

Health Letter

SIDNEY M. WOLFE, M.D., EDITOR

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Sleight-of-Hand: Merck Contemplated Vioxx Reformulation in 2000 While Denying Risk

Merck aimed to re-formulate the arthritis drug Vioxx five years ago to reduce the potential for heart attacks, adding to previous evidence that the company was fully aware of the dangers of the drug well before it withdrew it from the market last year.

The revelation came as Merck and plaintiffs' attorneys were gearing up for a trial in Texas, the first liability case over the drug to go to court.

Merck withdrew Vioxx from the market in September of last year after a clinical trial examining its potential effects in cancer patients showed that the drug significantly increased the risk of heart attacks and other heart-related problems.

But that clinical trial was hardly the first to show a link between Vioxx and cardiovascular problems. Clinical studies and company documents dating back to 2000 reveal the potential heart risks and company officials' concern over them. Vioxx was approved for sale by the U.S. Food and Drug Administration in May 1999.

Now a document obtained by plaintiffs' lawyers for Vioxx patients shows that Merck was, in fact, so worried about the potential for heart-related adverse effects that it sought to develop a safer formulation of the drug at about the same time it was reassuring doctors and physicians that Vioxx was indeed safe, in the

wake of the large clinical study in 2000 revealing the heart-attack risk.

The document names former Merck research chief Edward Skolnick, saying he suggested combining Vioxx, which is theorized to lead to blood clotting that causes heart attacks, with another drug that could potentially prevent blood clotting.

Vioxx is known as a COX-2 selective inhibitor because it blocks an enzyme in the body that causes pain but does not as completely block an

enzyme known as COX-1 as several older anti-inflammatory painkillers do. COX-1 protects the lining of the stomach, and the theory behind the development of Merck's Vioxx and Pfizer's Celebrex was that the newer drugs would be easier on the stomach and cause fewer ulcers than older painkillers such as aspirin because they blocked less of the COX-1 enzyme.

But the intended stomach benefits
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Can I Buy You Dinner? Pharmaceutical Companies Increasingly Use Doctors' Talks as Sales Pitches

Pharmaceutical companies have significantly escalated the frequency with which they are paying physicians to promote their products to fellow doctors, according to a new report in the *Wall Street Journal*. A July 15th article by Scott Hensley and Barbara Martinez, documented that doctors delivered considerably more drug talks to other doctors last year than did the companies' own

sales representatives. The article shows that, based on data from the market research company Verispan, in 2004 "237,000 meetings and talks sponsored by pharmaceutical companies featured doctors as speakers, compared with 134,000 meetings led by company sales representatives." In 1998, both doctors and sales representatives delivered only 60,000 talks.

The *WSJ* noted that this form of

marketing has replaced earlier forms that contravene the drug industry's own 2002 "Code on Interactions with Healthcare Professionals." Formerly, according to *WSJ*, pharmaceutical sales representatives would sweeten their sales pitch by "taking [doctors] on free golf outings or filling up their cars with a tank of gas," practices that the code advises against. Pharmaceutical compa-

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SLEIGHT-OF HAND, from page 1

barely came to fruition for Vioxx, which has only a moderately better effect on the stomach than older NSAIDs, and could not be proved at all for Celebrex or Bextra. Meanwhile, a much more serious problem, heart attacks, became suspected with Vioxx. This was confirmed by both Merck's 'VIGOR' trial reported in 2000 and by independent analysis from researchers elsewhere. The VIGOR trial suggested a five-fold increase in the risk of a heart attack for patients on Vioxx compared with patients on an older painkiller, naproxen.

But Merck continued to maintain the drug was safe and, in fact, armed its sales force with a handy card to show to doctors. The "Cardiovascular Card" suggested that Vioxx might be eight times safer than other painkillers, according to Rep. Henry Waxman (D-Calif.), who helped conduct government hearings on the issue this spring. The company ordered its sales reps never to discuss negative results related to Vioxx and heart attacks, Waxman wrote in the *New England Journal of Medicine*.

In addition, the thousands of lawsuits filed against Merck after the drug was pulled from the market have brought to light a series of unflattering internal email exchanges, particularly involving Skolnick, that essentially admit to the company's grave, but only private concern over

the Vioxx heart attack problem.

Publicly, Skolnick and other officials maintained that Vioxx was safe, that the clinical trial results thus far had been inconclusive, and they suggested that naproxen — the drug against which Vioxx was compared in the VIGOR study — may protect the heart, which would explain why fewer naproxen patients had heart attacks than Vioxx patients. Critics argued Merck was dragging its feet to conduct a clinical trial that definitively examined Vioxx's heart-related issues and that the naproxen 'cardio-protective effect', for which there was no evidence, was a ruse to shift the blame away from Vioxx.

