PUBLIC CITIZEN HEALTH RESEARCH GROUP

Health Letter

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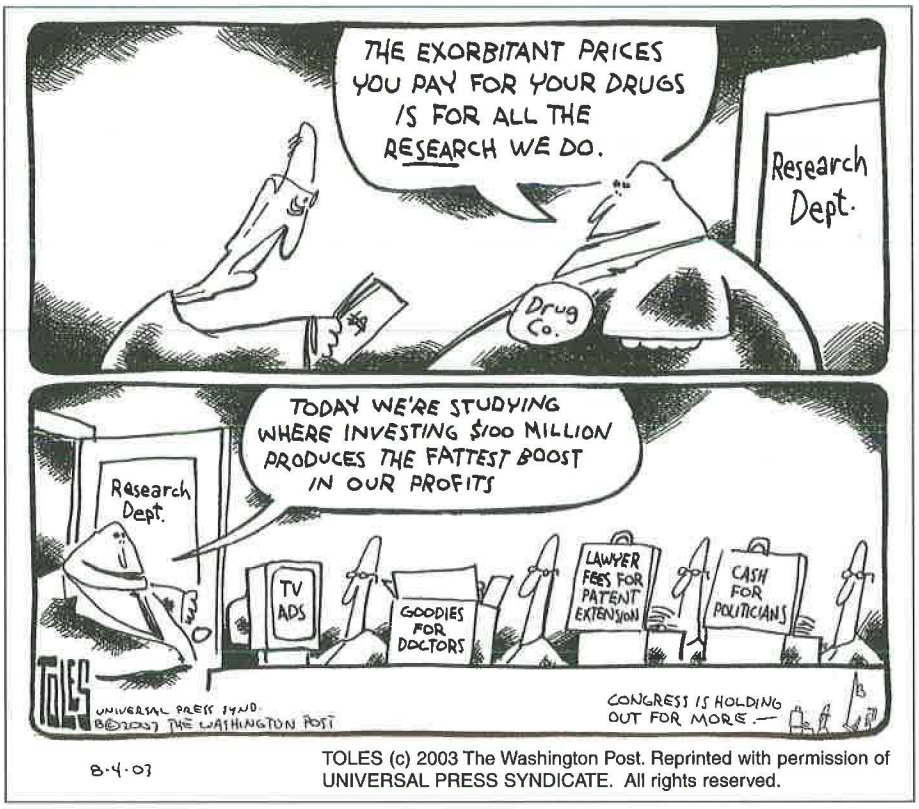

Sweetening The Pill

The following article appeared in the Sydney *(Australia)* Sunday Times *earlier this year and is reprinted with the permission of the author.*

Is the medication you're taking the one that's best for you? Or the one your doctor's been bribed to prescribe? Ray Moynihan reveals how the world's drug companies co-opt doctors with everything from free pens to luxury holidays — and why you might be paying the price.

Moynihan, an Australian journalist working in Washington D.C., has written extensively for the Australian media and for the British Medical Journal *about the pharmaceutical industry and doctor-drug company as well as government-drug company relationships.*

When two female representatives from the drug company TAP Pharmaceuticals entered Dr Joe Gerstein's office just west of Boston in 1997 and

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offered him a $100,000 bribe, they didn't realise they'd be making history. Gerstein is medical director of Tufts Health Plan, a health insurance company. The $100,000 was in the form of an "educational grant" and was offered to Gerstein as an incentive to get TAP's expensive cancer drug back on Tufts' approved drug list. Gerstein had replaced their drug, Lupron, with an equally effective cheaper one, spelling the potential loss of millions of dollars in sales.

The women told Gerstein that, in return for reinstating Lupron, they would hand over the money in a series of cheques made out to Tufts, but that it could be used for "whatever," and spent "at your discretion." At TAP, a joint venture owned by two of the world's biggest pharmaceutical corporations, "educational grant" had a broad definition — the money could end up helping to finance parties for doctors, funding golf outings or paying for bar tabs at country club functions.

Joe Gerstein had had the first hint of a bribe during a phone call with one of the women a few months earlier. "I was scandalised by the offer," he says, "and I considered it to be almost certainly illegal." After failing to interest reporters in his story, he went to the Boston headquarters of the U.S. Justice Department, where he met a young lawyer, Mike Loucks. "I told him my story and he said straight away, 'You'll have to wear a wire.'"

When the two women formally offered Gerstein the "educational grant," what they didn't know was that the FBI was recording the meeting on audio and videotape. And what Loucks and the FBI agents didn't know was just how big the case would become. "At that stage, we had no clue if this was a single event, or one of many," Loucks says. "After a month's investigation, we had a sense it was the tip of the iceberg."

In Australia, drug companies spend more than $1 million a day on promotion. In the U.S., the world's biggest prescription drug market, they spend almost $100 million a day trying to make sure doctors prescribe their latest, most expensive medicines. An army of 80,000 representatives make regular one-on-one visits — showering doctors with free gifts, meals and flattery — as the advance guard of the industry's $33 billion-a-year promotional blitz.

Likewise, much of a doctor's postgraduate education, and most of the scientific meetings he or she attends, are sponsored by the drug industry. In the U.S. alone, drug companies fund 300,000 such events every year.

