

Health Letter

SIDNEY M. WOLFE, M.D., EDITOR

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Profitably Inventing New Diseases

A recent article in *Medical Marketing and Media* (May 2003), aimed at the marketing departments of the pharmaceutical industry, provides an extraordinary view of this industry of which the public, unfortunately, remains unaware. Vince Parry, the "Chief Branding Officer" for a company called "InChord," tells his pharmaceutical company readers — and potential clients — how to increase sales by combining the "creation" of a disease with a drug to treat it.

There is no dispute that the pharmaceutical industry, first and foremost, is an industry needing and seeking ways to increase profits for its shareholders and that larger profits require a continuing increase in sales, a feat orchestrated by marketing departments. But in the past, simply letting the public know the uses for a drug too often failed to generate the robust growth in sales desired. The solution, as described by Parry, is something called "condition branding" in which a company defines a *new* condition (along with its worry-provoking symptoms) to convince physicians and patients that they must treat the condition and use one particular drug.

Parry begins with an early example: Warner-Lambert's desire to expand its market for Listerine, which in the 1920s had multiple uses but lacked sales growth. Warner-Lambert's strategy was to take a harmless concept, unpleasant breath,

and change its name to "halitosis," thereby creating "awareness — and anxiety — around a serious-sounding medical condition." Halitosis, in ads, was made responsible for problems ranging from lack of career advancement to divorce, and within six years, sales increased from \$100,000 to \$4 million.

Today, healthcare marketers are much more imaginative: they take their pharmaceutical product and add in "external thought leaders [usually physicians who vouch for the drug's worthiness], support groups and consumers." Parry lists three principal strategies that can be used to create a new condition:

"Elevating the importance of an existing condition
Redefining an existing condition to reduce a stigma

Developing a new condition to build recognition for an unmet market need."

An example of the second suggestion is Pfizer's marketing strategy that turned Viagra into an acronym for erectile dysfunction.

Drug companies are now masters of suggestion number three — developing a new condition — spectacularly so in the field of mental health. Parry advises, "No therapeutic category is more accepting of condition branding than the field of anxiety and depression." The manual used to describe mental disorders, the *Diagnostic and Statistical Manual of Mental Disorders* (DSM), is compiled by the American Psychiatric Association, an organization heavily funded by the pharmaceutical industry.

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Secret No More: Medicare Investigation Results Now Fair Game

This article was written by Amanda Frost, the Public Citizen attorney who successfully litigated this case.

The government is not allowed to keep secret the results of its investigations into complaints by Medicare beneficiaries, the United States Court of Appeals for the D.C. Circuit ruled on June 20, 2003. The decision handed a victory to Public Citizen in its lawsuit against the Department of Health and Human Services (HHS), in which Public Citizen challenged HHS' policy of keeping secret the results of its investigations into complaints by Medicare beneficiaries when the doctor under investigation refused to consent to disclosure. As a result of that policy, Public Citizen members, along with many other Medicare beneficiaries and their families, have been denied access to the results of investigations into their complaints about sub-standard medical care.

The case arose from Public Citizen member David Shipp's request that the government review whether his wife received appropriate care while being treated for cancer. Mr. Shipp's wife, Doris Shipp, had been diagnosed with cancer in December 1998, and she died six months later.

Several months after he requested an investigation, the government sent Mr. Shipp a letter informing him that the investigation had been completed, but that he would not be informed of the results because the doctors he had complained about had refused to allow him to obtain that information.

In its lawsuit, Public Citizen argued that the government's policy violated the Peer Review Organization Act because it did not provide a meaningful response for Medicare beneficiaries who complain about the quality of medical services they received. The D.C. Circuit, affirming the district court, agreed with Public Citizen on all counts, and ordered HHS to begin disclosing the results of its investigations to any Medicare beneficiary, or representative of a beneficiary, who complains about the quality of Medicare services.

Public Citizen hopes the litigation will help raise public awareness about the rights of Medicare beneficiaries to challenge the quality of medical care provided under Medicare. Few Medicare beneficiaries realize that the government has established Quality Improvement Organizations (QIOs, formerly called Peer Review Organizations) for the

purpose of overseeing Medicare services. QIOs are groups of independent doctors charged with the responsibility of ensuring that doctors provide Medicare patients with adequate care. Anyone on Medicare, or their representative (such as a family member), may file a complaint with their local QIO about the medical care received through Medicare. The QIO is required by federal law to investigate all complaints and — as a result of the recent legal victory in the D.C. Circuit — to provide the results of those investigations to the complaining party.

A directory of the names and telephone numbers for QIOs all over the country is located at www.cms.hhs.gov/qio/default.asp. Information about Medicare benefits more generally can be found at www.cms.hhs.gov/medicare. If you have questions or concerns about the quality of Medicare services that you or a close relative have received, you should write your local QIO and ask them to investigate. If you have questions about the process of filing a complaint with a QIO or obtaining the results of a QIO investigation, you should write to Amanda Frost, Public Citizen, 1600 20th Street, NW Washington, D.C. 20009.

