years may be indicated for persons at high risk for infection (e.g., persons residing in areas in which disease is epidemic). Counsel college freshmen, especially those who live in dormitories, regarding meningococcal disease and the vaccine so that they can make an educated decision about receiving the vaccination.

Note: The American Academy of Family Physicians recommends that colleges should take the lead on providing education on meningococcal infection and vaccination and offer it to those who are interested. Physicians need not initiate discussion of the meningococcal quadrivalent polysaccharide vaccine as part of routine medical care.

FIGURE 2. Recommended immunization for adults with medical conditions — United States, 2002-2003



* Covered by the Vaccine Compensation Program.

A. If pregnancy is at 2nd or 3rd trimester during influenza season.

B. Although chronic liver disease and alcoholism are not indicator conditions for influenza vaccination, give 1 dose annually if the patient is > 50 years, has other indications for influenza vaccine, or if the patient requests vaccination.

C. Asthma is an indicator condition for influenza but not for pneumococcal vaccination.

D. For all persons with chronic liver disease.

E. Revaccinate once after 5 years or more have elapsed since initial vaccination.

F. Persons with impaired humoral but not cellular immunity may be vaccinated.

G. Hemodialysis patients: Use special formulation of vaccine (40 ug/mL) or two 1.0 mL 20 ug doses given at one site. Vaccinate early in the course of renal disease. Assess antibody titers to hep B surface antigen (anti-HBs) levels annually. Administer additional doses if anti-HBs levels decline to <10 milliinternational units (mIU)/ mL.

H. Also administer meningococcal vaccine.

I. Elective splenectomy: vaccinate at least 2 weeks before surgery.

J. Vaccinate as close to diagnosis as possible when CD4 cell counts are highest.

K. Withhold MMR or other measles containing vaccines from HIV-infected persons with evidence of severe immunosuppression.

Product Recalls

December 18, 2002—January 8, 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*
Children's Tylenol (Acetaminophen) Oral Suspension, 160 mg, 4 Fl oz (120mL) bottles; Class III; Defective container, product packaged with incorrect dosing cups marked with metric measurements rather than with U.S. standard measurements	Bubblegum Flavor Lot #EFM041 exp. 7/04 and Grape Flavor Lot #EFM040 exp. 7/04; 116,172 bottles distributed nationwide; McNeil Consumer & Specialty Pharmaceuticals, Fort Washington, Pennsylvania

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*
Little Soothers Cold Pack; Class II; Microbial contamination	Day lot codes July 8, 9 and 10, 2002 (dates of manufacture); 1,609 units distributed nationwide; Joy House, China, Recalled by Avon Products, Inc., New York, New York

CONSUMER PRODUCTS

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

Name of Product; Problem	*Lot #; Quantity and Distribution; Manufacturer*
Bamboo Stick Sparklers; Sparklers' bamboo-stick handles can catch fire, burn, disintegrate and emit burning fragments during use, posing a fire hazard and risk of burn injury	Model numbers SP08, SP14 and SP20; 1.7 million boxes sold nationwide between January and May 2002; Elkton Sparkler Company Inc., North East, Maryland, (800) 322-3458 www.easylite.com