While many new medicines reduce suffering and extend life, there are often cheaper alternatives, as in the TAP Pharmaceuticals case. As drug companies induce doctors to prescribe the pricier new drugs, national drug bills are exploding around the world. It's one of the reasons authorities are beginning to take notice of a practice that has gone far beyond free pens for doctors' surgeries and ballooned into something that looks remarkably like a multi-billion-dollar influence-peddling scheme.

Mike Loucks and the FBI agents uncovered repeated instances of company salespeople apparently offering doctors substantial fake educational grants, free drug samples that could be resold by the doctors (in the U.S., doctors can sell drugs to patients), with windfall profits of up to $500 per patient, and payments for sham "consultancies" and "honoraria" sometimes worth more than $3000 per doctor. Then there were the "educational" trips which happily included time for leisure activities, whether it was skiing while staying at the Ritz-Carlton in Aspen or sun and surf and luxury accommodation at the famous Biltmore Hotel in Santa Barbara.

Doctors weren't the only ones on the receiving end. Investigators discovered alleged incentive schemes for sales representatives and their managers that included substantial bonuses, cash prizes, share options and trips. One of the most sought-after rewards was an invitation to a lavish party called the "Excalibur," thrown annually by TAP for its best-selling reps, and held at a desirable location — an event with a price tag of about $7 million.

When confronted with the alleged evidence of criminality, TAP's lawyers argued that the company was "simply engaged in routine business activities in the pharmaceutical

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THE PUBLIC CITIZEN HEALTH RESEARCH GROUP
Health Letter

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

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industry." The gifts, they said, were not inducements to increase prescribing, but were simply to gain access to the doctor and establish a "partnership". TAP was only doing "what all of its competitors were also doing."

Those arguments started to look a little thin, however, when several key doctors started confessing to taking bribes, a former executive turned whistleblower, and boxloads of company documents were subpoenaed. Loucks and his team were now alleging that TAP's most senior officers had knowingly breached the law through most of the 1990s by inducing doctors to prescribe their costly drugs, ultimately costing the U.S. government, which subsidises the care of elderly Americans, hundreds of millions of dollars.

Following protracted negotiations, in April 2001 the company agreed to pay $1.5 billion in criminal and civil damages, a record for health care fraud that also dwarfs anything seen in the recent round of Wall Street's merchant bank settlements.

"The case represents, at its core, corruption of medical judgement," Loucks told Good Weekend. Still a relatively young lawyer, he is now head of health care fraud with the U.S. Justice Department. "When a doctor recommends a course of treatment, you think it's solely in your best interests. Here you had folks with terminal prostate cancer getting recommendations on the basis of what course of treatment made their doctor more money."

Four medical specialists have so far pleaded guilty to health care fraud. The two women who offered $100,000 to Joe Gerstein, both managers as it turned out, are among a dozen drug company officials and one doctor facing criminal trials scheduled to start next year.

TAP says its employees facing trial are currently on "administrative leave," but it stresses the presumption of innocence. The company itself has acknowledged criminality only in relation to providing free samples: it rejects many of the government's other allegations about inducements.

Joe Gerstein is optimistic the case might lead to a reduction in the corporate bribery within medicine, but he is also angry that so many doctors still accept industry largesse. "The free dinners, the vacations, the lunches and the books ... what can I say? They are disgusting and totally improper."

Equally worrying is that much of the information doctors get about drugs comes from [drug] company-funded sources

Across the U.S. and Europe, legal authorities are now running investigations into drug-company bribing of doctors. But no similar probes have been launched in Australia. Here, doctors can't be bribed with free samples that they can resell as in the U.S., but it is an open secret that those categorised as "high prescribers" by drug company staff often get the invitations to the best junkets.

One of the few serious investigations came from Channel Nine's Sunday program, which broadcast footage two years ago of an "educational" meeting taking place on board a Sydney Harbour cruise. Along with the lectures, the 270 doctors on board were treated to a floorshow complete with scantily clad dancing girls. The evening was sponsored by drug giant Pfizer to teach doctors about heart disease — a condition for which the company had new drugs on the market.

The same program featured scenes of tipsy doctors emerging from an intimate dinner, funded by drug company Wyeth, at Forty One, one of Sydney's most exclusive restaurants. One boasted, almost slurring her words, of regular drug company invitations to the most expensive dining spots in the country. Despite formal complaints from the Australian Consumers Association (ACA) — initially upheld but later overturned — none of the wining and dining was found to be in breach of the pharmaceutical industry's code of conduct.

"Medical education doesn't include half-naked dancing girls," says ACA chief executive Louise Sylvan. "Fundamentally, companies don't do this for fun, they do it to influence doctors to prescribe the latest, most expensive drugs, unnecessarily driving up the national drugs bill" — and, she adds, undermining patient trust in doctors.

Ethical experts tell us that giving gifts, whether it's a pen or 10 days on a beach in the Caribbean, creates a sense of obligation towards the giver. In the case of doctors and drug companies, the obligation is in direct competition with the doctor's primary duty to their patient, and it can only really be repaid by prescribing the company's drug. Equally worrying is that much of the information doctors get about drugs comes from company-funded sources, either through visits from salespeople, or attendance at sponsored educational meetings like the Pfizer cruise and the Wyeth dinners.