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Bad Medicine

Why Bush's Malpractice Policy Will Only Help Insurers

The following article by Sasha Polakow-Suransky is reprinted from The American Prospect vol. 14 no. 7, July 3, 2003.

For the third time in as many decades, doctors across the country are protesting rising medical malpractice insurance premiums. The American Medical Association (AMA) is promoting its longstanding goal of medical liability reform in the shape of a \$250,000 cap on "pain and suffering" (noneconomic) damages in malpractice

cases. Karl Rove must be thrilled. For an administration determined to deplete the coffers of Democratic trial-lawyer donors — and damage presidential hopeful Sen. John Edwards (D-N.C.) in the process — malpractice reform is a godsend.

It is also a powerful wedge issue with the potential to alienate doctors from Democrats after their recent collaboration on the Patients' Bill of Rights. Just one year ago, the AMA and trial lawyers were working together to pass legislation allowing patients to sue HMOs. But with

reimbursements declining and malpractice premiums rising, trial lawyers are the physicians' new target.

President Bush's AMA-backed proposal to cap pain and suffering damages at \$250,000 will satisfy the AMA's desire to shield doctors from liability while curtailing maimed patients' rights to sue. But in the end it is more likely to line the pockets of insurance companies than reduce rates for doctors.

Depending on whose statistics

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NEW DISEASES, from page 1

As a result of carving out more and more subcategories, DSM has increased dramatically in size from 106 categories (in 1952) to 357 (in 1994). Parry states that, "Not surprisingly, many of these newly coined conditions were brought to light through direct funding by pharmaceutical companies, in research, in publicity or both."

Xanax. One example of such a newly created mental health need was Xanax for panic disorder, a condition first appearing in the third edition (DSM-III) in 1980. To create this need, the manufacturer, Upjohn, funded research, publications, and speaking tours. They also funded an unrestricted three-day "thought leader conference at NIMH [National Institutes of Mental Health]," a U.S. government agency. As a result, NIMH published a consensus on diagnostic criteria for panic disorder and Upjohn was able to get the first drug for this disorder approved from the Food and Drug Administration. Parry notes that since DSM-III first recognized the syndrome of panic disorder, its incidence has increased 1000-fold.

Sarafem. Lilly was a beneficiary of DSM-IV with its newly created "premenstrual dysphoric disorder" (PMDD). Unknown to many, except to industry insiders, was the fact that Lilly's drug to treat PMDD, Sarafem, was identical to Prozac. However, since Prozac connoted mental disorder, Lilly changed the brand name (to Sarafem) and pill color (to lavender) and in their ads, built public awareness, "recasting diagnosis to conform to the new criteria."

Zantac. In the digestive disease area, Zantac (made by GlaxoSmithKline; GSK) was originally used to treat ulcers, a limited market. By converting Zantac into a treatment for a disease, gastroesophageal reflux disease (GERD), GSK opened up a large market for a condition that could be treated chronically. GSK ads aimed to frighten the public with the potential for serious long-term consequences if GERD were left untreated. According to Parry, GSK went even further, creating the Glaxo Institute for Digestive Health for "education and awareness." The institute sponsored research awards, involved powerful third-party advocates such as the American College of Gastroenterology,

and established a public relations outfit, "Heartburn Across America," all of which succeeded in driving sales to \$2 billion at the peak of its popularity.

Parry lists questions to help industry determine whether "branding is right for your product." He concludes, "If you feel that your product could benefit from condition branding . . . remember the basic lessons learned over time: evaluate all the strategic options for what suits your product best, develop nomenclature, . . . and build consensus [convince the medical professionals] early on."

What is never mentioned is that many drugs that people are induced to take as a result of this pressure are not only not needed but may cause adverse reactions that result in extra doctor's visits or even hospitalizations and deaths. The public needs to become aware of the subterfuges employed by the pharmaceutical industry — to use Parry's phrase, "a better brand of illness" — and keep these clearly in mind in order to avoid being misled and potentially harmed.

BAD MEDICINE, from page 3

you use, the median jury award for malpractice ranges from \$125,000 to \$1 million. The Physician Insurers Association of America reports that claim payments of more than \$1 million have increased from less than 2 percent in 1990 to almost 8 percent in 2001, driving the median up from \$150,000 to more than \$300,000. Contrary to insurance industry claims, however, overall medical malpractice payouts have not increased substantially. During market downturns, insurers set aside vast reserves to pay anticipated claims, counting these reserves as "incurred losses" — even while these funds accrue investment income. But excluding these set-asides, actual insurance company payouts increased only 15 percent from 1998 to 2001, according to Americans for Insurance Reform (AIR) — far less than premium increases in most states.

