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## **Kids First?**

## How Vaccination Politics Can Undermine Public Health

The following article by Josh I Sharfstein is reprinted from the American Prospect magazine with their permission.

With clinical trials now underway, it is natural to expect that a safe and effective vaccine against HIV will soon spell the end of AIDS in this country. But consider a more likely scenario: Immediately after the Food and Drug Administration licenses the vaccine, the Centers for Disease Control and Prevention (CDC) recommend the immunization of all high-risk gay men, prostitutes, and intravenous drug users. Congress and state legislatures, however, do not rush to approve the funds needed to reach these groups. Years pass, and HIV infection rates barely budge.

Stymied, the CDC teams with the American Academy of Pediatrics to endorse vaccinating all newborn babies against HIV, which should eventually protect the entire population. This strategy Congress funds. But when scattered reports of possible vaccine complications mount, suburbanites start asking why their children are being vaccinated against a disease they're unlikely to contract. Politicians launch investigations. Some parents refuse to allow the shots. The infant vaccine strategy is threatened, and there's still scant funding for high-risk adults. And HIV marches on.

Not possible, you say? Think again. This scenario is precisely what is happening right now with a safe and

effective vaccine against a different national killer. Nearly 20 years after licensure of a vaccine against the hepatitis B virus, that severe and potentially fatal liver pathogen still infects an estimated 300,000 Americans each year, killing about 5,000 annually. The story of the hepatitis B vaccine is a lesson in what not to do next time.

The typical patient with hepatitis B in the United States is a young adult unfortunate enough to have had sex (or shared needles) with someone who is infected. Estimated to be 50 to 100 times more contagious than HIV, the hepatitis B virus (HBV) finds its way to the bloodstream and gradually takes over the liver. About two to six months after infection, the patient typically suffers severe abdominal pain, vomiting, and jaundice. While this acute hepatitis phase is occasionally fatal, it is much more likely that the patient recovers completely. In about 5 percent of adult cases, however, the virus neither kills nor dies. Instead, it renders the afflicted forever contagious and places him or her at high risk of chronic liver failure and liver cancer.

The development of a vaccineshown to be safe and effective by studies conducted in the 1970s-finally offered the hope that hepatitis B could be eliminated as a major cause of

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Mother Dies But Son Can't Get an Explanation Because Her Doctor

suffering and death. In 1982 the CDC recommended vaccination for those "persons at substantial risk of HBV infection"—including "illicit injectable drug users" and "homosexually active males." In 1985 the agency added to the list "persons who present for treatment of sexually transmitted diseases and who have histories of sexual activity with multiple partners." These three risk groups represented about half of all new cases.

Other than advise physicians on whom to vaccinate, however, public health officials in the Reagan era did little to bring the hepatitis B vaccine to those most likely to contract the disease. Over half the individuals actually immunized were persons at risk from occupational exposure to the virus (such as doctors and nurses), a group representing just 4 percent of new infections. As a CDC vaccine expert bluntly reported in Geneva at the 1989 International Conference on Prospects for Eradication of Hepatitis B Virus, "The U.S. has not put resources into vaccination of persons whose life-style puts them at risk, and that is unfortunate, but it is a fact."

As President Bush took office, CDC officials responsible for hepatitis B had little to show for their efforts. In a report meant only for internal discussion, the agency considered several new measures to jump-start the fight. One was to make the vaccine available to thousands of high-risk men and women in jails. Another was to regularly offer vaccination at clinics for sexually transmitted diseases (STDs). The CDC report assumed that Congress would fund only relatively small projects and that many of the people reached would fail to get the full regimen of three shots; nonetheless, the report estimated that such initiatives would prevent 49,350 acute infections and 3,950 chronic infections by the year 2000.

The report also considered expanding the popular system of universal childhood vaccination to include the hepatitis B vaccine. The political advantages of this approach were obvious: rather than pleading with Congress for money to locate and vaccinate drug users (or even worse, jailed drug us-

ers), health agencies could call for funds to protect the nation's babies. But the public health advantages of this strategy would be a long time coming. Eventually universal infant vaccination would ensure sustainable protection for the entire population. But the CDC report estimated that—even assuming excellent outreach and compliance—exclusively vaccinating babies would decrease the incidence of hepatitis B by only 2 percent in the first 10 years of the strategy; the nation would have to wait "twenty or more years" to control the raging epidemic.

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Recognizing the limitations of a babies-only approach, the CDC report favored a balance between targeted efforts to reach those at high risk and a more popular effort to universally vaccinate low-risk babies. But no comprehensive policy proposal or funding request went to Congress. It was not the CDC, but Dr. Sanford Kuvin from the private National Foundation for Infectious Diseases, who testified before the Senate in 1990 that:

our Public Health Service objectives for the year 2000 include a significant reduction in hepatitis B in all targeted groups.... Are these objectives attainable? Certainly, yes, but they will most certainly not be reached with the current level of national apathy, ignorance at the public level, lack of professional education, lack of public programs and public funding, and, in addition, the cost of the vaccine.

Dr. Kuvin went on to refer to the CDC's estimates of the costs of reaching infants and high-risk adults and adolescents, and decried the lack of funding.

In response, Democratic Senator Jeff Bingaman of New Mexico angrily demanded to know why administration officials and the CDC had never sought this money. "Is our public system incapable of prioritizing and responding to the changing demands that we encounter?" he asked. "As a public health issue, where is the Secretary of Health? Why isn't he testifying to the Congress like you are?"