When it withdrew the drug last year, Merck asserted that as soon as it had received the results of the most recent study that showed an increase heart attack risk once-and-for-all, it made the decision to suspend sales of Vioxx. But the evidence had been mounting for years.

Now, the revelation of the much earlier possible plan to reformulate Vioxx shows that Merck may not have believed its own public statements and marketing messages. Indeed, if the company was giving serious consideration to the proposed mixture of Vioxx and a heart attack preventing anti-inflammatory drug, such as aspirin, it clearly believed the Vioxx blood clotting effects were real and significant.

Merck said that as of March 31, it had been served with, or is aware of being named as a defendant in, about 2,300 lawsuits, which include about 4,600 plaintiff groups alleging personal injuries resulting from the use of Vioxx, and in about 225 putative class actions alleging personal injuries and/or economic loss.

Analysts have pegged Merck's potential liability in the Vioxx matter at up to \$20 billion, which would rank it with one of the worst product-liability disasters in drug history: the fen-phen diet drug recall that has plagued Wyeth (formerly American Home Products) to this day. However, Merck's payout may be much lower, depending on the outcome of upcoming trials and the amounts of the company's first group of settlements, analysts have said.

An advisory committee to the U.S. Food and Drug Administration in February narrowly voted to allow Vioxx back onto the U.S. market, with restrictions. The FDA usually takes the advice of its panels, but the Vioxx debacle has been so widely publicized, and the risks now seem so clear, that the decision to allow it to return to drugstores is certainly in doubt. The same panel also said Celebrex and Pfizer's follow-on drug, Bextra, could remain on the market despite links to cardiovascular safety problems. However, in April the FDA asked Pfizer to remove Bextra from the market. ■

DOCTORS' TALKS, from page 2

nies held conferences in vacation spots, paid physicians to attend and only required a nominal "consultation" of them. Now, consultation and speaker training must be "bona fide," according to the voluntary guidelines. The more ostentatious inducements of the 1990s are replaced by today's more subtle practice of paying physicians to trade on the rapport and trust between them and their colleagues.

The new form of marketing has proven both highly effective and highly profitable to the industry. Physicians turn out to be far more capable than pharmaceutical sales representatives in selling drugs to fellow physicians, internal documents from Merck show. According to a Merck slide show dated 2001 obtained by the *WSJ*, doctors who attended lectures given by their physician colleagues prescribed an additional \$623.55 worth of Vioxx, (which has since been removed from the market) during a 12 month period compared with doctors who did not attend a lecture. Those who attended smaller discussions led by doctors paid by Merck wrote \$717.53 worth of additional Vioxx prescriptions, whereas those who attended a lecture given by a pharmaceutical sales representative prescribed \$165.87 worth of additional Vioxx. Merck found that its return on investment for the physician-given talks was an impressive \$3.66 for each one dollar invested compared to a more modest \$1.96 per dollar spent for a talk given by a pharmaceutical sales representative, according to the *WSJ*.

The *WSJ* noted that the speaking engagements are frequently "small meetings, often over lunch or dinner" and describes the example of Dr. Lawrence Newman's dinner discussion with a dozen fellow physicians. Dr. Newman is a professor of clinical neurology at Albert Einstein College of Medicine in New York City, and his talk was sponsored by the pharmaceutical company GlaxoSmithKline, the makers of the migraine drug Imitrex. According to the *WSJ*, Dr. Newman recommended that migraine treatment "should be bread and butter from primary care doctors," and advised the attendees that a complaint of a sinus

infection may actually be a migraine headache, which is treatable with migraine drugs. Glaxo's sponsorship of the event included paying for dinner, paying Dr. Newman a speaking fee, providing some of Dr. Newman's slides for his talk, and providing the attendees with Imitrex note-pads.

Other physicians who similarly sold their services to the pharmaceutical industry were featured as well in the *WSJ* article. In 2002, Dr. Subir Roy, a gynecologist on the faculty at University of Southern California contracted with Wyeth and was paid \$61,250 in speaker's fees and \$11,117 in expenses for 53 speaking engagements, for an average of \$1365 per engagement. According to the *WSJ*, an internal Merck document shows that Dr. David Pitts, an internist in New Mexico, spoke 134 times for Merck in 1999 to promote Merck's cholesterol-lowering drug Zocor. Based on Dr. Pitts' characterization of his popularity as a speaker and Merck documents describing lecturing fees, the *WSJ* estimated that Dr. Pitts was likely paid between \$1500 and \$2000 per talk for a total of \$200,000 or more for the year.

The pharmaceutical industry has hit upon an extraordinarily profitable new form of marketing, in which indentured but respected physicians play a starring role. Doctor-salespeople bank on their reputation to push the company drug, and their trusting colleagues respond predictably by writing more prescriptions. Successful as a marketing technique, the dinner-infomercials inappropriately distort physician prescribing practices and therefore harm public health and increase the cost of the health system.