Medical malpractice law is a lucrative industry, as many a phone book cover will attest. But contrary to the administration's line, increasing jury awards are not single-handedly driving premiums through the roof. Rather, a steep decline in insurers' projected investment income is largely responsible for rising rates. Medical malpractice insurers do not invest heavily in stocks; in fact, approximately 80 percent to 90 percent of their investments are in the bond market, and bond income has been declining. Moreover, insurance companies are technically barred from recovering past losses by raising premiums, an argument the AMA parrots to dismiss claims that insurance companies are at fault. But insurance companies do regularly raise rates based on projected investment losses. For medical malpractice insurers, investment income represents a far greater share of profits than in other lines of coverage due to the long lag (up to 10 years) between premium payments and claim payouts. And when investment income evaporates, it hits hard. AIR's J. Robert Hunter, an actuary and former Texas insurance

commissioner, tracked premiums and insurance industry investment returns over the last 30 years. He found that each of the three malpractice insurance "crises" directly coincided with declining insurance investment returns.

Insurance competition in the 1990s, followed by steep drops in interest rates, drove premiums up sharply. As *The Wall Street Journal* exhaustively documented in 2002, malpractice insurers launched a price war in the 1990s after major companies realized they had set aside too much capital in loss reserves. As large insurers such as St. Paul Companies released reserves, medical malpractice suddenly appeared immensely profitable and multiple new companies entered the market, aggressively undercutting the larger companies and one another. The result was a bargain for doctors and a brewing storm for insurers. As claims piled up, the low rates no longer proved adequate to cover costs. The largest insurer, St. Paul, left the market. To add to the mess, falling interest rates meant declining yields on bonds. To stay afloat, insurers had to raise rates. "When interest yields decrease, rates must increase," Jim Hurley, a medical malpractice expert at the actuary firm Tillinghast-Towers Perrin, told the Senate Committee on Appropriations in March.

While general practitioners have not been particularly hard hit by rising premiums, neurosurgeons, obstetricians and other high-risk specialists have seen rates soar. According to the trade journal *Medical Liability Monitor*, annual premiums for obstetrician/gynecologists in Las Vegas increased from \$79,000 in 2001 to nearly \$108,000 in 2002, while those in Miami saw premiums skyrocket from \$159,000 to more than \$210,000. In states such as Pennsylvania, Nevada and Florida, doctors have retired early, left the state or stopped delivering babies to contain their insurance costs. While the overall number of doctors in these states is actually rising, certain specialties are feeling the pressure. Dr. Shripathi Holla, a neurosurgeon

in Scranton, Pa., has seen his total malpractice insurance payments double in the last few years to approximately \$150,000. Meanwhile, other area neurosurgeons have stopped practicing or retired early, and one recently moved to Maryland. "I am unable to recruit anyone to come to this town," says Holla. As a result, he finds himself on call for three different area hospitals on any given night, and he is sometimes the only surgeon willing to perform risky operations that trauma centers will no longer undertake. "Once some of us retire, this state is going to have a tremendous problem in terms of providing health care to its citizens," says Holla.

The Bush plan is modeled after California's 1975 Medical Injury Compensation Reform Act (MICRA). From 1976 to 2000, according to the AMA, California malpractice premiums remained stable, rising 167 percent compared with a 505 percent increase nationwide. However, California premiums increased dramatically in the years immediately following MICRA. They did not stabilize until 1988, three years after the California Supreme Court upheld MICRA and the same year that California voters passed Proposition 103, forcing publicly traded insurance companies to reduce rates by 20 percent. Both reforms likely played a role in stabilizing California's insurance rates.

But critics of caps insist that pain and suffering damages are necessary to deter careless medical practice and compensate for injuries such as blindness, disfigurement and the loss of sex function, which cannot be quantified in economic terms. Limiting these awards, they argue, will do nothing to reduce costs to doctors and will only trample patients' rights. Linda McDougal, the Minnesota woman whose breasts were mistakenly removed after she was incorrectly diagnosed with cancer because her files were mixed up with another patient's, suffered few quantifiable economic losses. She had health insurance, and her employer covered medical bills and

lost wages. But "she will have to go through life mutilated for no reason," says Carlton Carl of the Association of Trial Lawyers of America. George Annas of the Boston University School of Public Health contends that doctors in general are far too worried about being sued.

"Most doctors don't get sued," says Annas, referring to a 1990 Harvard study showing that only one in eight malpractice victims ever takes his or her case to court. "Compare that to patients who worry about being killed; it's not even in the same league."

Far more effective than an arbitrary cap on damages would be a more systematic effort to weed out bad doctors and prevent malpractice in the first place. Dr. Sidney Wolfe, director of Public Citizen's Health Research Group, says, "You should protect patients with doctor discipline and protect good doctors with low premiums." Public Citizen ranks state medical boards according to their records of disciplining negligent doctors. "Five percent of the doctors account for 50 percent of the malpractice payouts," he says. "The primary failing is at disciplining doctors. A lot could be remedied by taking bad doctors out of practice."