At the CDC, meanwhile, plans were slowly taking shape, but the political potency of babies was coming to overwhelm all other goals. In 1991 the CDC's policy-making committee on immunizations met to create new vaccine guidelines for clinicians. According to minutes from the committee's deliberations, experts said they didn't want to treat high-risk adults as "second-class citizens." Yet soon after approving a recommendation for universal infant vaccination, the committee squashed a recommendation that clinics provide the vaccine to all adolescents and adults upon diagnosis of the sexually transmitted disease gonorrhea. One reason for the decision was the notion that pressing to vaccinate both babies and high-risk adults, even though such a two-pronged approach was the best policy, would be impolitic. According to its minutes, the committee felt it "loses its credibility if it doesn't prioritize."

By 1992 the administration had requested funds to begin universal infant vaccinations, and Congress had provided them. But far away from the meeting rooms of the CDC, clinicians struggled to make sense of the new policy. As practitioners began to immunize hundreds of thousands of lowrisk infants (many with the federally funded vaccine), they remained largely unable to address the elevated risks of the babies' mothers, fathers, sisters,

and brothers. In Massachusetts, a January 1992 memo sent to physician offices statewide advised that the state health department (known as MDPH) "only has funding for enough vaccine to immunize infants. Use of MDPH-supplied hepatitis B vaccine for other individuals will result in a vaccine supply inadequate to ensure immunization of all infants. PLEASE RESTRICT USE OF MDPH-SUPPLIED HEPATITIS B VACCINE TO INFANTS ONLY."

In a 1993 research project (published later in the *Journal of the National Medical Association*), I found that only two of 178 high-risk adolescents and adults treated at a Boston community health center received any doses of the hepatitis B vaccine. Citywide, clinic directors cited the cost of the vaccine as the most significant barrier to administration and indicated that were free vaccine made available to high-risk adolescents and adults, their clinics could reach over 400 additional high-risk patients each month.

Nationally, only 32 percent of pediatricians and 17 percent of family practitioners, in initial surveys, agreed with the strategy of universal infant vaccination, so the CDC launched a major public relations campaign. In professional journals, at medical society meetings, and on audiotapes mailed to physicians, the agency teamed with vaccine experts to spread the word: Because the risk-based strategy had "failed," universal infant vaccination was the best option left to fight hepatitis B.

The campaign did highlight some good reasons for vaccinating infants. Hepatitis B infection among children, for example, is much more likely than infection in adults to become severe and chronic. And the disorder can be transmitted with relatively casual contact—like blood exposure from a cut so young children might become infected at camp or school. But when CDC officials and immunization experts argued that vaccination of highrisk adults had failed, they were misleading. The truth was that those efforts had never been adequately developed or funded. Pilot projects conducted in the 1980s at drug treatment centers, STD clinics, and school-based health clinics demonstrated that highrisk populations would accept vaccination if offered. Moreover, studies projected that such vaccination of highrisk individuals would save the health care system money.

Amidst all the rhetoric of failure, the chances of getting the federal government to launch any significant new initiatives aimed at high-risk adults grew slimmer and slimmer. Even the Clinton administration, which did expand access to the hepatitis B vaccine—funding vaccine for needy 11-and 12-year-olds in 1995 and older

Others blamed the vaccine for an assortment of dubiously related problems.

adolescents in 1997—has done little for high-risk adult groups.

Ironically, the basic public health facts, and the flaws in the infant-centered approach, were about to be exposed in a forum not known for frank discussions of high-risk behavior.

Do the benefits of administering the vaccine to infants outweigh the risks?" On May 18, 1999, Republican Representative John L. Mica of Florida called to order a hearing of the House Subcommittee on Criminal Justice, Drug Policy and Human Resources entitled "The Hepatitis B Vaccine: Helping or Hurting Public Health?" Three months later, Republican Representative Dan Burton of Indiana convened "Vaccines: Finding the Balance Between Public Safety and Personal Choice" in the

Government Reform Committee. Spurred by Internet-savvy antivaccine groups, such as the National Vaccine Information Center, conservative law-makers vowed to scrutinize routine childhood immunization against hepatitis B.

Their initial attacks focused on vaccine safety. Available evidence and years of experience around the world suggest that the hepatitis B vaccine is one of the safest vaccines ever made. Life-threatening immune reactions are extremely rare, and the possibility of an allergic response remote. Fewer than one in 10 children even experience the most common side effect, soreness at the site of injection. Yet antivaccine groups insisted that the hepatitis B vaccine is dangerous—causing sudden infant death syndrome, autism, diabetes, and multiple sclerosis. And they were not about to miss their day in Congress.

One after another, families came forward to testify about the severe medical complications their children had suffered after vaccination. While a few families did describe potentially real vaccine reactions, others blamed the vaccine for an assortment of dubiously related problems. For instance, an Indiana couple testified that their baby daughter suffered loose stools, low body temperature, and cyanosis in the first week of life. Her pediatrician told them she didn't need to come to the office. Another local pediatrician refused to see the patient because of her insurance—Medicaid. Soon afterward, the baby died. According to the parents, the coroner revealed that "the cause of death was the hepatitis B virus—which she could only have gotten from the vaccine." The congressional committee was sympathetic, but the story could not possibly have been true. The hepatitis B vaccine contains only a protein, not live virus, and so can never transmit active infection. Instead of blaming the hepatitis B vaccine, the family should have sued the pediatricians for denying care and question the competency of the coroner.

Responding to questions of vaccine safety, Dr. Susan Ellenberg, a senior official at the Food and Drug Administration, testified about extensive research demonstrating that the hepatitis B vaccine had "little in the way of verified serious risks." Congressional Republicans, however, questioned why children were being immunized at all, and to make their case, they exploited the very facts of the disease that the CDC had downplayed when it emphasized childhood immunization over high-risk immunization.