In its July 19th issue, the Wall Street Journal reported on responses to the article they had run on the 15th. Doctors from around the country expressed disapproval of the practice of physician-delivered drug talks, the article pointed out. Doctors expressed concern over the drug industry's stark focus on profit at the cost of corrupting prescribing practices and driving up drug prices.

Dr. William Bernstein, a recently

retired neurologist of Coos Bay, Ore., called the physician drug talks "a scandal in so many dimensions." The fact "that physicians take money from the big pharmas to speak and that they actually need to be trained to speak about something they're supposedly expert in" is bad enough. What is worse, said Dr. Bernstein, is that "their colleagues actually listen to them rather than, shudder, read and absorb the peer-reviewed literature."

Bill Hemeter, an ophthalmologist in New Orleans, explained the cynical arrangement and its effect on drug costs for all consumers. "We all sit listening attentively to the propagandist du jour, and in return, get a free meal...They send out all these attractive young reps to wine and dine us and lay a guilt trip on us if we don't reciprocate. The real scandal is that the drug companies get away with charging so much so they can fund this largesse."

Robert Israel, M.D., a professor of obstetrics and gynecology at the University of Southern California maintained that "travel funds, honoraria for minimal consultant visits, lunch for students/residents/faculty, elegant dinners associated with product demonstrations, and guest lecturers with favorable views of donors' products are all suspect. They threaten our integrity and our ability to put patients first in our medical decisions."

While these responses prove that many in the medical community have a conscience and will speak out about this abusive form of "education", the pharmaceutical industry will continue to buy off those doctors who are willing to trade on their reputation to push pills for the industry. The criticism of their fellow doctors can do a certain amount to make the drug industry's inducements to would-be physician-spokespeople less attractive, but the industry itself must be held accountable for paying off physicians — and the recipient physicians have to answer as to why they are so bribable. ■

Product Recalls

June 23 — July 25, 2005

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

DRUGS 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
a) Abilify (aripiprazole) 5 mg , Rx only; b) Abilify (aripiprazole) 10 mg , Rx only; c) Abilify (aripiprazole) 15 mg , Rx only; d) Abilify (aripiprazole) 30 mg , Rx only; Class II; Dissolution failure.	a) Lots 4B81979, 4C83077, 4C92612; b) Lots 3L69888, 3L69889, 4B81980; c) Lots 3L69891, 3L69892, 3L69899; d) Lot 4B79310; 566,836 bottles and 300,280 blister packs distributed nationwide; Bristol-Myers Squibb Company, New Brunswick, NJ.
Benazepril Hydrochloride Tablets , 40 mg, Rx only, Class II, Dissolution failure at 18 month stability.	Lot #W030655, exp. date 08/05; 9577 bottles distributed nationwide; Eon Pharma LLC, Wilson, NC.
a) Ciprofloxacin Tablets , USP, 250 mg; b) Ciprofloxacin Tablets , USP, 500 mg; c) Ciprofloxacin Tablets , USP, 750 mg.; Class II, Product testing deviations.	a) Lot number B040015, exp. date 04/06; b) Lot numbers B040017, B040018, B040019, B040020, B040021, exp. date 04/06; B040075, B040081, B040082, exp. date 08/06; B040120 exp. date 10/06, B050012 and B050022 exp. date 01/07; c) Lot number B040016, exp. date 04/06; a) 8,289 units; b) 45,996 units; c) 6,290 distributed nationwide; Martec Scientific, Inc., Kansas City, MO.
Climara Pro (Estradiol/Levonorgestrel Transdermal System) 0.045/0.015 mg/day. Rx only, Class III, Mispackaging.	Lot 040731, exp. date 10/06; 40,931 cartons distributed nationwide; Berlex, Inc, Wayne, NJ.
a) Estraderm® (estradiol transdermal system) 0.05 mg/day, Rx only; b) Estraderm® (estradiol transdermal system) 0.1 mg/day, Rx only, Class III, Labeling: patient booklet does not include required black box warning.	a) F0003 (exp. 2/28/06), F0004 (exp. 3/31/06), F0005 (exp. 4/30/06), F0006 (exp. 5/31/06), F0007 (exp. 6/30/06), F0009 (exp. 6/30/06); b) F4066 (exp. 3/31/06), F4067 (exp. 4/30/06), F4068 (exp. 4/30/06), F4069 (exp. 6/30/06), F4070 (exp. 7/31/06); 514,026 patient calendar packs distributed nationwide and in Puerto Rico; Novartis Pharmaceuticals, Corp, Suffern, NY.
a) Eyedrops, Extra Relief , Naphazoline hydrochloride 0.012%, Glycerine 1.2%, 20mL; b) Eyedrops, Seasonal Relief , Naphazoline hydrochloride 0.012%, Glycerine 1.2%, Zinc Sulfate, 0.25%, 20mL; c) Eyedrops, Artificial Tears , Polyvinyl alcohol 0.5%, Povidone, 0.6%, 20mL, Class II, Lack of assurance of sterility.	a) Lot Numbers: 1235, 1045, 0915; b) Lot Numbers: 1185, 0835; c) Lot Number: 1105; unknown quantity distributed nationwide; Natureplex LLC, Memphis, TN.
Furosemide Tablets , USP, 20 mg, Rx only, Class II, Mold growth on product.	Lot No. T055L04A, exp. date 12/06; 5,064 bottles distributed in CA; Vintage Pharmaceuticals, LLC, Huntsville, AL.
Hydrocodone bitartrate and acetaminophen capsules , 5 mg/500 mg, Class III, GMP violations.	Multiple lots; 109,256 bottles distributed nationwide; Mallinckrodt, Inc, Berkeley, MO.