Meanwhile, CEO Richard Anderson and President Manuel Puebla of the Doctors' Company, a so-called physician-owned mutual, each earn approximately \$2 million per year. Wolfe declares that doctors are "being used as a human shield by the malpractice insurance companies" who want tort reform to protect only themselves. After all, in many states where caps have been enacted, insurance premiums have continued to rise. Nevada, Missouri and Ohio all have some form of cap, but all three figure prominently on the AMA's "crisis states" map. Instead of turning their backs on the real causes, Wolfe says, doctors "should be marching for discipline reform and insurance reform."

Dr. Marcia Angell, former editor of *The New England Journal of Medicine* and now a professor at Harvard Medical School, is not surprised.

"[Doctors] are not economists. They don't think in terms of how a business makes up for a loss of profits. They have been at loggerheads with the trial lawyers for so long that it's always a knee-jerk reaction." Moreover, she observes, many lawsuits arise due to the lack of a social safety net. "As long as we have a system based on avoiding sick people and not taking care of them, you leave sick and injured people with very little alternative other than to sue and to get some care that way," says Angell.

Remarkably enough, insurance companies don't even promise that a cap on lawsuits will solve the problem. In 2002, the American Insurance Association noted, "The insurance industry never promised that tort reform would achieve specific premium savings." And American Tort

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Reform Association President Sherman Joyce told *Liability Week* in 1999, "We wouldn't tell you or anyone that the reason to pass tort reform would be to reduce insurance rates." If doctors are genuinely concerned about reducing the cost of malpractice premiums and not simply shielding themselves from liability, it would only be logical to demand that for every dollar an insurance company saves as a result of tort reform, doctors should save a dollar on their

premiums.

Ironically, Bush boasted about just such a policy during the 2000 campaign, when he proudly credited a Texas law with saving consumers billions of dollars. But these days the White House won't give its blessing to any such reform. Enticed by the prospect of passing widespread tort reform, Rove and Senate Majority Leader Bill Frist (R-Tenn.) have other things in mind. In early April, a far-reaching bill cracking down on class action lawsuits was approved by the Senate Committee on the Judiciary, bringing it to the floor even before malpractice reform.

AMA President-elect Dr. Donald Palmisano concedes that other remedies are available. In Massachusetts, Indiana and Louisiana, malpractice lawsuits undergo a pre-screening process, substantially reducing the number of questionable lawsuits without restricting the rights of patients to sue. Other top AMA officials admit that the caps for which they are lobbying hard may not even bring premiums down. "Dropping premiums would be great, but stabilizing is what we want," says an AMA spokeswoman. But stabilizing rates at levels that are already driving neurosurgeons and obstetricians out of business is no solution. While a cap on pain and suffering damages may result in marginal savings for general practitioners, there is no evidence that it would provide relief to those who perform the riskiest procedures. If the AMA succeeds in passing a \$250,000 cap without a provision forcing insurance companies to pass their savings on to doctors, rates may well continue to climb, in which case growing numbers of obstetricians will stop delivering babies, more neurosurgeons will retire early or shy away from risky procedures, and more mutilated patients will be denied compensation.

And in the end, Karl Rove and his buddies in the insurance industry will be laughing all the way to the bank.

Product Recalls

June 12, 2003 — July 14, 2003

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

DRUGS AND DIETARY SUPPLEMENTS

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

Name of Drug or Supplement; Class of Recall; Problem

Cholestyramine for Oral Suspension, USP Powder, 4 grams cholestyramine resin, per packet, 60 single dose packets, Apothecon; Class III; Superpotent (6 month stability)

Coppertone Bug & Sun Sunscreen with Insect Repellent, (N, N-diethyl-m-toluamide 9.5% and other isomers 0.5%), SPF 30, Kid's Formula, 4 FL OZ (118mL) and 8 FL OZ (237mL) bottles; Class III; Incorrect inactive ingredient; product contains Benzophenone-4 rather than Benzophenone-3 and product contains undeclared preservative

Levsin Elixir (hyoscyamine sulfate elixir USP), 0.125 mg/mL, 473 mL (1 pint) syrup, Rx only; Class III; Mislabeled; front label incorrectly states the product strength as 0.125 mg/mL rather than correctly as 0.125 mg/5 mL

Lisinopril Tablets, 10 mg, 10 tablet bottles, Sample Not To Be Sold; Class III; Mislabeling; product label does not contain Rx only legend

Premarin Tablets (conjugated estrogens tablets, USP), 1.25 mg, 100 and 1000 tablet bottles, Rx only; Class III; Dissolution failure by manufacturer (Wyeth)