"Start off with hepatitis B cases," Representative Burton began in his cross-examination of Surgeon General David Satcher. "Can you tell us what percentage of hepatitis cases are not from sexual transmission or from blood or needle-exchange properties?" Satcher and his colleagues estimated about 25 to 30 percent. Later in the hearing, Republican Representative Dave Weldon of Florida contended that while "hepatitis B is a very serious illness and it costs a tremendous amount of money . . . being that a major mode of transmission is sexual transmission, we have never proposed inoculating the whole population for a sexually transmitted disease. Am I correct?" Yes, a federal official conceded, he was.

These questions hit their mark. Unable to point to significant initiatives to reach those at highest risk of hepatitis B, the nation's public health leaders were left defending vaccination of infants for a disease that, by their own estimation before Congress, strikes children under nine in just 6 percent of new cases.

Vaccinate enough babies, of course, and you will eventually protect the entire country. But it would have been much better for the CDC to have also funded targeted high-risk vaccination all along and then responded, We are attacking hepatitis B at every turn, and we're turning the tide, but full victory will not be achieved until we act to protect all our children.

By failing to frame infant vaccination as part of a comprehensive attack on hepatitis B, the CDC's strategy has unwittingly fueled the antivaccine effort. So far, vaccine opponents have not convinced Congress to roll back funding for infant and adolescent immunization. But they can take heart from swelling legislative battles in several states over immunization requirements for school entry. In New Jersey, they recently won: Hepatitis B vaccination now is not required for children to start school. The American Academy of Pediatrics is worried about parents nationwide refusing the vaccine.

In January 1999, the CDC updated its hepatitis B recommendations to remind clinicians that "because most HBV infections in the United States occur among adults, vaccinating infants and adolescents aged 11-12 years alone will not substantially lower disease incidence for several years." The CDC suggested that practitioners "identify settings where adolescents and adults with high-risk drug and sexual practices can be routinely accessed and vaccinated (e.g., STD clinics, family planning clinics, drug treatment clinics, community-based HIV prevention sites, and correctional facilities)." Yet to this day, there's little federal funding to provide vaccine in these locations. The CDC spent \$111

million in 1999 to purchase hepatitis B vaccines for children, but when CDC experts meet with prison officials to discuss the need to protect inmates from hepatitis B, the CDC side cannot offer funding for the vaccine.

It is high time for the CDC to propose to Congress large-scale efforts to reach high-risk individuals in jails, STD clinics, needle-exchange programs, and detoxification centers. Universal infant immunization should continue, but paired to a program of free vaccine for high-risk parents and other relatives. The message must be that protecting babies is just one part of a comprehensive solution to the hepatitis B epidemic.

If America's unfortunate experience with the hepatitis B virus yields any lesson, it is that we must confront public health challenges honestly in order to conquer them decisively. Nearly two decades after the hepatitis B vaccine was approved for use, CDC researchers recently concluded in the Journal of Infectious Disease that "from 1976 to 1994...the estimated incidence of infection did not change." It peaked in 1985, according to experts, and what gains have been made since then are largely due to improved health practices among high-risk groups rather than to vaccination. America's poor use of the hepatitis B vaccine will surely cast a shadow over efforts to prevent HIV, a disease with remarkably similar transmission patterns. To be successful, an HIV vaccine must not only be a safe and effective pharmaceutical. It must also reach the people who need it most.



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# **Product Recalls**

April 12-May 11, 2000

#### DRUGS & DIETARY SUPPLEMENTS

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

The recalls noted here reflect actions taken by a firm to remove a product from the market. Recalls may be conducted on a firm's own initiative, by FDA request, or by FDA order under statutory authority. A Class I recall is a situation in which there is a reasonable probability that the use of or exposure to the product will cause serious adverse health consequences or death. Class II recalls may cause temporary or medically reversible adverse health consequences. A Class III situation is not likely to cause adverse health effects. If you have any of the 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 website is http://www.fda.gov.

#### Name of Drug or Supplement; Class of Recall; Problem

#### CombiPatch(tm) Transdermal System, (estradiol-0.62 mg/ norethindrone acetate-2.7mg), Rx used for treatment of vasomotor symptoms associated with menopause, vulvar and vaginal atrophy, and treatment of hypoestrogenism; Class III; Dissolution and appearance specification failure (excess crystals)

**Isoxsuprine HCL Tablets,** 10 mg and 20 mg, in 100 and 1,000 tablet bottles, Rx indicated for the relief of symptoms associated with cerebral vascular insufficiency under the Eon and Major labels; Class III; Dissolution failure (42 month stability)

Nasacort(r) AQ, Nasal Spray (Triamcinolone acetonide-16.5 grams), 120 metered acutations, Rx for the treatment of the nasal symptoms of seasonal and perennial allergic rhinitis in adults and children 6 years of age and older; Class II; Super-potency (stability)

#### Lot #; Quantity and Distribution; Manufacturer

Lot Numbers: 8F0308E1C1 EXP 4/00 and 9D2703E1C1 EXP 2/01; 65,160 boxes distributed nationwide, and in Bermuda and Puerto Rico; Noven Pharmaceuticals, Inc., Miami, Florida. Recalled by Aventis (formerly Rhone Poulenc Rorer), Collegeville, Pennsylvania

All lots within expiration date; 84,168 bottles distributed nationwide; Eon Labs Manufacturing, Inc., Laurelton, New York

Lot #MN3270 EXP 12/00; 45,900 units distributed nationwide and in Thailand; Rhone Poulenc Rorer, Puerto Rico, Inc., Manati, Puerto Rico. Recalled by Aventis (formerly Rhone Poulenc Rorer), Collegeville, 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 details. You can also call the FDA's Device Recall and Notification Office at (301) 443-4190. To report a problem with a device, call 1-800-FDA-1088. The FDA website is http://www.fda.gov.