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Name of Product; Problem	*Lot #; Quantity and Distribution; Manufacturer*
Bicycles; Frames on bicycles can break, which can cause riders to lose control and crash	2002 Diamondback X-10 and X-20; 2,800 sold nationwide between September 2001 and October 2002; Sun Rise Bicycle Industrial Co. Ltd., Taiwan and Raleigh America Inc., Kent, Washington, (888) 805-6396 www.diamondback.com
Camping Stoves; Burner assembly in stoves can restrict the flow of gas, which can cause a leak, leaking gas can ignite, posing a fire hazard	Model numbers 4660, 4665, 4675, 4730, 4960, 72861 and 4960LLB; 6,300 sold between May and September 2002; Century Tool and Manufacturing Co. Inc., Cherry Valley, Illinois, (800) 435-4525 www.centurytoolmfg.com
Children's Fleece Pant Sets; Small pieces of fabric at end of sleeves, along hem and on pockets can be torn off easily, posing a choking hazard	Two-piece children's fleece pant sets including First Moments and Second Step brands; 9,600 sold nationwide between September and November 2002 at Kohl's Department Stores; Kohl's Department Stores Inc., Menomonee Falls, Wisconsin, (800) 694-2647 www.Kohls.com
Children's Soap Making Kits; Soap may get too hot when heated in microwave oven and leak from mold tray, posing a burn hazard	Sold as "Soap Making for Kids," included a plastic mold tray, three bars of glycerine, string and an instruction book; 145,000 sold nationwide between March 1998 and November 2002; Pace Products Inc., Apopka, Florida, (800) 541-7670 www.paceplace.com
Christmas Tealight Candles; Wick is not properly set inside tealight, which may cause plastic holder to melt, posing a fire hazard	Candles were available in red, white and green, have a clear plastic holder and "Merry Christmas," "Christmas Morning," "Candy Cane," or "A Christmas Avenue" written on packaging; 60,000 sold nationwide at Eckerds, Kerr Drugs, Snyders Drugstore and Farmacias El Amal between September and December 2002; Atico International USA Inc., Fort Lauderdale, Florida, (800) 645-3867
Cigarette Lighters; Lighters do not have child-resistant mechanisms, as required by law	UPC numbers 3-86120-600020 and 3-086120-600051; 247,000 sold in the central U.S. between September and December 2002; Montrose Wholesale Candies & Sundries Inc., Chicago, Illinois; For more information, call CPSC's Hotline at (800) 638-2772
Circular Saws; Lower blade guard of saw can become jammed, posing risk of contact with blade and serious injury	Model 5740NB; 180,000 sold nationwide between April 1998 and November 2002; Makita U.S.A. Inc., La Mirada, California, (800) 462-5482
Electric Fans; Fans have undersized wiring, use a power plug that is not polarized, have an improperly sized grill, and overheat, all of which could cause electrocution, electric shock, fire and finger entrapment hazards to consumers	Model numbers V1185, V1186, V1865 and V1783; 22,000 sold in the metropolitan New York area between May 2000 and July 2002; Brooklyn Lollipop Imports & Exports, Inc., Brooklyn, New York, (718) 388-9526
Electric Grinders; Grinder's switch can stick in "on" position, posing an injury hazard	Catalog numbers 6086-20, 6088-20 and 6089-20; 24,000 sold nationwide between June 2001 and November 2002; Milwaukee Electric Tool Corp., Brookfield, Wisconsin, (800) 414-6527 www.milwaukeetools.com/media.nsf
Infant Girls' Garments; Paint on "smiley face" zipper-pull attached to sweat jacket contains lead, presenting a lead poisoning hazard	Joe Boxer brand style numbers 40801002 and 40801003; 3,000 sold nationwide between August and October 2002 at Kmart stores; Wear Me Apparel Corp., New York, New York, (866) 469-6257

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Tamoxifen (Nolvadex) for Breast Cancer Prevention?

A new study published in the medical journal *The Lancet* (September 14, 2002) titled "First results from the International Breast Cancer Intervention Study (IBIS-1)" documents breast cancer incidence in women who took either tamoxifen or placebo (a "sugar pill") for four years. IBIS-1 is the most recent of four large randomized, placebo-controlled trials aimed at seeing if giving tamoxifen to "high risk" but healthy women could lower breast cancer risk. The four studies completed, thus far, are the National Surgical Adjuvant Breast and Bowel Project P-1 Study (NSABP-P1) (U.S.), the Royal Marsden Hospital Study (London, UK), the Italian National Study (Italy) and most recently, IBIS, conducted primarily in the UK, Australia and New Zealand. These studies all began in 1992, with the exception of the Royal Marsden trial, which began as a pilot study in 1986.

Effectiveness of Tamoxifen Trials (Risk Reduction)

The reduction of breast cancer incidence shown in Table 1 is the "absolute" reduction, i.e., the difference in breast cancer incidence between women on placebo and women on tamoxifen, treated for the times indicated. The low absolute reduction in breast cancer risk (around 1 percent or less) means that between 77 (NSABP trial) and 500 healthy women (Royal Marsden trial) would have to take tamoxifen from four to seven years to prevent one case of breast cancer.