Lot #: Quantity and Distribution; Manufacturer

Lot no. 1A32512 Exp. Date 2/29/2004; 2,011 ctns/60 packets ea. distributed nationwide; Bristol-Myers Squibb Company, New Brunswick, NJ

Numerous lots; 902,519 units distributed nationwide; Schering-Plough Health Care Products/DBA Bain de Soleil, Co., Cleveland, TN

Lot 20920; 393 bottles distributed nationwide; Schwarz Pharma Manufacturing, Seymour, IN

Lot # 117955; 3,600 bottles distributed in California; Nucare Pharmaceuticals, Inc., Orange, CA

Lots: #9000073B (100s) and #9000073W (1000s). Exp. Date on both lots is 07/04; 34,378 bottles distributed nationwide; National Pharmapak Services, Inc., Zanesville, OH

MEDICAL DEVICES

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

Name of Device; Class of Recall; Problem

LIFEPAK CR Plus Defibrillator; Class II; Defibrillation therapy may be delayed or not delivered for persons needing defibrillation therapy

Lot #: Quantity and Distribution; Manufacturer

All serial numbers below 31058753; 7,095 units distributed nationwide and internationally; Medtronic Physio Control Corp., Redmond, WA

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

Adjustable Beds; When exposed to severely cold temperatures and impact, such as may occur during shipping, the power cord insulation on the electric air pump can crack, creating a short-circuit or exposing live electrical wires and presenting a shock or electrocution hazard

ATVs; Kawasaki KFX700 "V-Force"; The throttle cable adjuster on the carburetor can loosen during operation, causing it to stick, which can cause the rider to lose control and possibly crash

"Egg Dippers" Easter Plush Toys. There have been two reports of children ingesting beads coming out of these plush toys

Electric Blankets; Blankets can overheat, posing a risk of burn injuries to consumers, especially when the blanket is folded or bunched

Extension Cords, Portable Lights, and Fluorescent Work Lights. The extension cords and lights have undersized wiring, are not properly polarized, have inadequate grounding, faulty electrical connections, and plastic handles that once ignited continue to burn and spread flames, posing a shock, electrocution and fire hazard to consumers

Fireworks; "TNT" Reloadable Tube; The firework device has a defective base and can break during launch. If reused, the launching device could then send fireworks in unintended directions, possibly causing injury

Food Choppers. Consumers can cut their fingers and hands while using the product

Food Slicers; The exposed slicing blade on top of the unit can cut a consumer's fingers or hand during use

Lot #: Quantity and Distribution; Manufacturer

Includes all Sleep Number(r) Beds by Select Comfort sold from November 2002 through March 15, 2003 that were shipped through or to cold weather locations; 90,000 sold nationwide from November 2002 through March 15, 2003; Select Comfort Corporation; Minneapolis, MN; (800) 326-3541; email at questions@selectcomfort.com

The Kawasaki KFX700 "V-Force"; 3,000 sold nationwide from March 2003 through June 2003. Kawasaki Motors Corp., U.S.A.; Irvine, CA; (866) 802-9381; www.kawasaki.com

Four animal plush toys: white rabbit, green rabbit, purple bear and yellow duck; each toy has a permanent label affixed which reads "The Boyd's Collection, Ltd." 75,000 sold at department and specialty stores nationwide from February 2003 through April 2003; Small World, Englewood, NJ; (800) 377-3050

SOIREE(r) (only those sold at Belk stores) and Soft n' Warm(r) (only sold at K-mart), both of which were sold in king, queen, full and twin sizes; 18,000 sold at K-mart and Belk stores nationwide from September 2002 through February 2003; Perfect Fit Industries, Charlotte, NC; (877) 882-9478

150,000, 180,000, and 54,000 respectively sold nationwide at traveling sales shows, the company's two retail stores (in Huntington and Lafayette, IN) and online at www.homier.com from January 2000 through May 2003; Homier Distributing Co. Inc., Huntington, IN; (800) 348-5004 or email Homier at customerresponseteam@homier.com

Black base with a multicolored PVC material tube; each product is sold with six shells with fuses. Product labeled "Model No. CP983," "Item No 460070," "TNT," and "#1 SELLING BRAND"; 22,700 units sold at firework display stands and tents and retail operations in those states where the sale of consumer fireworks is legal from June 2003 through July 2003; American Promotional Events Inc., Florence, AL; (800) 243-1189

Little Red Chef; 7,300 sold nationwide from February 2002 through July 2002; QVC Inc.; West Chester, PA; (800) 455-2259; www.qvc.com

Little Red Chef, also known as The Kitchen Magic Food Slicer; 32,000 sold from August 2000 through May 2003 through QVC, TV direct sales, and trade promotion shows nationwide; Ontel Products Corp., Fairfield, NJ; Send an email requesting a protective blade cover to littleredchef@ontelproducts.com or write to Ontel Products Corporation, 21 Law Drive, Fairfield, New Jersey, 07004