#### Name of Device; Class of Recall; Problem

**Contact Lenses (CSI Daily Wear Clear);** Class III; Mislabeled for corrective power. The label indicates sphere power of +8.00. The lenses are actually -20.00

Eye Pads (Hermitage), Sterile 2 1/8" X 2 5/8", Product of China, sterilized in the U.S. for use as a bandage over the eye for protection or absorption of secretions; Class II; Product was not sterilized and incorrectly transferred to released inventory without being gamma sterilized

#### Lot #; Quantity and Distribution; Manufacturer

Sub lot # 700022570404 Master lot #60300195; 27 lenses distributed in California, Illinois, Maryland, Massachusetts, Michigan, Minnesota, Missouri, North Carolina, Virginia; Wesley Jessen Corporation, Cidra, Puerto Rico

Item No. EP-1600 and EP-2000 - Lot #5588; 85,800 distributed in Arkansas, California, Oklahoma, Puerto Rico; Shaoxing Life Surgical Dressing Company, Ltd., Zhejiang Province Shaoxing County, China. Recalled by Hermitage Hospital Products, Inc., Niantic, Connecticut

#### MEDICAL DEVICES, cont.

#### Name of Drug or Supplement; Class of Recall; Problem

First Ald Kits containing Clinipad Products; Class II; The kits contain Clinipad Alcohol Prep which have been recalled by the Clinipad Corporation for possible microbiological contamination and lack of sterility

#### LIFEPAK 500 Automated External Defibrillator (AED),

designed to be used by first responders to cardiac emergencies; Class II; Potential damage/failure of resistor R4 could result in unusable unit next use

Rascal and Chauffeur Heavy Duty 3 and 4-wheel scooters for walking assistance; Class II; The drive train gears fail allowing the scooters to coast without control for stopping

#### Lot #; Quantity and Distribution; Manufacturer

Numerous models of kits; 2,233,141 products were repackaged into kits of at least 22 different configurations (models) distributed nationwide; Acme United Corp., Fremont, North Carolina. Recalled by Acme United Corporation, Fairfield, Connecticut. Cramer Products, Inc., Gardner, Kansas. Component Manufacturer Clinipad Corporation, Charlotte. North Carolina

All serial numbers with more than 8 digits, all serial numbers with 6 digits. 7 digit serial numbers less than 7925937 and serial number 8631084; 8,031 units distributed nationwide and internationally; Medtronic Physio-Control Corporation, Redmond, Washington

Models 205, 235, 245, 255, 275, 215, 305, and 315. The prefixes to the serial numbers affected by the recall are: UR, RO, RU, RUF, RUU, RDEM, CVU; 10,778 scooters were affected nationwide and internationally; Electric Mobility Corporation, Sewell, New Jersey

#### 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 (CPSC), call their hotline at 1-800-638-2772. The CPSC website is http://www.cpsc.gov.

#### Name of Product; Problem

**Baby Garments;** Snaps on these garments can detach, posing a choking hazard to babies; 58 different styles sold as one-piece and two-piece infant garments for boys and girls

Battery Chargers; Chargers can overheat and ignite, melting the charger housing and posing a fire hazard; used in Flotec and Sears back-up sump pump systems

**Bicycle Components—Forks;** tube that attaches the fork to the bicycle can fail, causing riders to lose control and fall

Bicycle Components—Ballistic front suspension forks; Forks can break apart, causing riders to lose control and fall

Homelite® Handheld Power Blowers/Vacuums; Fuel line location can cause it to contact the edge of the engine shroud, causing the line to prematurely wear. This can result in a gasoline leak, presenting a fire hazard and causing burn injuries to consumers

Infant Swings; New safety restraints offered; Restraint systems on the older swings consist of a waist belt only and a hinged or removable tray, which serves as a restraint. If parts are missing, restraints are not used, or the tray pops off, infants can slip down into the seat and strangle or fall from the swing

#### Lot #; Quantity and Distribution; Manufacturer

Call the company to see if your garment is part of the recall; 260,000 sold nationwide in stores and on the Healthtex web site from May 1999 through December 1999; Healthtex, a division of VF Playwear Inc., Greensboro, N.C (800) 554-7637 http://www.healthtex.com/Pages/shop\_recall\_page1.asp

Flotec model FP2000DCC-02 or 2P667B, Sears model 390.306062; 29,000 sold nationwide from December 1994 through September 1997; Sta-Rite Industries Inc., Delavan, Wisconsin (800) 845-6541

Model 2000 forks sold on more than 30 models sold under Answer and Manitou brand; 17,500 sold nationwide from August 1999 through May 2000; Answer Products Inc. Valencia, California (800) 423-0273

Installed on Mongoose S-20 and MGX S-20, and the Roadmaster Ridge Rider Mountain Bikes. Serial numbers BA10044001 through BA10049000, BA10050001 through BA10051000, BAX0001251 through BAX0006750, BAX0006781 through BAX0007080, 98022087 through 98027843;13,500 sold nationwide from September 1998 through May 2000; By Us International Co. Ltd., Taiwan. Call Brunswick Bicycles (877) 211-3525