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DRUGS AND DIETARY SUPPLEMENTS *cont.*

Name of Drug or Supplement; Class of Recall; Problem

a) **Jr. Tylenol Meltaways Bubblegum Burst**, 160 mg, 24 counts blister, OTC; b) **Children's Tylenol Meltaways Bubblegum Burst Flavor**, 80 mg, 48 and 64 counts blister, OTC; c) **Jr. Tylenol Meltaways Grape**, 160 mg, 24 and 48 counts blister, OTC; d) **Children's Tylenol Meltaways Bubblegum Burst Flavor**, 80 mg, 30 counts bottles, OTC; e) **Children's Tylenol Meltaways Watermelon Flavor**, 80 mg, 30 counts bottles, OTC; f) **Children's Tylenol Meltaways Grape Flavor**, 80 mg, 30 counts bottles, OTC; g) **Children's Tylenol Soft-Chews Fruit Flavor**, 80 mg, OTC; Class II, Confusing packaging may lead to overdose.

a) **Perfection Tablets**, All New Dietary Food Supplement with Chromium, (Phenylpropanolamine HCl), 25mg (appetite suppressant, time release); b) **The Perfect Solution, GARPRIN Tablets**, All Natural Dietary Food Supplement, For The Heart, Pharmaceutical Grade, 60 count bottles, each tablet contains: Garlic. Odorless 325 mg, White Willow Extract 100 mg, Aspirin 93 mg, Magnesium Stearate; Class II, Unapproved New Drug, a) contains phenylpropanolamine; b) contains aspirin.

Premarin (conjugated estrogens USP), 0.45 mg; b) Premarin (conjugated estrogens USP), 1.25 mg, Rx Only, Class III, Dissolution failure.

Premarin (conjugated estrogens) USP, 1.25 mg, Class III, Failure to conform to USP dissolution specifications.

a) **Tebamide Suppositories** (Trimethobenzamide HCl Suppositories w/Benzocaine). 200 mg (Adult), 200 mg trimethobenzamide hydrochloride and 2% benzocaine; b) **Tebamide Suppositories** (Trimethobenzamide HCl suppositories w/Benzocaine). Rx product, 100 mg, (Pediatric), 100 mg trimethobenzamide hydrochloride and 2% benzocaine, Class III, Failure to meet assay specs through expiration date.

Vivelle-Dot, Transdermal System, (estradiol) 0.1 mg, Class III, Stability failure.

Lot #: Quantity and Distribution; Manufacturer

All lots; 10,485,008 distributed in nationwide and internationally; McNeil Consumer & Specialty Pharmaceuticals, Port Washington, PA.

All lots; a) 50 bottles; b) 11 bottles distributed nationwide.

a) A52584, exp. date. 06/05 and A84755, exp. date 03/06; b) A36363, A34501, A52586 exp date 07/05, A77945 exp. date 10/06; a) 173,870 units; b) 69,128 units distributed nationwide; Division of Wyeth Pharmaceuticals, Richmond, VA.

Lot 034038B, exp. date July 31, 2005; 10,658 bottles distributed nationwide; Amerisource Health Services, Columbus, OH.

a) Lot 010804001, exp. date 1/06, Lot 010804002, exp. date 2/06; Lot 010804003 exp. date 10/05; b) Lot 010704001, exp. date 9/05; 85,764 boxes distributed nationwide.

Lots: 76061011, 76991011, 74961021, 74961012, 74961022, 76981011, exp. date 05/05; 79151011, 79151012, 79751011, 80251011, exp. date 06/05. 340,726 units distributed nationwide; Novartis Pharmaceuticals, Corp, East Hanover, NY.

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

Bicycle wheels. The rear wheel freehub mechanism can malfunction causing no resistance when pedaling. The bicycle rider could lose balance, fall and suffer injuries.