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Name of Product; Problem

Infant Car Seats/Carriers; When the seat is used as a carrier, the plastic handle locks can unexpectedly break or release from the carrying position, causing the seat to unlatch or flip forward

International Adapter Plugs; The adapter plug can separate, exposing live electrical conductors, posing an electrocution and shock hazard to consumers

Mobile Crib Toys; If batteries used in the mobile leak, the caustic liquid can seep out of the battery compartment, posing a risk of chemical burns to babies

Rear Projection Televisions; If capacitors short circuit due to a very high electrical surge, such as from a lightning strike, the metal parts on the television could present a shock or electrocution hazard. In addition, the metal jacks on the back of the television or another metal box attached to the television could present a shock or electrocution hazard as a result of the capacitors' failure

Snowmobiles; The Start/RER switch for the SDI models and the Start switch for the V-1000 models may be defective

"Spit Smatter" Spray Foam; The aerosol cans can forcefully break apart, posing a risk of serious injury to nearby consumers

Water Heaters with S.I.T. temperature controls; A potential burn hazard from ignition flashback or an increase in tank water temperature

Lot #: Quantity and Distribution; Manufacturer

Cosca Arriva and Turnabout; 1.2 million car seats/carrier sold nationwide from September 10, 1997 through December 2000; Dorel Juvenile Group; Columbus, IN; (800) 880-9435; www.djgusa.com

Black or white plastic adapter plugs have names of specific countries or regions where the plugs are intended for use written on the side, including "NORTHERN EUROPE," "GREAT BRITAIN," "NO. AMERICA," "AUSTRALIA," and "SO. EUROPE"; 29,000 sold at catalog and retail stores nationwide; sold in sets of five from April 2002 through June 2003; Franzus Company LLC, Beacon Falls, CT; (800) 706-7063 or email at service@franzus.com

Sparkling Symphony(tm); Activated by remote control; 233,000 sold at discount department stores and toy stores nationwide from December 1999 through December 2001; Fisher-Price, East Aurora, NY; (800) 357-9460; www.service.mattel.com

Models 50A62, 51H83, and 57H83; 3,400 sold nationwide from April 21, 2003 through May 8, 2003; Toshiba America Consumer Products, Inc., Wayne, NJ; (877) 290-6064; www.tacp.toshiba.com/service/safety_notice.asp

Ski-Doo(r), model year 2003, Legend(tm) and Grand Touring(tm) SDI and V-1000 models; 548 sold nationwide from December 2002 through January 2003; Bombardier Motor Corporation of America; Grant, FL; (800) 375 -4366

Comes in a pressurized can and emits a colored foam based on one of six brands: "Original Smatter," "Blueberry Smatter," "Banana Cream Smatter," "Lemon Meringue Smatter," and "Fatter Smatter." Brand name printed on can and word "Nickelodeon" printed on orange trigger mechanism; 1.3 million sold at discount department and toy stores nationwide from February 2002 through June 2003; JAKKS Pacific Inc., Malibu, CA; (800) 554-5516; www.jakkspace.com

GSW water heaters with S.I.T. model 650 AC4 gas/temperature controls; temperature control knobs on GSW propane water heaters red and control knobs on GSW natural gas water heaters blue; found on GSW Water Heaters with serial numbers ranging from 0202694162 to 0304507825; 13,000 sold in USA and Canada at regional appliance distributors from February 2002 through April 2003; GSW Industries Inc., Fergus, Ontario, Canada; (800) 263-3502; www.gsw-wh.com

Do Not Use Finasteride (PROSCAR, PROPECIA) For Preventing Prostate Cancer

The results of a major study examining the effect of finasteride (PROPECIA, PROSCAR) in reducing the risk of prostate cancer was released early, June 24, 2003, on the web site of the *New England Journal of Medicine* (www.nejm.com). The results of the study were mixed, with the increased risk of high-grade cancer caused by the drug outweighing the decreased risk of cancers that may be of little clinical significance.

Finasteride is sold by Merck & Company, Inc. of West Point, PA as Proscar for the treatment of symptomatic benign prostatic hyperplasia (enlarged prostate) and as the life-style drug Propecia for male pattern baldness.

The study is known as the Prostate Cancer Prevention Trial (PCPT) and was sponsored by the U.S. Public Health Service and the National Cancer Institute, one of the National Institutes of Health.

The rationale for trying finasteride to reduce the risk of prostate cancer is the mechanics by which the drug works. Finasteride inhibits the enzyme 5 alpha-reductase that is responsible for converting the male hormone testosterone to the more potent dihydrotestosterone. The theory is that lowering the level of the more potent hormone in the prostate would reduce the risk of prostate cancer.