Medical journals, as well as most of the media, have presented a misleadingly rosy picture of tamoxifen's effectiveness by relating not the reduction in *absolute* risk but only the reduction in *relative* risk. In the NSABP-P1 trial, for example, the authors stated that the reduction in

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CONSUMER PRODUCTS *cont.*

Name of Product: Problem	*Lot #; Quantity and Distribution; Manufacturer*
Motion Lamps; Wires near light's socket can become exposed, posing a risk of electric shock or electrocution	Pumpkin and Snowman model motion lamps with liquid-filled globes that move when heated; 27,000 sold between August and October 2002; Cracker Barrel Old Country Store, Lebanon, Tennessee, (888) 645-6516 www.crackerbarrel.com
Plastic Stack Chairs; Chairs can collapse during use	UPC numbers 0-82294-319754 (white) and 0-82294-319785 (green); 80,000 sold nationwide between April 2000 and September 2002; S.I.T. Inc., Quincy, Massachusetts, (800) 611-4664
Stuffed Bunny Toys; Buttons on front of jacket can detach, posing a choking hazard	10-inch tall "Hip Hoppy" stuffed bunny; 3,000 sold nationwide between July 2000 and December 2002; Zutano Inc., Cabot, Vermont, (800) 287-5139
Subwoofers; Screw inside subwoofer can cause a high voltage short, which could cause severe injury through electric shock	Revel Performa B-15 model; 1,300 sold nationwide and in Puerto Rico between January 2001 and October 2002; Madrigal Audio Laboratories, Inc., Middletown, Connecticut, (800) 424-8043 www.revelspeakers.com
Talking Dolls; Buttons could detach, posing a choking hazard	Includes 13-inch "Talking Learn n' Play" dolls dressed in pink jumpers with pink and white plaid shirts; 160,000 sold nationwide between June and December 2002; Lovee Doll & Toy Co., Inc., New York, New York, (800) 307-5911
Tea Lights; Flames from tea lights can flare, excessive heat can cause plastic holders to melt, posing a fire hazard	Red or ivory, packaged 12 per box; 211,000 sets sold by Home Interiors' direct sales associates exclusively between September and November 2002; Home Interiors and Gifts Inc., Carrollton, Texas, (800) 749-4545 www.homeinteriors.com
Wooden Toy Vehicles; Wheels on candy-filled toys may break off into small parts, posing a choking hazard	UPC codes 694405900012 (wagon), 694405900029 (truck) and 694405900036 (train); 50,000 sold nationwide at Kmart stores between November and December 2002; Kmart Corporation, Troy, Michigan, (800) 63KMART

TAMOXIFEN, *from page 9*

risk (for getting breast cancer) by taking tamoxifen was 50 percent but never mentioned that the absolute risk was reduced only 1.3 percent (from 2.6 percent to 1.3 percent, Table 1). Likewise, the IBIS trial authors stated that tamoxifen produced a 32 percent risk reduction without mentioning anywhere that the absolute risk reduction was less than 1 percent over 4.2 years. The two European trials stated that they found no reduction in risk at all.

Table 1. Total Breast Cancer Incidence in the Four Prevention Trials

TRIAL NAME	Duration of Trial (Years)	Breast Cancer Incidence in trial (%)		Reduction in Incidence (%)
		Placebo	Tamox	
NSABP-P1	4.0	3.6	1.9	1.7 (statistically significant)
IBIS	4.2	2.8	1.9	0.9 (statistically significant)
Royal Marsden	5.8	2.9	2.7	0.2 (not significant)
Italian National	6.8	1.7	1.3	0.4 (not significant)

Safety (Adverse Events Due to Tamoxifen)

The other part of the picture that needs to be addressed is the increase in risk for having one of the adverse events that can occur when taking tamoxifen. The risks about which we know the most are those that occur after only a few years exposure, a relatively short time if one is concerned about causing cancer. Given that tamoxifen is known to be a human carcinogen (i.e., it is known to cause cancer in people) and that cancer can take 10 to 20 years to develop, it is clear that we have only a partial picture of tamoxifen safety from trials that last four to seven years.