Lot #: Quantity and Distribution; Manufacturer

2003 Rolf Prima Vigor and Elan Bicycle Wheels (rear wheel only); about 870 sold at bicycle specialty stores nationwide from Mar 2003-Dec 2003; serial numbers between 03926 and 06586; Rolf Prima Inc., of Eugene, Ore.; (800) 741-6941 or www.rolfprima.com.

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<i>Type of Product; Problem</i>	<i>Lot #: Quantity and Distribution; Manufacturer</i>
Blow dart guns. Consumers may have mistakenly purchased the dart gun thinking it was a decorative walking stick, posing the risk of injury if someone used the gun for its intended purpose.	African Blow Dart Guns; about 300 units sold at Value City stores nationwide from Jun-Jul 1, 2005; Value City Department Stores, of Columbus, Ohio; (888) 278-6370 or www.valuecity.com .
Candles. The birch and bark surrounding the candles can ignite, posing a fire and burn hazard.	Birch and Bark Candles; about 230,000 sold at Target stores nationwide from Sept 2004-Jan 2005; Target Corp., Minneapolis, Minn.; (800) 440-0680 or www.target.com .
Candles. The candles can burn at an excessive height or cause the outer shell to catch fire, posing a potential fire and burn hazard.	Sea Urchin Shell Candles; about 18,000 sold at various gift and specialty stores nationwide from Apr-Jun 2005; Two's Company Inc., of Mount Vernon, N.Y.; (800) 896-7266 or www.twoscompany.com .
Exercise benches. A weld on the bench frame under the seat can crack and separate from the main frame, allowing the bench to collapse and the user to fall and suffer injuries.	Nautilus NT 1020 Exercise Benches; about 10,000 sold at specialty health and fitness stores nationwide from Nov 2000-Jan 2004; Nautilus Inc., of Vancouver, Wash.; (800) 621-4570 or www.nautilus.com .
Golf cars. The accelerator pedal can temporarily stick when depressed, resulting in unexpected acceleration or difficulty braking.	Precedent and Precedent Champion Golf Cars; 71,700 sold at authorized Club Car dealers nationwide from Oct 2003-June 2005; Club Car, Inc., of Augusta, Ga; (800) 227-0739, Ext. 3580; www.clubcar.com .
Handgun boxes. The door on these safe-boxes may not latch properly when closed, possibly giving children and others unauthorized access to a firearm.	Inprint™ Safe-Box used to store handguns and valuables; 500 units sold at Biometrics Direct, Cabelas and the Inprintsafe.com Web sites; Cabelas and Impact Guns stores and other gun shops; in Cabelas catalogs; Russ Bassett Company; and Perm-a-Store between Dec 2004-Jun 2005; Perm-A-Store, of Golden Valley, Minn.; (800) 366-7535 or kschneider@perm-a-store.com .
Lawn tractors. The axles on these lawn tractors can crack and break if subject to extreme load amounts. Should the axle break, it could cause a loss of control and result in injuries to the rider.	Lawn Tractors; about 21,000 sold at home and hardware stores nationwide from Dec 2004-May 2005; Tecumseh Power Co., of Grafton, Wis.; (888) 271-4048 or www.tecumsehpower.com .
Multivitamins. The vitamins contain iron, but do not have child-resistant packaging as required by federal law. They could cause serious injury or death if ingested by a child.	Nature's Bounty and Natural Wealth Brand Multivitamins; about 12,000 bottles sold at various drug and grocery stores and independent distributors nationwide from Jul 2004-Mar 2005; (800) 433-2990 or www.naturalwealth.com or www.naturesbounty.com .
Outdoor trunks. A problem with the lid support on the trunk could cause the lid not to stay open, posing the risk of an impact injury to a child's head, fingers or hands.	Chesapeake Outdoor Trunk; about 80 sold on Pottery Barn Kids Web site and catalog from Mar-Apr 2005; Pottery Barn Kids of San Francisco, Calif.; (800) 699-0449 or www.potterybarnkids.com .
Plush toys. The stuffing of the toy may contain tips of sewing needles which could pose a puncture hazard.	Pokémon Plush Toys; about 9,200 sold at Nintendo World, 10 Rockefeller Plaza, New York City, and on the firm's Web site from Apr-Jun 2005; Pokémon USA Inc. of New York, N.Y.; (800) 930-6613 or www.pokemoncenter.com/recall.asp .
Refrigerators. A faulty component in the condenser fan motor can short circuit. This could cause the condenser fan motor to overheat, posing a potential fire hazard to consumers.	LG and Kenmore Elite® Trio™ Three-Door Refrigerators; about 20,000 sold at Sears stores and other major retailers nationwide from May 2004-May 2005; Sears, Roebuck and Co., of Hoffman Estates, Ill.; (888) 294-5782, (800) 659-7026, http://us.lge.com , or www.sears.com .
Strollers. The handlebar can crack or break causing the handlebar to	Mountain Buggy Urban Single and Urban Double Jogging Strollers; about 2,200 sold at baby furniture and baby product stores nationwide

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Pennsylvania Data Show Large Number of Hospital-Acquired Infections

Nearly 12,000 patients acquired new infections while in Pennsylvania hospitals last year, and 15.4 percent of them died from the infections, according to data recently released from a state initiative.