Some of the speakers at these events may be being directly paid by the company. It's not unusual for drug companies to put medical experts on the payroll, as "thought leaders" or members of "advisory boards," so they become part of the paid stable of speakers at the same time as holding down "independent" positions at academic institutions and hospitals.

In Holland, where Merck Sharp & Dohme came under investigation in 2001, one of the nation's senior migraine specialists admitted to investigators that his role on MSD's advisory board was somewhat dubious. Like several colleagues, neurologist

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Dr Tijssen was quietly being paid $15,000 a year by the company, at the same time as he was "educating" other doctors at meetings about migraine treatments: "People in attendance do not know that I am under contract with MSD. They consider me independent: I don't think they connect me with a certain company. The practice is deceptive: nobody suspects it, yet the neurologist is on the company's payroll."

If doctors think they're above being influenced by gifts and freebies, a famous study involving doctors at the prestigious Cleveland Clinic, a major hospital in the U.S., puts paid to that idea. Researchers in Cleveland, Ohio, tracked the prescribing habits of 20 senior specialists before and after they attended company-funded educational meetings at luxury locations. One group was flown, all expenses paid and with their partners, to a resort on the U.S. West Coast to learn about a new antibiotic, and the other group went to a Caribbean island to learn about a new heart drug. Interviewed beforehand, 17 of the 20 doctors told the researchers they would not be influenced by the trip.

As it turned out, graphs of the prescribing rates show dramatic increases occurring immediately after the junkets. Prescription of the new antibiotic rose tenfold, and for the new heart drug, fourfold. Well, perhaps the new drugs were simply better? Interestingly, the study found that the prescription rates of the older drugs the new medicines were supposed to replace did not decline, leading researchers to speculate that the trips may have led to excessive and inappropriate prescribing.

"We physicians think we're scientists and we are shrewd and they can't put things over us but, in fact, we are putty in the hands of these people," says Joe Gerstein, who, apart from his role with Tufts, is also an associate professor at Harvard and a practising physician. "It's like going up against the big-league pitchers."

In many cases, the hype peddled by promotional campaigns ends up being quite different from reality. This is exactly what happened with Celebrex, one of the most aggressively promoted drugs of all time. Marketed jointly by Pharmacia and Pfizer, who have since merged to form the world's largest drug company, Celebrex was hyped for years before its launch as a new breakthrough treatment for a serious form of arthritis.

Under the influence of a massive promotional blitz, backed by scientific evidence purporting to show it was safer than the older alternatives, Australian doctors prescribed Celebrex with such passion that this one drug cost the taxpayer-funded Pharmaceutical Benefits Scheme more than $160 million in its first year on the market. This in turn contributed to an almost 20 per cent surge in the cost of the PBS in 2001, sparking a minor political crisis as Canberra struggled to regain control of the nation's runaway drug costs.

A key pillar of the scientific evidence for the excited claims about Celebrex was a study published in the prestigious *Journal of the American Medical Association* (JAMA), in 2000, which found the drug caused significantly fewer ulcers than the alternative arthritis medicines — suggesting it would be superior for older people at risk of these side effects. But the sheer magnitude of promotion saw Celebrex being prescribed to a much bigger group than that, and the PBS was subsidising it all. Such was the inappropriate overuse that the then health minister, Michael Wooldridge, was forced to warn that too many people with mild problems were being prescribed the drug. Ironically, Wooldridge had not long before given Celebrex a very enthusiastic public endorsement.

Quite apart from the overprescribing and the damaging effects on national budgets, there is another more worrying aspect to the Celebrex story. The 2000 JAMA paper's conclusion that Celebrex caused fewer ulcers than the older drugs was based on a six-month trial. Like many medical journal articles these days, it included a financial disclosure statement, this one revealing that Celebrex manufacturer Pharmacia funded the study, six of the authors were employees of Pharmacia, and the rest of the academic authors were paid consultants to Pharmacia. What the JAMA paper did not reveal was that the six-month results being reported were not the full results of the trial, which went considerably longer than six months. Even though the longer-term results were available, the authors chose to report only the six-month results, without explaining this to the JAMA editors — or to readers.

Independent analysis of the results of the full trial published elsewhere paints a different picture of Celebrex's widely touted safety advantage: in fact, the drug may be no safer and even slightly more harmful than the cheaper alternatives. A respected group from the University of British Columbia in Canada asserts that Celebrex actually has an "increased incidence of serious adverse events" when compared to the older, less expensive medicines.

Yet even knowing all this, many Australian doctors, urged on by drug reps and company-sponsored education, have continued their prescribing frenzy, racking up a cost to the PBS of $350 million in just 2 1/2 years. For their part, the JAMA authors and the company stand by their conclusions, and say they used the six-month results because they were more scientifically valid than the longer-term results. They do admit, however, that they could have "avoided confusion" by initially being more upfront with the JAMA editors.

"There is a distortion of the scientific evidence here, because claims that Celebrex had a huge advantage were based on incomplete data," says Dr Sid Wolfe, head of the Health Research Group at the powerful Washington D.C.-based consumer lobby, Public Citizen, a long-time campaigner against misleading drug

promotion.