In the PCPT trial, 18,882 men 55 years of age or older with normal physical examinations and prostate-specific antigen (PSA) levels of 3.0 nanograms per milliliter or lower were randomly assigned to receive finasteride, five milligrams per day, or a placebo for seven years. This type of study design is the scientific "gold standard" for showing a cause and effect relationship between a treatment and an outcome.

men included in the final analysis. In 4,368 men given finasteride, 803 cases (18.4%) of prostate cancer were diagnosed. In the group of 4,692 men receiving the placebo, 1,147 men (24.4%) developed prostate cancer. (As discussed below, most of these are low-grade cancers of little clinical significance.)

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The results were reported in the study and in the news media as a 24.8 percent relative reduction in prostate cancer risk after seven years. Regular readers of *Worst Pills, Best Pills News* know that the reporting of a relative risk reduction can be misleading unless it is reported along with the absolute risk reduction between the finasteride and placebo groups. In the PCPT study, the difference in the risk of developing prostate cancer between the finasteride and placebo groups was six percent (24.4% - 18.4% = 6.0%).

By knowing the absolute risk reduction between the finasteride

and placebo groups, the number of men who need to be treated with finasteride to prevent one case of prostate cancer can be calculated: 16 men must be treated for seven years to prevent the detection of one case of prostate cancer.

In other words, 16 men must be treated for seven years to prevent one case of prostate cancer; we can not predict which one of the 16 men will benefit; and the other 15 men face the risks of using the drug, which may be substantial.

At the end of the study, 5.1 percent of men receiving the placebo and 6.4 percent of those taking finasteride who had biopsies of their prostate glands had developed high grade cancers. This is an increase of 1.3 percent. High grade prostate cancers are known to behave aggressively.

Because the difference in the percentage of high grade cancers between the finasteride and placebo groups is known, a number analogous to the number needed to treat, the number needed to harm can also be calculated. This number is 77. In other words, at the end of seven years of taking finasteride, for every 77 taking the drug one additional man will develop a high grade cancer.

The table accompanying this article summarizes the other adverse effects and the effects on the urinary systems of the men who participated in the PCPT trial.

The editorial appearing in the same issue of the *New England Journal of Medicine* as the PCPT trial, written by a urologist from the Memorial Sloan-Kettering Cancer Center, addressed the important question "What should we advise the public and our patients?" about using finasteride to prevent prostate cancer. His conclusion was "On balance, finasteride does not seem to

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At seven years there were 9,060

FINASTERIDE, from page 9

be an attractive agent for the chemoprevention of prostate cancer." We agree.

The editorial went on to say that although finasteride was shown to reduce the incidence of cancers, and that because the study required that prostate biopsy be recommended for all men, this may have led to the overdetected of cancers of little clinical significance:

We do not know the malignant potential of such cancers and have no evidence that any benefits would be worth the risk associated with treatment. Furthermore, the study results suggest that finasteride may accelerate the growth of high-grade cancers, which may pose a threat to life and health if they are not treated successfully. Finally, the effects of finasteride on sexual function lessen the attractiveness of the drug as a preventive agent [see the table accompanying this article].

The Health Research Group has consistently held the position that before any drug can be recommended to prevent cancer, or any other disease, in otherwise healthy people, it must be almost entirely free of adverse effects.

The editorial also raised the question of what to tell men who are

ADVERSE EFFECTS REPORTED IN THE PCPT TRIAL — NUMBER AND PERCENTAGE OF MEN EXPERIENCING AN ADVERSE EFFECT

ADVERSE EFFECT	FINASTERIDE GROUP	PLACEBO GROUP
Sexual and Other Adverse Effects		
Reduced volume of ejaculate	5,690 (60.4%)	4,473 (47.3%)
Erectile dysfunction	6,349 (67.4%)	5,816 (61.5%)
Loss of libido	6,163 (65.4%)	5,635 (59.6%)
Gynecomastia (breast enlargement in males)	426 (4.5%)	261 (2.8%)
Effects on the Urinary System		
Enlarged prostate	488 (5.2%)	823 (8.7%)
Increased urinary urgency or frequency	1,214 (12.9%)	1,474 (15.6%)
Urinary incontinence	183 (1.9%)	208 (2.2%)
Urinary retention	398 (4.2%)	597 (6.3%)
Prostate surgery performed (transurethral resection of the prostate)	91 (1%)	180 (1.9%)
Prostatitis	418 (4.4%)	576 (6.1%)
Urinary tract infection	90 (1%)	126 (1.3%)

This table is adapted from a table in the New England Journal of Medicine on the PCPT trial.

taking finasteride long term to control the symptoms of enlarged prostate. The editorial suggests that these men be monitored carefully for the development of cancer by periodic physical examinations and following PSA blood levels. Unfortunately, the definition of periodic was not given and we are not aware of the optimal time for monitoring the possible development of aggressive prostate cancer in men taking finasteride long term for the symptoms of enlarged prostate.