The Pennsylvania data reflect a disturbing national trend, as hospital-acquired infections become even more commonplace. The Centers for Disease Control and Prevention have estimated that there are at least two million health care associated infections each year. Of these, 90,000 people die, and a third of the deaths are likely preventable.

In the Pennsylvania report, urinary infections represented the most

common type of infection, accounting for 6,139, or 53 percent, of the 11,668 cases that were recorded. Bloodstream infections accounted for 17 percent, surgical-site infections represented 11 percent, pneumonia comprised 11 percent, and 8 percent acquired multiple infections.

The report showed that 1,793 patients with hospital-acquired infections died last year in Pennsylvania at a mortality rate of 15.4 percent, compared with a rate of 2.4 percent for patients without infections. Therefore, the report reasoned, there were about 1,510 additional deaths directly attributable to hospital-acquired infections. The mortality

rates for those acquiring bloodstream infections and pneumonia were higher than for those acquiring urinary tract infections or surgical-site infections.

The data was gathered as part of a Pennsylvania initiative to reduce unnecessary health care costs in the state. Very few states have undertaken data-gathering to track hospital-acquired infections, and rarely has the public had access to a thorough study of nearly all general acute-care hospitals in a particular state.

However, the report noted that not all hospitals have met complete reporting requirements for the initiative. *continued on page 8*

CONSUMER PRODUCTS *cont.*

Type of Product; Problem

possibly detach while in use, posing a risk of injury to young children.

Strollers. These strollers can fail to latch properly and unexpectedly collapse while in use. This can result in broken bones, cuts, bumps, bruises and other injuries to young children riding in the stroller and consumers pushing the stroller.

Tiki torches. The head and cover of these torches can come loose or be dislodged during use, allowing torch fuel to spill. This poses a risk of burn injuries and property damage.

Toy chests. A problem with the lid support on the toy chest could cause the lid not to stay open, posing the risk of an impact injury to a child's head, fingers or hands.

Toy trucks. Small parts could break off the truck, posing a choking hazard to young children.

Water scooters. Hydrogen gas can build up in the battery compartment and cause the battery cover and the battery package to forcefully expel from the product, posing a risk of injury to the user or bystanders.

Lot #; Quantity and Distribution; Manufacturer

and Web retailers from Dec 2004-Jul 2005; Sycamore Kids Inc., of Fort Collins, Colo.; (866) 524-8805 or support@mountainbuggyusa.com.

Graco Duo Tandem Stroller, Graco MetroLite Stroller; about 1 million Duo Tandem strollers sold at discount, department and juvenile product stores nationwide from Jan 1994-Dec 2000; about 143,000 MetroLite strollers sold at discount, department and juvenile product stores nationwide from Nov 2000-Dec 2002; Graco Children's Products Inc., of Exton, Pa.; (800) 981-4412 or www.gracobaby.com.

Tiki® Cone Metal Torch; about 350,000 sold at Wal-Mart stores nationwide from Dec 2003-early Jun 2005; Lamplight Farms Inc., a Division of W.C. Bradley Company, of Menomonee Falls, Wis.; (800) 645-5267 or www.lamplightfarms.com.

Cameron Toy Chest; about 5,800 sold through Pottery Barn Kids' Web site, catalog and retail stores nationwide from Dec 2003-Apr 2005; model numbers 4825378, 6252852, and 4825386; Pottery Barn Kids of San Francisco, Calif.; (800) 699-0449 or www.potterybarnkids.com.

"So Hot Way Cool Free Wheel Trucks"; about 17,400 sold at Target Stores nationwide from Apr 2005-May 2005; Target Corp., of Minneapolis, Minn.; (800) 440-0680 or www.target.com.

Aqua Water Scooters; about 2,200 sold at Checker Auto Parts and Kragen Auto Parts stores in California, Arizona, Nevada and Minnesota, and on the firm's Web site from Apr-Jun 2005; CSK Auto Inc., of Phoenix, Ariz.; (800) 842-3070 or www.cskauto.com.

Decreased Child Mortality a Possibility with Appropriate Funding, Study Shows

While the United States spends hundreds of billions of health care dollars a year to pay for immense paperwork, bloated insurance companies, and often unproven supplements and drugs, millions of children around the world die each year from diseases and illnesses that could be prevented with a small fraction of this amount.