Wolfe set up a "Doctors Bribing Hotline" in 1990, which produced cases that he testified about during Congressional hearings held the same year. According to his evidence, drug company Wyeth was giving doctors 1000 frequent flyer points in return for each new patient prescribed a new heart drug; Roche was paying $1700 kickbacks to doctors to prescribe an expensive antibiotic; and a number of companies were offering straight cash payments of $160 for doctors who attended "educational" dinners at hotels including the San Francisco Hyatt Regency.

Some of the strategies are even more insidious.

One that will be familiar to many Australian GPs involved a consortium of drug companies offering doctors almost $20,000 each in 1990 to help them buy expensive new prescribing software. What appeared to be a boon to doctors also enabled the companies to deliver drug ads straight to the desktop, and track prescribing patterns at the same time. The offer was taken up by thousands of doctors.

Perhaps the most costly contemporary example of misleading promotion is in the treatment of high blood pressure, an extremely common complaint among older Australians. For more than a decade, new, heavily promoted classes of drugs known as ACE inhibitors and calcium channel blockers have dominated the prescribing habits of doctors in Australia and elsewhere, without good scientific evidence they were any better than the older, cheaper alternatives for people with uncomplicated high blood pressure.

When a major, long-term trial was finally completed last year, it found that the older diuretics, or "water pills," were better at preventing some forms of heart disease than the newer, far more costly drugs. Leading researchers estimated the U.S. alone could have saved at least $5 billion a year by using the more effective, cheaper drugs. Australia could save an estimated $50 million a year at least. Significantly, it was public agencies that ran this study because they provided the bulk of its funding, though with important contributions from Pfizer and other drug companies.

Private industry now funds two-thirds of all bio-medical research and development in the U.S., and in Australia drug companies sponsor a large proportion of drug trials. While investment in finding new drugs is welcome, there is growing evidence of a "systematic bias" in medical research. Researchers studying this phenomenon are finding that company-sponsored studies are consistently far more likely to find favourable results for the sponsor's product, when compared to similar studies independently funded.

"The medical profession is being bought by the pharmaceutical industry, not only in terms of the practice of medicine, but also in terms of teaching and research," says Dr Arnold Relman, a Harvard professor and former editor of *The New England Journal of Medicine*, a pillar of the medical world.

"The academic institutions of this country are allowing themselves to be the paid agents of the pharmaceutical industry. I think it's disgraceful."

Relman is calling for a fundamental change in these relationships. For research, he is proposing new, not-for-profit bodies that could act as intermediaries, or "blind trusts," to put some genuine distance between scientists and their sponsors. As for education, he says doctors who rely on company-sponsored meetings are abdicating responsibility to their patients, and the profession should end its "financial and intellectual reliance on the pharmaceutical industry."

Many groups are encouraging doctors to seek more independent sources of information, including the Adelaide-based Healthy Scepticism — which argues that "misleading drug promotion harms health and wastes money," and the New York-based nofreelunch.org, which has the motto: "Just say no to drug reps."

The 30,000-strong American Medical Student Association has just launched a PharmFree campaign, to end all gift-giving, free lunches, sponsored education, and paid speaking by doctors. Students are being urged to take a recently revised Hippocratic oath which includes the following commitments:

"I will make medical decisions ... free from the influence of advertising or promotion.

I will not accept money, gifts, or hospitality that will create a conflict of interest in my education, practice, teaching, or research."

Professional organisations have been much slower to answer the calls for change, partly because they, too, are so reliant on industry funding for their annual conferences, education and other activities. Yet there are tentative signs of reform. The Society of General Internal Medicine (SGIM), representing thousands of specialist physicians in the U.S., adopted a policy last year limiting pharmaceutical funding to just 10 per cent of its annual budget. Sponsorship of its annual meeting shrank as a result but, says its president, the policy is here to stay.

Explaining the thinking behind the new policy, SGIM president, Professor Martin Shapiro, says: "You walk through the rooms of some other professional meetings and medical conferences and it just stinks with pharmaceutical propaganda and paraphernalia."

Even more significantly, there are plans afoot on the prestigious campus of the University of California, San Francisco, to end the drug-company-funded free lunches for doctors and totally remove drug representatives from their hospital wards.

Not surprisingly, those who represent the industry aren't embracing the trend towards disentanglement, although they are, under the pressure of growing concern, slightly revising their own codes of conduct. Medicines Australia's latest code, revised since the Pfizer harbour cruise revelations, prohibits companies providing entertainment at

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CPSC says consumers continue to use dangerous products despite recalls, warnings

Although we warn Health Letter *readers each month about recalls of unsafe drugs, medical devices and consumer products, the Consumer Product Safety Commission warns that consumers continue to use dangerous products despite recalls and warnings.*

The Consumer Product Safety Commission (CPSC) has warned that common consumer products that were recalled or the subject of warnings are still being used in many households. The CPSC released a list of several commonly found products in April. The list includes old power tools, which may lack modern features to prevent electrocution; old cribs, featuring widely spaced slats, corner posts higher than 1/16 inch, or cutouts in the headboard or footboard that may cause suffocation or strangulation; and children's jackets or sweatshirts with drawstrings around the neck, which can catch and strangle the child.

The products continue to be used, resulting in deaths, injuries, and property damage, according to CPSC Chairman Hall Stratton. "These products may be in any home. They may be sold at yard sales or donated to charity or thrift shops." Many cannot be made safe, and should be destroyed, he added.