New adverse events become known over time. Adenocarcinoma of the uterus has been known for many years as an adverse effect of tamoxifen use, but only this year the manufacturer issued a new warning: patients on tamoxifen are also at an increased risk for uterine sarcoma, a different type of uterine cancer with a poorer prognosis and shorter survival time than the adenocarcinoma. Other adverse events that were more common in women taking tamoxifen included deep vein thrombosis (blood clots in the veins), pulmonary emboli (blood clots in the lungs), stroke and cataracts. Bothersome, but less serious, adverse events due to tamoxifen were hot flashes and vaginal discharges.

Public Citizen published an analysis of the largest prevention trial, NSABP P-1 (*Worst Pills Best Pills* June 1999), showing that over four years, the decrease in new breast cancer cases (benefit) was almost exactly offset by an increase in serious adverse events (risks). In that case, we felt that at the minimum, women should have a Medication Guide with these risks spelled out clearly.

In order that they suffer the least harm, women need to be fully informed about the results coming from these tamoxifen "prevention" trials.

International Breast Cancer Intervention Study (IBIS)

The IBIS trial tested a total of 7,152 women (3576/group) who were randomly assigned to either 20 mg/day of tamoxifen or placebo for four years. To enter this trial, women had to have an elevated risk factor for getting breast cancer. These risks included having a first-degree relative that developed breast cancer at or before the age of 50 and/or having at least two first- or second-degree relatives with breast cancer.

Death rates: The IBIS results have provided a further cautionary note to those coming from previous trials, for although breast cancer incidence decreased by 0.9 percent (the absolute rate), the death rate (deaths from any cause) more than doubled, from 0.31 percent in the placebo group to 0.70 percent in the tamoxifen-treated group. Interestingly, there were the same number of deaths from breast cancer (2) in each group, but the total number of cancer deaths doubled in the tamoxifen group compared to the placebo group (12 vs. 6).

Tamoxifen produced a **reduction** of 0.9 percent in cases of breast cancer (good) but **increased** the number of life-threatening adverse events (uterine cancer, blood clots, stroke) and deaths (bad). The result is that the percentage of women experiencing serious risks is greater than the percentage of women who benefit. In addition to the risks listed above, there was a significant increase in four gynecological procedures and seven gynecological symptoms.

A commentary accompanying the IBIS article, in the same issue of *The Lancet*, acknowledges that tamoxifen can reduce the number of breast cancer cases, yet "none of the trials have the power as yet to determine whether tamoxifen reduces breast

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TAMOXIFEN, *from page 10*
cancer mortality." (And isn't this the whole reason to take tamoxifen anyway?) These authors continued that, in addition, "The IBIS trial adds a new concern about tamoxifen: an increase in all-cause mortality."

The commentary states the obvious: "A cardinal requirement of chemopreventive agents is that they must be safe" and continues, "Tamoxifen clearly does not have a safety profile that would allow it...to have a large impact on the overall incidence of breast cancer." The authors conclude with conditions that should be met in order for women to benefit from taking a drug for reduction of breast cancer risk: better risk assessment tools (to more clearly target those at risk), a good safety profile (so women don't suffer serious adverse events) and a demonstrated reduction in breast cancer mortality. (We would hope that there should be a demonstrated reduction in all-cause mortality, as well — certainly not an increase.)

Table 2. Risks and Benefit of Tamoxifen Therapy in the IBIS Study

	Placebo	Tamoxifen	Difference between tamoxifen and placebo
Benefit			
Breast cancer incidence	2.8%	1.9%	**-0.90%**
Risks			
Uterine cancer	0.14%	0.31%	+0.17
Blood clots in lungs	0.28%	0.36%	+0.08
Blood clot in veins	0.14%	0.67%	+0.53
Stroke	0.31%	0.36%	+0.05
Death from any cause	0.31%	0.70%	+0.39
Sum of Serious Events and Deaths			**+1.22**

Comparison with Incidence of Lung Cancer

Since 1987, lung cancer has been the leading cause of cancer death among women, yet it is the fear of breast cancer that has permeated U.S. society. In the most recent year (2000) for which there is data, 67,600 women died of lung cancer (mostly from smoking) vs. 40,800 women who died of breast cancer. The Centers for Disease Control concluded that, "Smoking is now the leading known cause of preventable death and disease among women." Yet, this is not where medical efforts are aimed.