What You Can Do

You should not be using finasteride at this time to reduce the risk of developing prostate cancer because of the increased risk of developing high grade aggressive tumors.

If you are now using finasteride long-term to manage the symptoms of enlarged prostate you should discuss the result of the PCPT trial with your physician.

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the "legal" grounds for non-disclosure, evidently takes precedence over the public's right to know how its government conducts its business.

Recently, however, the General Accounting Office (GAO) lifted the lid of secrecy on one of these CRADAs — and the contents were not pretty. The drug in question was Taxol, an extract of the bark of the Pacific Yew, now marketed by Bristol-Myers Squibb (BMS) to treat breast, ovarian, lung and AIDS-associated cancers. At the request of Senator Ron Wyden of Oregon, the

GAO reviewed the history of the Taxol CRADA and uncovered a remarkably one-sided deal — with taxpayers clearly on the short end.

It is fair to say that without the NIH there would have been no Taxol. The agency identified a component of the Pacific Yew as having anti-tumor activity as long ago as 1963 and identified the chemical responsible for this activity back in 1971. In 1983, the NIH began the first of several clinical trials of Taxol; BMS was essentially absent from the scene until it signed a CRADA with the NIH in 1991. When in 1992 the

Food and Drug Administration approved Taxol for the treatment of ovarian cancer, BMS relied upon six studies, five of which had been conducted by the NIH. BMS went on to conduct additional studies, particularly for other cancer indications. Between 1993 and 2002, BMS grossed a tidy \$9 billion in Taxol sales worldwide. From 1977 to 1997, when the CRADA ended, the GAO estimates that the NIH spent \$183 million in research on Taxol. The vast majority of this actually took place after the CRADA took effect.

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What does the NIH (and the public) have to show for all these years of government creativity and investment? A paltry \$35 million, according to the GAO. Even this minimal cost to BMS has been recouped many times over from the Federal government itself; through its Medicare program, the U.S. spent \$687 million on Taxol between 1994 and 1999.

And what of the royalty rate that the court deemed so secret that it had to be shaded from public disclosure? The GAO, which can examine documents not available to the public (with the apparent exception of the records of the Dick Cheney/Enron Energy Task Force), learned that the government received a feeble 0.5% royalty rate, based on worldwide sales, well below what Public Citizen believes private companies negotiating with each other typically are granted.

In a further twist, Florida State University (FSU) also had a licensing agreement with BMS, ironically based on NIH-funded research. These investigations had led to a method for the synthesis of Taxol that lessened dependence upon the uncommon Pacific Yew. Under yet another shortsighted Federal law, the so-called Bayh-Dole Act of 1980, universities that develop patentable technologies using NIH research funds can license the technology to the private sector in exchange for royalties. Even though FSU's patent was merely for a synthetic pathway to produce Taxol, as opposed to the NIH's multiple clinical trials first proving the effectiveness of Taxol, FSU collected royalties at a rate of about 4.2% of worldwide sales — worth about \$65 million in 2000

alone.

The GAO report suggests a likely NIH motive for resisting disclosure of its royalty rates that transcends legal niceties. What if taxpayers actually knew what a lousy deal the NIH had negotiated on its behalf?

Under the circumstances, the GAO's conclusion is remarkably pallid: "In light of the significant

federal investment, questions remain regarding the extent to which NIH used its broad authority in its negotiations with BMS on the royalty payments ..." The time is long overdue for either the GAO or the Congress itself to answer these remaining questions by conducting a more wide-ranging investigation into NIH's royalty practices.

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Taxol: How the NIH Gave Away the Store

The old-growth trees and luxuriant, rolling lawns give the National Institutes of Health (NIH) campus in Bethesda, MD the outward appearance of an insurance company's sprawling headquarters. Appearances can be deceiving. The campus is home to as concentrated a focus of medical brainpower as you are likely to encounter anywhere on the planet. Several of the great discoveries of modern medicine have taken place here — from unglamorous basic science research to drugs for AIDS and cancer.

While some of the research may not lead to commercial products, pharmaceutical companies eye the work being conducted at NIH like hawks, continually on the lookout for tasty morsels of technologies that can

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be brought to market profitably. In their efforts, the companies are aided by the Federal Technology Transfer Act of 1986 that established contracts called Cooperative Research and Development Agreements (CRADAs)

to facilitate the commercialization of technologies developed at the NIH. In exchange for licensing its technology to a private company, the NIH can collect royalties based on sales.

Because of concern that NIH was not adequately bargaining for higher royalty rates and believing that the terms of those licensing agreements should be made public, Public Citizen brought suit against the NIH in 2000. Incredibly, the Federal District Court for the District of Columbia ruled that, even though taxpayers (through the NIH) are parties to the agreements, they are not allowed to learn these royalty rates. In modern America, the confidentiality of commercial information,

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