A list of the most hazardous products available at the agency's Web site is at www.cpsc.gov.

Product Recalls

July 15, 2003 — August 15, 2003

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

DRUGS AND DIETARY SUPPLEMENTS

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

Name of Drug or Supplement; Class of Recall; Problem	*Lot #; Quantity and Distribution; Manufacturer*
Amiloride Hydrochloride Tablets, USP, 5 mg, 100 tablet bottles, Rx only; Class II; Mislabeled; Bottle labeled as containing 5 mg Amiloride Hydrochloride tablets actually contains Minoxidil 2.5 mg tablets	Lot 035607; Expiration Date: 12/2004; 4,821/100 count bottles distributed nationwide; Par Pharmaceutical, Spring Valley, NY
Children's Kaopectate (Bismuth Subsalicylate), 87mg/5mL, 6 fl oz (177 mL), Anti-Diarrheal, New & Improved, Cherry; Class II; Mislabeled; the dosing cup does not contain the appropriate dosing units of measure for teaspoon or mL as listed on the product's label dosing chart	Lots 86JHT and 01JKC; 385,241 bottles distributed nationwide and in Barbados and Guyana; Pfizer, Inc., Morris Plains, NJ

DRUGS AND DIETARY SUPPLEMENTS *cont.*

Name of Drug or Supplement; Class of Recall; Problem	*Lot #; Quantity and Distribution; Manufacturer*
Clobetasol Propionate Topical Solution; USP, 0.05%, (0.5 mg/g), Rx Only, 25 mL (0.85 FL OZ) and 50 mL (1.7 FL OZ) plastic bottles; Class III; Largest Related Substance Failure; Benzophenone (from varnish coating on container label)	Numerous lots; 295,228 bottles distributed nationwide; Alpharma USPD, Baltimore, MD
Levsin Elixir (hyoscyamine sulfate elixir USP), 0.125 mg/mL 473mL (I 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	Lot 20920; 393 bottles distributed nationwide; Schwarz Pharma Manufacturing, Seymour, IN
Levoxyl Tablets,(Levothyroxine Sodium Tablets, USP), 112 mcg, 1000 tablet bottles, Rx only; Class II; Tablet mixup; bottles labeled to contain Levoxyl 112 mcg were found to contain Levoxyl and Soloxine 0.2 mg tablets (Vet/Animal brand-Levothyroxine)	Lot No. 7941, Exp. Date 05/2004; 2,639 bottles distributed nationwide; King Pharmaceuticals, Inc., Bristol, TN
Lipitor Tablets (ATORVASTATIN CALCIUM) 10 mg, 90 tablets and 20 mg, 90 tablets; Rx only; Class II; Counterfeit product	Numerous lots; Approximately 174,955/90-tablet bottles distributed nationwide; Albers Medical Distributors, Kansas City, MO
Lipitor Tablets, (ATORVASTATIN CALCIUM), 20 MG, 90 and 1000 TABLETS bottles, Rx only; Class II; Counterfeit product	Lot 0511022; 7,189/90-tablet bottles, 15 1000-tablet bottles distributed nationwide; Local Repack, Inc., Richton Park, IL
Lithobid Tablets (Lithium Carbonate, USP) Slow Release Tablets, 300 mg, 100 tablet bottles; Class III; Rx only; Dissolution failure; 12 month stability	Lot 92263; 14,029 bottles of 100 tablets distributed nationwide; Solvay Pharmaceuticals, Inc., Marietta, GA
Premarin 0.625 mg Tablets, U.D. 100's (conjugated estrogens tablets, USP) Rx only; Class III; Dissolution failure (by manufacturer Wyeth)	Lot Number IJ00170; 5 cartons, 100 unit dose tablets distributed nationwide; Amerisource Health Services Corp., Columbus, OH
Ray Block Sunscreen Lotion, (Octyl Dimethyl PABA 5% and Benzophenone 3.3%) SPF 15, 1 FL OZ (29.6mL) and 4 FL OUNCES (118.3 mL); Class III; Superpotent; octyl dimethyl PABA and oxybenzone	Lot D32, expiration date 04/05; 319/4-oz and 324/1-oz bottles distributed nationwide; DEL-RAY LABS, INC., Birmingham, AL
0.9% Sodium Chloride Injection, USP, 100 mL, ADDS Unit Single-dose container, For I.V. use, Rx only; Class III; Mislabeled; incorrect bar code on overwrap of the product	Numerous lots; 980,592 bags distributed nationwide; Abbott Laboratories HPD/ADD, Abbott Park, IL

MEDICAL DEVICES

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

Name of Device; Class of Recall; Problem	*Lot #; Quantity and Distribution; Manufacturer*
AMO PhacoFlex II Model SI40NB, Intraocular Lenses; Class III; Post-operative complaints of cloudiness in the intraocular lenses	Numerous lots; 98 units sold in Brazil; Allergan Medical Optics Inc., Santa Ana, CA
Hill-Rom Newborn Bassinet; Class II; The caster/wheel may come off of the bassinet, causing the bassinet to tip	Model P247 and P248; 2,901 distributed nationwide and internationally; Hill-Rom, Inc., Batesville, IN