Conclusion

In order that they suffer the least harm, women need to be fully informed about the results coming from these tamoxifen "prevention" trials. They need to realize that the current poor risk assessment tool coupled with the increase in possible serious illnesses or death is a poor foundation on which to base their hopes by taking tamoxifen for many years. A competent clinical breast exam coupled with a mammogram (for those over 50) offers a safer approach. Not smoking is clearly a number one health priority.

OUTRAGE, *from page 12*
(see *Health Letter*, December 2001)? Yes, it could.

Surprisingly, perhaps, there is some useful information on the Philip Morris Web site, mostly obtainable by linking to more reliable sources of tobacco information such as the National Cancer Institute (http://dccps.nci.nih.gov/TCRB/Smoking_Facts/facts.html) and the Centers for Disease Control and Prevention (http://www.cdc.gov/tobacco/how2quit.htm). And the brochure does acknowledge in relatively plain language that "the overwhelming medical and scientific consensus [is] that cigarette smoking is addictive." Similarly, the brochure notes that "public health officials have concluded that secondhand smoke from cigarettes causes disease, including lung cancer and heart disease...." Finally, the company states that "there is no such thing as a 'safe' cigarette" and that "'low tar' and 'ultra low tar' cigarettes are no exception."

But couldn't Philip Morris be doing more to reduce the massive toll its products wreak than simply to provide a stable source of funding for advertising companies eager to produce the latest company makeover? At the risk of being accused of having chutzpah ourselves, here are some modest suggestions about how Philip Morris might successfully pull off something more than a cosmetic corporate face-lift:

- Stop undermining the World Health Organization's international Framework Convention on Tobacco Control.
- Inform smokers in developing countries of the same dangers from smoking as it does for U.S. smokers (see *Health Letter*, October 1998).
- Give up the ridiculous claim that "low tar" is (in the brochure's phrase) a "brand descriptor," rather than a transparent effort to imply lower health risks.
- Instead of filing a petition with the Federal Trade Commission that would allow it to continue to use the terms "light" and "low tar," simply stop using these terms.
- Cut off its congressional bribery division, which in 2001 contributed over $8.4 million in campaign donations — in a non-election year.
- Stop funding industry front groups that oppose smoke-free workplace measures and oppose tobacco tax increases.

Wanna Quit Smoking? Who you Gonna Call? Philip Morris?

Leo Rosten's classic book *The Joys of Yiddish* defines "chutzpah" as "that quality enshrined in a man who, having killed his mother and father, throws himself on the mercy of the court because he is an orphan." May we suggest a new definition: "that quality enshrined in a company that, having already been responsible for the deaths of millions of its customers worldwide (with millions more to follow), tries to present itself as an objective source of information on its products' dangers."

Were Rosten still around to revise his dictionary (he died in 1997), we feel confident that he would make a place for our new definition. And the example of corporate chutzpah would no doubt be Philip Morris, the largest tobacco producer in the U.S.

In mid-November we received at both our office and in the home-delivered *Washington Post* a slick four-color brochure that posed the intriguing question: "Where can you find information on...the serious effects of smoking, quitting smoking, cigarette ingredients, how to talk to your kids about not smoking, and more?" The answer, believe it or not: www.philipmorrisusa.com.

Yes, it seems that Philip Morris, the prolific producer of such lethal products as Marlboro and Virginia Slims, is trying to turn over a new leaf. Not only does the company plan on jettisoning its blood-stained corporate moniker (in early 2003 its name will likely be changed to Altria — similar to altruism, another example of chutzpah), but it now wishes to present itself as a source of information on the dangers of the very product it has been foisting on often-unsuspecting customers for decades.

Could this be the very same Philip Morris whose chief executive told the House of Representatives that tobacco is not addictive? Or that for years has consistently opposed anti-smoking legislation in the U.S. and abroad? Or that obstructed the promotion of smoking cessation aids for products like nicotine gum and the nicotine patch (see *Health Letter*, October 2002)? Or that recently touted the "positive effects" of smoking on the Czech economy, because premature deaths due to smoking would save the government money

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