Gas-powered, handheld power red and black blowers/vacuums numerous UT and serial numbers; 200,000 sold nationwide from August 1998 through January 2000; John Deere Consumer Products, Inc., Charlotte, North Carolina (800) 242-4672

Many different models made before November 1997—call the company to determine if your swing needs a new safety restraint; 7 million sold nationwide through January 1998; Graco Children's Products Inc., Elverson, Pennsylvania (800) 934-9082 http://www.gracobaby.com/serv/ga3rcal7.htm

# The Health Research Group Launches 'eLetter' Web Site On Prescription Drugs for the Seriously Mentally Ill

he Health Research Group launched The eLetter on Drugs for Severe Psychiatric Illnesses at www.citizen.org/eletter on May 8, 2000. Its purpose is to provide objective and up-to-date information on such drugs to psychiatrists and other mental health professionals, as well as to individuals affected with these illnesses and their families. The eLetter covers antipsychotic, antidepressant, and mood stabilizer medications that are used to treat schizophrenia, manic-depressive illness, severe depression, and some other disorders. Although basic information on serious mental illness is included, the principal focus is alerting readers to new information about the risks of older drugs and to provide information about new drugs as they come on the market.

Pharmaceutical companies have had an increasingly influential effect on the prescribing habits of psychiatric professionals. As documented in the January 19, 2000 issue of the *Journal of the American Medical Association* (JAMA), pharmaceutical companies provide such goodies as gifts, free meals and travel subsidies to psychiatric residents and psychiatrists in the hope of persuading them to prescribe certain products. Influential psychiatrists are paid up to \$10,000 by pharmaceutical companies to give a single talk; repeat invitations are implicitly dependent on the positive notes struck by the speaker about the company's product.

Some clinical trials of new antipsychoticand antidepressant medications have been compromised by unethical professionals who falsify information to the pharmaceutical company in order to make more money. Even patient and family advocacy groups have been unduly influenced by accepting financial support from the pharmaceutical companies, making them less likely to protest high prices or

unethical corporate policies.

The purpose of The eLetter, therefore, is to collect the most recent and objective information available on antipsychotic, antidepressant, and mood stabilizer medications and make it available without charge. The eLetter's attitude regarding the pharmaceutical industry is neither pro- nor anti-. It recognizes the fact that such medications are critical for the treatment of severe psychiatric illnesses and that many lives are being improved by them. It also recognizes that these medications are often prescribed for people who do not need them, that their adverse effects are being underreported, and that high prices puts many of them beyond the means of some people who need them.

Funding for *The eLetter* comes from an anonymous individual. No funding from pharmaceutical companies is accepted.

## CONSUMER PRODUCTS, cont.

#### Name of Product; Problem

**Jogging Strollers;** Stroller's front wheel connector can crack during use, causing the wheel to separate from the frame

Jogging Strollers—recall to inspect; Strollers were shipped without straps attached to the frame to secure the seat. Unless the frame straps are attached, a child in the seat of the stroller can lean forward and fall out

**Lawnmowers;** Fuel tanks' seams can split or crack, leaking fuel, and creating a fire and burn hazard to consumers

**Toasters;** Heating elements can remain on after the toast pops up which poses a fire hazard

Weed Wizard Trimmer Heads with metal chains and about 857,000 trimmer replacement chain sets; The end link of the trimmer's metal chain can rapidly and unexpectedly detach during use, propelling the link into the air at a high velocity. If the metal link strikes the user or a bystander, it can penetrate skin and bone, causing injury or death

#### Lot #; Quantity and Distribution; Manufacturer

Sport Utility and Sport Utility D'lux; 3,700 sold nationwide from November 1998 through March 2000; BOB Trailers & Baby Trend, San Luis Obispo, California (800) 893-2447 http://www.bobtrailers.com/safetynotice.html

Baby Trend model 9592T; 1,500 sold nationwide at Baby's "R" Us stores from January through April 1999; Baby Trend, Ontario, California (800) 328-7363 www.babytrend.com

Harmony II walk-behind mowers with model numbers HRT216, HRR216 and HRS216; 112,000 sold nationwide from May 1998 through January 2000; American Honda Motor Co. Inc., Torrance, California (800) 426-7701 http://www.hondapowerequipment.com/recall.html

Model 24205 (white) and model 24208 (black) traditional upright toasters with series codes A0379 through A3279 or A2589 through A3289; 95,000 sold nationwide from April 1997 through September 1999; Proctor-Silex Inc., Glen Allen, Va. (800) 992-4616 http://www.proctorsilex.com/recall/

With metal chains, sold with yellow heads with black or silver chains; 2.7 million sold nationwide from May 1987 through April 2000; Weed Wizard Acquisition Corp., Bradley, Michigan (888) 810-7536 http://www.weedwizard.com

# Dr. Ross (or Nurse Hathaway) Will See You Now

The age of cost-cutting in medicine exemplified by the growth of managed care has ushered in efforts to steer patients away from expensive physicians and toward nurses. All things being equal, this should be lauded if it leads to cost savings. But are all things equal?

Until now, there have been no published reports of research that used that "gold standard" of clinical research, the randomized, controlled trial, to compare nurses and physicians with respect to quality of care, length of visit, cost-effectiveness or patient satisfaction. But the April 15, 2000 issue of the *British Medical Journal* included four such reports, providing the best opportunity so far to examine objectively a topic of debate hitherto marked primarily by dataless turf-protecting. The studies were so groundbreaking that the *Journal* ceded its traditional staid blue cover to

a four-color photograph of Dr. Ross (George Clooney) and Nurse Hathaway (Julianna Margulies) of TV's ER.