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MEDICAL DEVICES *cont.*

Name of Device; Class of Recall; Problem	*Lot #; Quantity and Distribution; Manufacturer*
Soft Contact Lenses (toric) packaged under the following labels: CV/ENCORE toric (methafilcon A) and ONEVUE 55 toric (methafilcon A) flexible wear; Class III; The actual sphere power of the lens is lower than the labeled value	Numerous lots; 23,762 6-packs / 76,748 singles (trial lenses) distributed nationwide and internationally; Coopervision, Inc., Scottsville, 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	*Lot #; Quantity and Distribution; Manufacturer*
Bicycle Forks. The forks on the bicycles can develop cracks near the crown area resulting in failure of the fork and posing a risk of injury to the rider.	317 sold at bicycle specialty stores nationwide from April 2003 through July 2003; Cervélo Cycles Inc., Toronto, Canada; (866) 296-3137; www.cervelo.com/wolfrecall
Big Boy Trucks (Dump Truck & Tow Truck). Small parts can break off of the toy trucks posing a choking hazard to young children.	220 sold nationwide from September 2002 through March 18, 2003; Magic Cabin, Viroqua, WI, HearthSong, Madison, VA; (888) 623-6557
Cordless Drill Drivers; Switch can malfunction and overheat, posing the possibility of a fire hazard to consumers.	Models CD1800, PS3700, PS3725, PSS3750; 265,000 sold nationwide from September 1997 through February 2002; Black & Decker Inc., Towson, MD; (866) 821-5444; www.blackanddecker.com
Earlyears Bobbie Bear Stacking Rings. Plastic knobs on the rings can detach, posing a choking hazard to young children.	Model number E00421; 5,000 sold nationwide from April 2002 through March 2003; International Playthings Inc., Parsippany, NJ; (800) 445-8347; www.intplay.com/recall.htm
Happyvillagers Toy Sets. The head can detach from the body of the villagers, posing a choking hazard to young children.	3,250 sold nationwide from Sept. 30, 2002 through March 11, 2003; HearthSong, Madison, VA; (888) 623-6557
Home Trends Kiddy Sling Chair. The small plastic bolt covers pose a choking hazard to small children.	75,200 sold at Wal-Mart stores nationwide from November 2002 through May 2003; (800) 925-6278; www.walmartstores.com
Ideal Solenoid Voltage Testers. These testers can short out at high voltages. Consumers can suffer burns.	Model numbers 61-065, 61-066, 61-067, 61-076, 61-079, and 61-080; 122,000 sold nationwide from December 1999 through July 2003; Ideal Industries Inc., Sycamore, IL; (877) 557-8598; www.idealindustries.com
Novelty Cigarette Lighters. The novelty lighters are not equipped with child-resistant mechanisms. They pose fire and burn hazards to young children.	8,000 sold in Texas from November 2002 through December 2002; De Bon Sales Inc., Houston, Texas; (713) 541-2100
Oil Lamp Boxed Sets. The bottles of paraffin oil in these sets do not have the child-resistant closures required by federal law.	Item number 054 11 0229; 4,000 sold at Target stores nationwide from February 2003 through March 2003; DesignPac, Northlake, IL; (800) 440-0680; www.target.com
Slow Cookers. The handles on the base of the slow cookers can break, posing a risk of burns from hot food spilling onto consumers.	Hamilton Beach and Proctor-Silex; 2.7 million sold nationwide from January 1999 through December 2002; Hamilton Beach/Proctor-Silex, Glen Allen, VA; (800) 429-6363; www.proctor-silex.com

CONSUMER PRODUCTS *cont.*

Name of Product; Problem	*Lot #; Quantity and Distribution; Manufacturer*
Smart Dive Computers. The computer's alert signal system may not work properly and the computer screen may freeze. This may cause inaccurate information to be displayed, such as water depth, tank pressure, and ascent rate, posing a risk to the safety of a diver.	UWATEC Smart PRO and the Smart COM dive computers; 6,000 sold nationwide from February 2002 through June 2003; UWATEC AG, Hallwil, Switzerland; (800) 808-3948; www.uwatec.com
Toad Lawn Ball Sprinkler. A small hose inside the toad can fail, allowing water to fill the toad's cavity. The increased water pressure can cause the toad to explode, posing the risk of injury to anyone nearby.	Model number 738449 508893; 4,000 units sold nationwide from August 2002 through June 2003; Midwest, Cannon Falls, MN; (800) 776-2075
Trampolines. Welds on the frame of these trampolines can break during use, causing consumers to fall to the ground and suffer injuries.	116,000 sold nationwide from January 2003 through May 2003 under the brand names Hedstrom and NB; Hedstrom Corp., Bedford, PA; (800) 841-4351; www.hedstrom.com

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educational meetings which they organise.

In the fine print, however, entertainment can take place at events sponsored by companies, but organised by a third party, as long as it is not "significant." Similarly, the code allows companies to continue flying doctors to favoured destinations — via business class — for their "education," and continue paying all their expenses once they get off the plane.

The Pharmaceutical Research and Manufacturers of America's new code explicitly allows a drug company to gather together 300 doctors, fly them all to a golf resort and pay them for coming — in order to train them to become part of the company's stable of paid speakers. PhRMA's senior vice-president for scientific and regulatory affairs, Dr John Kelly, says the new code is designed for the benefit of patients, because their doctors will get the "best available information" about medicines at company-sponsored educational events.