In fact, it would cost the world just \$5.1 billion annually to save six million children in the countries where 90 percent of child deaths occur, according to research published in the British medical journal *The Lancet* this June. That may sound like a lot of money, but to give some perspective, \$5.1 billion represents...

- About 1.2 percent of the estimated U.S. defense budget for fiscal year 2006.
- Less than one-third of one percent of the \$1.7 trillion spent on health

care in the United States in 2003.

The research published in *The Lancet* was conducted partly to assess the feasibility and economic impact of accomplishing one of the Millennium Development Goals, a set of eight major objectives established in a global effort coordinated by the United Nations and intended to be achieved by the year 2015. The goal pertaining to child mortality aims to reduce by two-thirds the mortality rate of children under five years of age from the rate observed in 1990.

As a starting point, the researchers established 18 "contacts" that mothers and children could have with a primary-care provider to prevent illness. They listed 23 prevention and treatment interventions that would be necessary and estimated the costs of those interventions in each of the 42 countries that account for the most child deaths per year, or six million total

deaths.

They also examined the potential cost of drugs, medical materials, delivery costs, and program management costs, such as training and personnel. Included in those estimates was the cost of hospitalizations and clinical interventions because it is unlikely, the researchers reasoned, that children would be disease-free even with decent preventive care.

They then tallied the estimated number of children who currently receive each type of intervention, and then projected the costs to provide universal care on each of those measures. In the end, they estimated that \$5.1 billion in additional costs were needed to provide the proper sanitation, preventive care, and treatment to all children in the 42 countries.

While attaining the eradication of
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HOSPITAL-ACQUIRED INFECTIONS, from page 3

tive, so the true totals are not completely known. There was a wide disparity in the level of information and detail provided by hospitals to the state initiative.

The Pennsylvania report estimated that the hospital-acquired infections cost an additional \$2 billion in charges and some 205,000 additional days in the hospital for the patients infected in that state alone.

A recent *New England Journal of Medicine* review of various studies indicates that the incidence of infections acquired in hospitals per 1,000 bed days increased by 36.1 percent between 1975 and 1995, the Pennsylvania report noted.

Some hospitals nationwide have responded with aggressive quality-control and monitoring, but others have been lax about implementing tighter standards to prevent infections

and to catch them quickly when they do occur.

One key culprit of hospital-acquired infections is the contamination of the water supply that is used for drinking, bathing and to wash medical equipment. Staph infections are another major problem, caused by staphylococcus aureus bacteria that can enter the body through cuts or breaks in the skin.

The Joint Commission on Accreditation of Hospitals (JCAHO), the organization that certifies hospitals to operate and presumably monitors quality, has listed for a long time as one of its main annual goals the reduction of hospital-acquired infections. But it gives no precise target for a percentage reduction for each facility (or nationally) and barely has any formal recommendations for policies to be implemented to accomplish the goal.

JCAHO recommends that health-

care workers clean their hands properly, cover their noses and mouths, and that workers who have infections avoid close contact with patients. But JCAHO has been criticized for not cracking down on hospitals over quality control and not mandating precise monitoring systems that require reporting of every infection that occurs. The commission does report all "sentinel" events, or unexpected problems that occur in a health care setting on its web site without identifying the specific hospitals but the number is likely an underestimate because of underreporting.

Public Citizen supports public disclosure of hospital-specific infection rates and death-causing infection rates, both on a risk-adjusted basis, for all hospitals, so that the public can examine the potential risk of infection associated with medical facilities and exert pressure on those hospitals with poorer records. ■

FDA Issues Guidelines for Consumer Prescription Drug Information

The FDA has recently issued a Draft Guidance on Useful Written Consumer Medication Information. Below are the comments submitted by Public Citizen researchers regarding these guidelines and the need to ensure that consumers have useful, scientifically accurate information about the drugs they are prescribed.

Since our founding in 1972, Public Citizen, a consumer organization with a membership of over 130,000 people, has been actively advocating for the distribution of Food and Drug Administration (FDA) approved drug information written specifically for consumers that will be distributed with each new and refill prescription and is based on a

drug's professional product labeling or package insert. Numerous times over the past 30 years, we have submitted comments, petitions, and testimony on the unequivocal right and need for prescription drug consumers to have reliable access to objective, scientifically accurate, useful information about the drugs they are prescribed.

Public Citizen served as member of the Steering Committee that met in Washington, DC between September and December 1996, facilitated by the Keystone Center, to develop The Action Plan for the Provision of Useful Prescription Medicine Information. The Action Plan, or Keystone process as it is sometimes known, forms the basis for defining

useful written drug information for consumers. It is the basis for the draft guidance about which the FDA is requesting public comment. The Action Plan was agreed to by private sector information vendors and accepted by Donna E. Shalala, Secretary of the Department of Health and Human Services, in 1996.