Three of the studies randomized patients in general practices to receive

> In all three studies, the nurses' patients were slightly more satisfied than the doctors' patients with the care they received.

care either from a physician or from a nurse or nurse practitioner. The results were generally consistent with one another. In all three studies, the nurses' patients were slightly more satisfied than the doctors' patients with the care they received. Visits with nurses lasted two to four minutes longer and in one of two studies measuring this, the nurses ordered more tests, primarily screening tests such as Pap smears. The nurses also tended to provide patients with more information about their illnesses. However, the prescribing patterns of physicians and nurses were similar and there were no detectable differences in clinical outcomes. Only one study evaluated costs to the health service-nurses were about 20 percent less expensive than doctors—but this difference did not reach statistical significance.

continued on page 10

# 'Summer Is Icumen In'

## And So Is Deadly Melanoma For Avid Sun-worshipers Who Don't Follow Rules For Safe, Successful Tans

A 13th century English poet heralded the onset of summer with the words at the top of this story—summer is a-comin' in. Seven centuries later a Tin Pan Alley versifier hailed "the hazy, lazy, crazy days of summer." True, it's a time that we all look forward to, whether in the backyard or at the beach, but it's also a time to be very, very careful to avoid the deadly cancer called melanoma that has been linked with overexposure to the ultra violet radiation from the sun.

Of course, there are measures one can take to protect oneself: minimizing one's time in the sun, particularly in the hottest midday hours, protecting the skin with clothing or by wearing a hat, and use of sunscreens. In this article, we focus on some myths (and even dangers) of sunscreen use.

The Sun Protective Factor (SPF) is defined as how many times longer it will take skin protected with sunscreen to burn compared to unprotected skin. An article in the January 15, 2000 issue of the *British Medical Journal* estimated that for most people (or at least most British people), a sunscreen with an SPF of 10 would suffice to prevent sunburn, with perhaps an SPF of 15 needed in the tropics. This is far less than the often-expensive sunscreens now available that claim SPF's of 50 or higher.

But, as the British would say, here's the rub: most consumers apply considerably less sunscreen than is used in clinical tests measuring SPF. Thus, actual protection may be only 20 percent to 50 percent of that indicated on the product label. Moreover, when applying sunscreen, many people miss critical areas: the tops of feet, the ears, the backs of legs. There is even evidence that people who use high SPF sunscreens may be more likely to report sunburn than those who rarely or never use sunscreen, perhaps because sunscreen users, believing themselves to be protected, spend more time in the sun.

Here are the bottom lines:

- Avoid exposure to the sun for more than 20 minutes, particularly at midday, without clothing and a hat.
- If you expect prolonged sun exposure for more than 20 minutes without clothing or a hat, use a sunscreen.
- If you apply about double the amount of sunscreen most people currently do, an SPF of 15 should provide adequate protection.

# Dangerous Gap in the Drug Safety System

## Companies May Be Failing To Keep Their Post-marketing Research Promises

n April 13, 2000, the Health Research Group released results of a report on the drug industry's performance in finishing post-marketing research (Phase IV) studies. We found that a majority of drugs for which companies agreed to do studies after the drug is approved are listed by the Food and Drug Administration as having failed to fulfill this commitment.

There are two explanations for this situation—or maybe three. One is that the companies are not keeping their promises very well; a second explanation is that the FDA is not keeping its records very well, and a third possibility is that both explanations No. 1 and No. 2 are correct. In any case, this situation is not acceptable from a public health perspective.

The complete text of the report is available on our web site at www.citizen.org/brg/PUBLICATIONS/1520.htm. Newsletter readers who are not on-line can obtain a copy by writing to us at 1600 20th Street, NW, Washington, DC 20009.

Phase IV studies are those that the FDA requires a company to perform after a drug has been approved and that are frequently a condition for a drug's approval. These studies constitute an important part of the postmarketing safety surveillance system of new drugs. The results of Phase IV studies can provide important safety information to augment the FDA's voluntary adverse drug reaction reporting system known as MedWatch and could lead to more expeditious safety labeling changes or withdrawal of a new drug from the market, if necessary.

The types of Phase IV studies agreed to by pharmaceutical manufacturers are diverse. For example, studies may focus on a specific adverse drug effect or a specific drug

toxicity in defined patient populations such as age or gender groups. Or studies can examine possibly toxic interactions between the new drug and other drugs or foods. They may also seek to determine a drug's long-term effectiveness in studies that can last two years. Other, much shorter, studies examine the way in which a drug is broken down (metabolized) in the body. And some Phase IV studies ascertain whether a drug product's chemistry or manufacturing can be improved.

Using the Freedom of Information Act, we obtained from the FDA all Phase IV commitments made by the industry for all drugs approved from January 1, 1990 through December 23, 1999. The information we obtained included the status of Phase IV commitments indicated as either "P" for drugs for which there were still studies pending or "C" for complete as determined by the FDA. As indicated by the FDA, "C" means that all Phase IV studies for a specific drug have been completed. We restricted our analysis to Phase IV commitments on drugs approved for the first time in the U.S. (New Molecular Entities or NMEs) and did not include those drugs previously approved for a new use or drugs which are combinations of two older drugs.

Because of this difficulty in determining the actual number of studies committed to by a drug manufacturer, we analyzed our results on the basis of the number of NMEs with at least one Phase IV study commitment and determined whether the commitment(s) for that drug had been recorded as completed or pending by the FDA. We limited the primary analysis to NMEs approved between January 1, 1990 and December 31, 1994. This gives companies at least five years and, for some, as long as ten years to have completed their commitments.