Doctors and industry commonly justify continued company sponsorship of medical education by arguing there is no alternative — without it, important events and meetings would simply not happen. "Nonsense," says Dr Drummond Rennie, a deputy editor with JAMA and a strong critic of doctor-drug company entanglement. "That argument presupposes that some of the most well-off in our society can't afford to pay for their lunches, their education, their conferences. But guess what, all sorts of poorer people pay every step of the way. No one is handing out money to them. When I hear doctors crying poverty ... and an inability to pay for their education, I feel ashamed of my profession, because these are self-evident lies."

For Joe Gerstein, who was offered the fake "educational grant," the current wave of change, such as it is, has been a long time coming. He recalls the day he graduated as a doctor. He was presented by the dean's office with a beautiful leather doctor's bag, his name engraved in gold lettering on the side. Asking what prize he had won, he was told the bag was a gift from a large pharmaceutical company. Much to the annoyance of the dean's office, he rejected the gift, and the following year, according to Gerstein, the entire class of medical students did likewise. That was in 1961.

It's everywhere: the kickback pandemic

In Germany, more than 1000 doctors and hundreds of employees of SmithKline Beecham — now part of GlaxoSmithKline (GSK) — are being investigated over incentives to doctors. Since the scandal broke, GSK has announced new guidelines.

In Italy, 3000 doctors and scores of GSK staff are under investigation over alleged payments of illegal incentives, including trips abroad and large cash payments with fictitious justifications. According to news reports, more than 10,000 hours of phone taps revealed examples of sales reps offering gifts in return for increased prescriptions. Police raids have uncovered documents suggesting "lavish gifts such as stereos, books and personal computers." A senior prosecutor was quoted saying that some company executives could face jail sentences of up to five years if found guilty of illegal gift-giving, and GSK officials were reportedly cooperating with authorities. Italian police have since announced the investigations have widened to include other pharmaceutical companies.

In Holland in 2001, Merck Sharp & Dohme (MSD) was fined by authorities for funding phony educational meetings at holiday destinations, where doctors enjoyed dinners, bike tours, walks and performances, along with listening to "thought leaders" talk about MSD's latest migraine product, according to the Dutch daily newspaper *Trouw*.

In 2001, the Health Care Inspectorate in Holland analysed the marketing strategies of 10 companies, finding that doctors were offered computers as part of dodgy scientific studies, sponsored educa-

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tional activities were not "independent," lavish hospitality was regularly provided, and payments to "thought leaders" could be seen as illegal inducements.

The New York attorney-general has just launched a major criminal case against GSK, alleging that the company engaged in "commercial bribery" and "repeated fraudulent acts" by offering financial kickbacks to doctors to induce them to prescribe GSK drugs, including the well-known Ventolin. GSK rejects the allegations and is defending itself vigorously.

California's attorney-general is taking action against several large companies, including Wyeth and Abbott Laboratories (parents of TAP), alleging they offered doctors an "unlawful financial inducement ... in order to increase their market share and profits."

Like the New York investigation, this case allegedly involves doctors being offered free or cut-price drugs, which they can then resell at greatly inflated prices to patients or the government. Both companies say they have abided by the law, and are fighting the action.

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provided, as measured by 8 objective consensus-based criteria, was about 50 percent." The notion that consumer drug information can be 50 percent useful is unfathomable. Drug information that communicates only half of what it should is misleading, and misleading drug information is potentially dangerous.

Second, the FDA's conclusion and recommended course of action was extraordinary: "Because the agency sees progress in meeting the goals set under Public Law 104-180, FDA will continue to work with private sector partners to improve the usefulness of patient information, and meet the goal for the year 2006, ..." Amazingly, the FDA determined that the failure of all 1,300 leaflets to comply with the Action Plan guidelines was "progress."

Public Citizen had no option but to file suit since the FDA seemed content with the "progress" thus far and was not planning to challenge the well-documented failure by convening a public meeting as required by the law.

Underscoring the lack of public access to useful, scientifically accurate drug information are the results of a survey by Public Citizen assessing the content quality of black box warning information intended for consumers. The survey involved 23 top-selling drugs in the U.S. in 2002 that are required to include a black box warning in their professional labeling. (It should be noted that the above-mentioned Wisconsin study commissioned by the FDA did not include any drugs with black box warnings.) Using the guidelines of Public Law 104-180[1] the major results of this survey are:

1. None of the patient drug information leaflets (0/23) being distributed in a Washington, D.C. CVS Pharmacy or available on the web site of CVS Pharmacy for the top-selling drugs with black box warnings complied fully with the guidelines. This information was produced by First DataBank, Inc of San Bruno, CA.

2. None of the information (0/23) from the United States Pharmacopeia Drug Information (USP-DI) Advice for the Patient used under license to Micromedex, a business of Thomson Healthcare Inc., for these drugs meets the quality goals for communicating black box warning information to consumers.

3. Information for only four drugs (4/22) from MedMaster, a product of the American Society of Health-System Pharmacists (ASHP), fully complied with the quality guidelines concerning black box warning information as defined in Public Law 104-180.