The process to provide the public with access to useful drug information has been hampered immeasurably by the consistent failure of private sector information vendors. This failure discredits the professional trade groups representing pharmacy, medicine, and the pharmaceutical industry because they have long placed a dogmatic aversion for all

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CHILD MORTALITY, *from page 8*

childhood illnesses in developing countries seems a far-flung dream. the research in *The Lancet* makes such a goal appear feasible in two ways: by simply putting a pricetag on it, the goal seems tangible and within reach; and by arriving at an estimate that represents a pittance of health care costs in developed nations such as the United States, the paper demonstrates that we have the resources to devote to such a project.

Many of the problems afflicting

children in the developing world involve sanitation and care that we regard as basic in the United States: clean water, prenatal care, immunizations, and access to vitamins such as zinc and vitamin A.

But a major problem with implementing these preventative measures and interventions is the obstacle of delivery itself, an issue that often looms large for global health workers: adequate distribution channels for medical equipment and drugs, access to remote areas, and sympa-

thetic governments are all needed.

But if the governments that agreed to the Millennium Development Goals — all 191 member states of the U.N. — are serious about accomplishing them and do not intend to leave an unfulfilled promissory note to the world's poor, they will jointly and promptly finance the health workers and organizations dedicated to eliminating preventable childhood mortality and make the massive saving of children's lives a reality. ■

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FDA Approves Depression Device Without Proof of Effectiveness

On May 11th, 2005, Public Citizen wrote a letter to the FDA urging against the approval of the Vagus Nerve Stimulator for the treatment of depression that is resistant to other treatments because the available evidence did not prove that it was effective for that indication and raised serious safety concerns. On July 15, the FDA approved the device. Below is the response statement of Dr. Peter Lurie, Deputy Director of Public Citizen's Health Research Group.

The decision by the U.S. Food and Drug Administration (FDA) to approve the Vagus Nerve Stimulator (VNS) for treatment-resistant depression is one of its most questionable regulatory decisions made by the agency in recent memory. As a consequence of the FDA's data-free decisionmaking, hundreds of thousands of patients with severe depression are likely to undergo surgery to implant a device that has not been proved to work.

This device was a resounding failure

in its main clinical trial. And the other main analysis by Cyberonics Inc., the device's manufacturer, was deemed

Devices for which medical claims are made should meet the same approval criteria as drugs.

"highly questionable" by the FDA's statistical reviewer. No adequately controlled long-term trials have addressed the FDA reviewer's safety concerns, which stem from cases of worsening depression, suicide and sudden death among patients who received the device.

Devices for which medical claims

are made should meet the same approval criteria as drugs. In effect, the FDA has lowered the approval bar for this device. There is simply no convincing evidence that this device works. Until and unless such data are generated, patients are better off without this device.

VNS is an electronic device implanted surgically at the base of the neck that sends pulses of electricity into the brain and elsewhere in the body every five minutes. It was deemed not-approvable by the FDA in August 2004 due to a lack of convincing evidence that the device is effective and concerns that it may actually worsen depression in some patients. However, in the absence of substantially new data, the FDA reversed its position and on Friday approved the device. In May, *The Wall Street Journal* reported that the Senate Finance Committee was examining the FDA's handling of Cyberonics' application. ■

GUIDELINES, from page 9

regulation, particularly FDA regulation, of patient drug information before the public interest.

The Draft Guidance on Useful Written Consumer Medication Information was written by the FDA to inform private sector information vendors of what will be expected in the next legislatively mandated survey of the quality of prescription drug information distributed to consumers by pharmacists, which is due in 2006. The Draft Guidance does appear to accurately reflect the intent of Keystone Steering Committee, and we urge the FDA to apply this guidance to its letter.

Consumers are concerned that the FDA may once again capitulate to

the private sector and lower the bar for assessing useful information as they did with the failed 2001 survey. In a June 2002 Talk Paper, the FDA proclaimed the "... success of private sector patient information," and that the "overall usefulness was about 50 percent" for the information being distributed to the public. These statements were made by the FDA despite the fact that the patient information leaflets for four commonly prescribed drugs surveyed failed to meet the minimum voluntary quality criteria outlined in The Action Plan.

The notion that information intended to warn consumers about preventable adverse drug reactions that could result in serious injury or death that, according to a nationwide

study commissioned by the FDA, is only 50 percent useful is a success is unfathomable.

Medication Guides are FDA-approved drug information written for patients that may be required by the agency, through regulation, to be distributed with drugs that pose a serious and significant public health concern. Public Citizen estimates that there are now, or soon will be, about 75 drugs that are required to be dispensed with Medication Guides. This regulatory path is the track the FDA should have followed for the thousands of other FDA-approved drugs after the private sector vendors failed in 2001 to provide consumers with any useful drug information. ■

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