We found that from 1990 through 1994 a total of 122 NMEs were approved. Of these, 88 (72 percent) were approved with at least one Phase IV commitment. Only 13 percent (11 of the 88 drugs) were classified by the FDA as complete as of December 23, 1999. Completion rates per year continued on page 10

## NMES WITH AT LEAST ONE PHASE IV COMMIT-MENT FROM 1990 THROUGH 1999

	-			
		1990-1994	1995-1999	
Number of Phase IV Co	NMEs with at Least 1 ommitment	88	107	
	Phase IV Commitment as of 12/23/99	s 11	0	
Percentage	Completed	13%	0%	

#### DRUG SAFETY GAP, from page 9

of approval ranged between 5 percent (1993) and 26 percent (1991). For the 107 NMEs with Phase IV commitments approved after 1994, no drug has been classified by the agency as complete as of December 23, 1999. These results are shown in the table on page 9.

This result suggests grossly inadequate compliance by drug companies in meeting their Phase IV study commitments. However, an additional possible explanation is the FDA's inability to accurately track Phase IV study commitments, despite the additional authority provided in 1997 with the passage of the Food and Drug Administration Modernization Act (FDAMA). The Office of Inspector General of the Department of Health and Human Services issued a report in 1996 regarding the FDA's oversight of Phase IV study commitments. This study found that the FDA did not have formal standards or procedures for monitoring Phase IV studies or for establishing whether a postmarketing study commitment had been met by a drug company.

Previous research by the Health Research Group sheds additional light on the Phase IV study issue. In late 1998 we surveyed FDA Medical Officers, who review New Drug Applications, regarding their attitudes towards the quality of the agency's drug approval process. This survey can be found on our web site at: www.citizen.org/brg/PUBLICA-TIONS/fdasurvey/fdasurvey.htm.

Some of the Medical Officers' comments on the issue of relying on postmarketing studies for approval of new drugs included the following:

We don't trust that the companies will carry out Phase IV studies with due diligence, either before or after PDUFA [Prescription Drug Users Fee Act].

My office director told me that he was going to overrule me because the sponsor (Wyeth-Ayerst) would just go over our heads to Capitol Hill. He felt it was best to approve the drug for an indication not studied and have the sponsors do a Phase IV post-marketing trial in support of the indication. I reminded him that this sponsor had failed to honor other Phase IV studies. He went ahead and approved the drug.

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These comments by FDA Medical Officers support the explanation that the failure of manufacturers to finish their Phase IV commitments is the most likely reason for the results of our study. This explanation is extremely troubling when taken together with the fact that the Medical Officers stated in our survey that 28 drugs had been approved in the previous three years only because Phase IV studies

were required.

We wrote to FDA Commissioner Dr. Jane Henney asking that copies of our report be sent to all FDA advisory committee members. At this time she has not responded to our request. Advisory committees are made up of experts from outside the FDA that are asked to make recommendations to the agency to approve or not approve a new drug. Often these advisory committees recommend that Phase IV studies be undertaken if a new drug is approved.

FDA advisory committee members may be more likely to recommend approval of a new drug when there are questions of its safety and effectiveness if the manufacturer commits to Phase IV safety and efficacy studies. But, if advisory committee members were aware of the extraordinary failure of manufacturers to honor their Phase IV commitments, they might be less likely to recommend approval of a new drug based on the promise of a Phase IV commitment when lingering questions about safety and effectiveness exist.

#### What You Can Do

We ask you to forward a copy of our Phase IV report to your elected representatives in Washington urging them to ensure that the FDA has adequate financial resources to implement FDAMA's Phase IV tracking provisions as soon as possible. In addition, Congress must be told that if it is truly interested in assuring that drug companies comply with their Phase IV commitments, it should pass legislation to give the FDA authority to levy civil fines against companies that do not complete their commitments in a timely manner.

#### DR. ROSS, from page 8

Cost was the central focus of the fourth study which evaluated the impact of an after-hours nurse-operated telephone consultation service on a general practitioner service with 97,000 registered patients. It was estimated that the service cost £81,237 (about \$126,000), but saved £94,422 (about \$146,000), a net saving of £13,185 (about \$20,000), primarily from reduced emergency hos-

pital admissions.

These studies do not leave all issues resolved. For example, while it seems clear that nurses and nurse practitioners are well qualified to handle minor, self-limiting medical problems, much of the art of medicine resides in the practitioner's ability to detect rare but important medical conditions.

The studies did not have enough patients to answer this question. Of course,

the ideal situation is to have physicians readily available to consult with nurses should any questions arise; in one study, a doctor as well as a nurse also saw the patient in about 20 percent of the cases.

These studies will bolster the movement toward greater delegation of clinical responsibilities to nurses. It seems that the future holds more collaboration for Dr. Ross and Nurse Hathaway.

# Canadian Update on the Arthritis Drug Celecoxib (CELEBREX) Confirms HRG's Warning About Its Use

More than a year ago, in April 1999, we invoked our "five-year rule" about a then-new arthritis drug celexicob (CELEBREX) because it was the 20th compound in its class and thus far from a "breakthrough" drug. Now, in the April 2000 issue of the *Canadian Adverse Drug Reaction Newsletter*, comes ample justification for our earlier warning—a summary of problems involving this drug in the short period of eight months in the relatively small Canadian market.

Celecoxib was first made available in that country for osteo- and rheumatoid arthritis on April 14, 1999—one month after its introduction in the U.S. Between that date and December 23, 220 reports of suspected reactions from the drug came to the attention of Canadian authorities.