These results are extremely troubling. First, the information contained in black box warnings is the most serious type of warning the FDA can require and is the most important to the health and safety of prescription drug consumers. Second, the information from Micromedex-Thomson Healthcare Inc. and the American Society of Health-System Pharmacists was downloaded from the web site of the National Library of Medicine's MEDLINEplus web site. This is a site that proclaims that both health professionals and consumers can "... depend on it for information that is authoritative and up to date."

We find it irresponsible that the management of the National Library of Medicine, a part of the prestigious National Institutes of Health, uncritically features on its web site drug information that is unregulated and fails to meet minimum quality standards. By allowing this information on its web site, the National Library of Medicine gives credibility to drug information that misleads the American public. We strongly urge the Director of the National Library of Medicine, Donald A. B. Lindberg, M.D., to eliminate this information from the library's web site and to replace it with more accurate and complete information.

Consumer access to useful drug information through FDA regulation or by voluntary private sector programs has been at the center of a contentious debate for more than 25 years. The divisions have been along ideological lines, with industry, professional trade groups, and industry-supported organizations favoring a "marketplace for information" and consumers preferring a government-regulated program with quality standards and oversight.

The research has been done and the history is clear. There is no longer any legitimate argument in continuing to consider voluntary private sector programs as a solution for providing consumers with useful, scientifically accurate, written drug information. This is a failed paradigm.

The fact that manufacturers are required to write professional product labels that must be approved by the FDA before they are distributed, but that consumer drug information has been left in the hands of unregulated commercial information vendors who have consistently failed to follow voluntary quality guidelines, is irrational for the following reasons:

1. The FDA has the authority to require agency-approved, written consumer drug information to be distributed with each new and refill prescription for a limited number of drugs under a rule that took effect on June 1, 1999. Only a minor modification of this rule would be needed to cover consumer information for all prescription drugs.

2. Multinational pharmaceutical companies operating in the European Union have been required for a decade to produce and distribute written consumer drug information based on a drug's professional product labeling that is approved by member states' drug regulatory authorities. Why does government-regulated consumer information exist for all drugs in Europe and not in the U.S.?

3. The infrastructure already exists in the U.S. for distributing written information to the majority of prescription drug consumers. The University of Wisconsin study found that 89 percent of consumers were receiving some sort of information even though it was clearly substandard. Obviously the cost of distributing this information has already been passed on to consumers and it would be no more expensive to distribute useful, scientifically accurate information than inferior information.

Dr. Mark B. McClellan, the new FDA commissioner, has listed, as one of his top five priorities, helping consumers to get truthful information about products they use so they can make informed decisions. The commissioner can go a long way in achieving this priority by immediately moving forward with a long-overdue initiative to require the mandatory distribution of FDA-approved written drug information with each new and refill prescription. It is time to end the double standard wherein doctors and other health professionals use and are informed by FDA-approved labeling but patients, like second-class citizens, get whatever the out-of-control purveyors of patient information leaflets choose to have dispensed to them with their prescription drugs.

[1] Action Plan for the Provision of Useful Prescription Medicine Information, December, 1996, adopted by HHS Secretary Shalala in January, 1997. The recommendation concerning placement and content of black box warning information was that it should be placed immediately after the name of the drug in the patient information leaflet (the first item) and should be "a prominently displayed statement that is consistent with or derived from any "black box" warnings (as required by FDA on the professional labeling) that are relevant to the consumer."

FDA-Approved Patient Information Needed

The following comments by Sidney M. Wolfe, M.D., and Larry D. Sasich, Pharm.D., were presented at the FDA Hearing on the Current Status of Useful Written Prescription Drug Information for Consumers on July 31, 2003.

Twenty-two years ago, in 1981, the carefully researched regulation requiring FDA-approved patient information leaflets to be dispensed with prescriptions was cancelled by the Reagan administration just before it was to have gone into effect. This abrupt reversal was at the behest of drug companies, pharmacy organizations and some physician groups, and private sector-designed leaflets, not approved by the FDA, thereby continued to be the norm.

This meeting marks the start of the process that must culminate in the restoration of FDA-approved patient information leaflets as a safer alternative to the dangerously-failed voluntary private sector labels. The fact that Public Citizen had to file suit in Federal District Court in February of this year to compel the Food and Drug Administration (FDA) to hold this public meeting on the failure of voluntary private sector programs to provide consumers with useful, scientifically accurate written drug information escapes all reason. The law is clear. If private sector initiatives fail to achieve the information quality and distribution goals defined in Public Law 104-180 of 1996, the Secretary of Health and Human Services "shall seek public comment on other initiatives that may be carried out to meet such goals."

In June 2002, the FDA announced the results of a University of Wisconsin assessment of the quality of drug information being distributed by pharmacists as required by Public Law 104-180. None of the approximately 1,300 leaflets studied for four common drugs achieved the minimum goals for useful, scientifically accurate drug information. This failure was not at all surprising and is consistent with the private sector's performance since (and before) the creation of the National Council on Patient Information and Education (NCPIE) in 1982, with significant support of the pharmaceutical industry.

This FDA announcement last year of the findings of the University of Wisconsin study was remarkable in two respects. First, the FDA said " ... the overall usefulness of information

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