This is precisely the sort of thing that brought about our five-year rule in the first place. The pre-marketing testing of candidate drugs normally involves, at the most, a few thousand volunteer subjects. Possible adverse reactions may not show up until many thousands of people are exposed. That is why we have always said that unless a drug is a new breakthrough in fighting a certain disease, it is prudent to wait five years for its risks in a large population to become obvious.

As noted earlier in this article, celecoxib does not meet "breakthrough" qualifications, and indeed has not been shown to be any safer than the other 19 members of the nonsteroidal anti-inflammatory drug (NSAID) family. What is more, it was not approved by the U.S. Food and Drug Administration (FDA) for the treatment of pain, and is much more expensive than older generic NSAIDs such as ibuprofen (MOTRIN) and naproxen (NAPROSYN).

The 220 reports involving celecoxib in its first eight months on the market in Canada actually enumerated 562 adverse reactions (multiple reactions were described in some reports), of which 101, involving 59 women and 41 men, were classified as serious. (Gender was not specified in one report.) Their ages

ranged from 21 to 92 years, with almost half (48 percent) 70 or older.

Of the 220 reports, adverse reactions most frequently involved the following body systems:

 Gastrointestinal effects—75 reports (34 percent): included gastrointestinal hemorrhage, black or tarry stools, abdominal pain, vomiting of blood, vomiting, nausea, pancreatitis (inflammation of the pancreas), gastric ulcer, diarrhea, and duodenal ulcer.

Unless a drug is a new breakthrough in fighting a certain disease, it is prudent to wait five years for its risks in a large population to become obvious.

- Skin reactions—74 reports (34 percent): itching, various type of rashes, and skin eruptions.
- General reactions—66 reports (30 percent): included were weakness, chest pain, fatigue, fever, stiffness, anaphylactoid reaction (severe, possibly life-threatening allergic reaction), and other allergic reactions.
- Central and peripheral nervous system—41 reports (19 percent): dizziness, headache, muscle tension, and stupor.

- Respiratory system effects—27 reports (12 percent): included were difficult breathing, bronchospasm, and pulmonary edema (fluid in the lungs).
- Psychiatric reactions—26 reports (12 percent): confusion, depression, insomnia, drowsiness, and hallucination were listed.
- Metabolic and nutritional reactions—
   19 reports (9 percent): elevated liver enzymes and weight loss.
- Cardiovascular system—18 reports (8 percent): cardiac failure, low blood pressure, slow heart rate, heart attack, and high blood pressure.
- Urinary system—17 reports (8 percent): acute renal failure, facial edema, and frequent urination.
- Hematological (blood)—15 reports
   (7 percent): prothrombin time increase, bleeding time increase, cerebral hemorrhage, intracranial hemorrhage, pulmonary embolism (blood clot in the lungs), thrombocytopenia (decreased platelets).

Twelve reports, including 11 classified as serious, involved the use of celecoxib with the blood thinner warfarin. The professional product labeling or "package insert" for celecoxib was amended in the U.S. to warn about this potential drug interaction, which could lead to an increased risk of bleeding.

There were 74 reports of suspected allergic-type reactions, two of which were anaphylactoid in nature. In 16 cases, the reports indicated that the patient had a previous reaction to sulfa. Celecoxib should not be used in patients who have experienced an allergic reaction to a sulfa drug.

#### What You Can Do

You should wait until February 2004 to use celecoxib—if then. Celecoxib is not as effective for pain as the older NSAIDs and there is no clear evidence that it is safer. In addition, it is much more expensive than the older drugs in its class.

# Mother Dies But Son Can't Get An Explanation Because Her Doctor Won't OK Inquiry's Disclosure

The death of a loved one is always a traumatic event. For one Public Citizen member, whose mother died of a stroke eight days after being admitted to a Florida hospital under Medicare, the pain of loss was compounded by his suspicion that she had not received adequate care. His mother had been hospitalized after an asthma attack, and he believed her stroke may have been caused by an inappropriately high dose of the asthma medication theophylline. So he did the sensible thing: He wrote to the Peer Review Organization ("PRO") that oversees Florida Medicare facilities and asked for a review of the quality of care his mother had received during her hospitalization.

A PRO is a private group of doctors that contracts with the federal government to oversee delivery of services under Medicare. One of its tasks is to investigate complaints about the quality of care that Medicare patients receive.

The member expected to be informed about the results of the investigation. Instead, he received a letter stating that the PRO would not release the results to him because his mother's admitting physician—the very person he suspected of providing inadequate care—refused to consent to disclosure.

Understandably upset, the member contacted Public Citizen. Lawyers at Public Citizen Litigation Group discovered that, despite the fact that the law clearly required PROs to disclose the results of their investigations, the Department of Health and Human Services (HHS) has maintained that PROs are prohibited from doing so without the consent of the doctor involved. A lawyer for HHS admitted that

the policy is in conflict with the law, and gave a predictable answer: So sue us.

Taking HHS up on this invitation, Public Citizen has filed a lawsuit challenging the Department's policy of prohibiting PROs from disclosing the results of their investigations. Public Citizen has sued not only on behalf of the member who was denied information about the investigation into his mother's care, and on behalf of Public Citizen itself, but is also prepared to act for others similarly situated. We invite anyone who has been denied information about PRO investigations into their complaints about the quality of care at Medicare facilities to contact Amanda Frost at (202) 588-1000, or at Public Citizen, 1600 20th Street, NW. Washington, DC 20009, to learn more about the lawsuit and determine whether it could benefit them.

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