Health Letter

SIDNEY M. WOLFE, M.D., EDITOR JULY 2002 ◆ VOL. 18, NO. 7

Big Pharma Buys Psychiatry: An Aura of Scandal

This article appeared in the American Prospect *magazine.*

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In an era of mega-mergers and acquisitions, eyebrows have nonetheless been raised by the virtual wholesale purchase of the psychiatric profession by the pharmaceutical industry. This is the first acquisition of a medical specialty by Big Pharma, as the large pharmaceutical corporations are widely known, but almost certainly not the last. Cardiology is rumored to be next on the auction block.

The purchase had been anticipated since antidepressant and antipsychotic drugs became top-selling pharmaceuticals. For example, last year fluoxetine (Prozac) and olanzapine (Zyprexa) together accounted for almost half of Eli Lilly's total sales. Sales of antipsychotic medications quadrupled in the past four years to over $4 billion. These drugs are a major reason why during the 1990s the profitability of the 11 pharmaceutical companies in the Fortune 500 "was almost four times greater" than the median for all Fortune 500 companies, according to a report by Public Citizen.

In contrast to companies selling computers or other consumer products, pharmaceutical companies cannot sell their prescription required products directly to consumers. Physicians must be persuaded to write the prescriptions, and in the United States it has been estimated that pharmaceutical companies spend $8,000 to $13,000 per physician per year to accomplish this. For psychiatric drugs, this means psychiatrists must be persuaded by almost whatever means works.

I had the opportunity to observe the persuasion of my psychiatric colleagues in July 2001 at the 7th World Congress of Biological Psychiatry in Berlin. Some 4,000 individuals crowded the convention center to hear five days of talks. Until a decade ago, such meetings consisted of small booths in which pharmaceutical companies passed out pens or notepads with their companies' logos, and most speakers were assumed to be presenting data and

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opinions based upon their true scientific beliefs.

That all changed when Big Pharma arrived. One of my colleagues refers to the current "scientific" meetings as "pharma jamborees." For example, in Berlin, there were 15 major displays one had to pass through just to reach the lunch area. The displays included an artificial garden (Janssen-Cilig), a brook running over stones (Lundbeck), and a 40-foot rotating tower (Novartis). Many displays featured flashing lights and mirrors, and almost all offered free coffee, juice, sweet rolls, sodas, candy, wine, T-shirts, or other inducements designed to get psychiatrists to pause so that an army of smiling sales representatives could give their sales pitch. In walking through the displays, I was reminded of an old-fashioned carnival in which hucksters in booths vied with each other to separate the unsuspecting from their loose change.

Eli Lilly's display was of particular note. It included two large, walk-through tunnels set up like funhouses. One tunnel, labeled "Zyprexa," included a mirrored room with dozens of telephones dangling from the ceiling. I pondered briefly whether Lilly was trying to persuade me that God was calling, telling me to prescribe Zyprexa, but the sales representative said no, the phones were just to illustrate the communication problems that are common in schizophrenia and that Lilly claims Zyprexa improves. The other funhouse was labeled "Prozac" and included as its central display a large, 10-foot mouselike creature sitting in front of a blank television screen. I asked the staff whether Lilly was recommending Prozac for mice, but the representatives said no, the creature was really a depressed man who was out of energy and needed Prozac. I suspect what they were really trying to convey, subliminally, was that Prozac would transform this creature from a mouse into a man.

My favorite display, however, was one set up by Organon, a Dutch pharmaceutical firm, to advertise mirtazapine (Remeron), an antidepressant. The center of the display was a small multihued tent with purple doors and the head of a genie painted on its top. Inside the tent was a red robed young woman with sprinkles in her hair, taking Polaroid pictures, one by one, of psychiatrists who had waited patiently in line for 20 minutes or more for this unusual opportunity. This was no ordinary picture but rather a picture of one's aura, being taken, as the Organon brochure noted, "with advanced biofeedback equipment." The equipment consisted of two small machines, sitting on purple draped tables, on which I placed my hands. The result was a picture of my head peering out of a red, orange, and yellow cloud. According to the brochure, "the aura colors give you information about your appearance, character, talents and future energy." After taking my picture, the red robed young woman escorted me to a yellow robed young woman who had even more sprinkles in her hair. "Hi! My name is Amber," she said, and then proceeded to interpret the picture of my aura as indicating intelligence and good judgment, although she said she detected some hints of skepticism among the colors.

Such experts are normally given business class airline tickets, four star hotel accommodations, and an honorarium by the pharmaceutical company.

I privately asked members of the Organon sales staff if they thought it was a wise sales approach to associate their product with auras, magic, New Age thinking, and anti-science. They said the decision had been made at "a higher level" but pointed out that the waiting line was an ideal place for engaging psychiatrists in brief, friendly chats about the virtues of mirtazapine, and that indeed was taking place.

In addition to an opportunity to view one's aura, the Congress offered 136 symposia plus a variety of workshops and lectures. Among the symposia, 23 were clearly labeled as being sponsored by pharmaceutical companies; all focused on the pharmacological treatment of psychiatric disorders, e.g. "Treating Patients with Schizophrenia," sponsored by Pfizer. Each symposium utilized two to four psychiatric experts brought to the Congress by the sponsoring pharmaceutical company.

Such experts are normally given business class airline tickets, four star hotel accommodations, and an honorarium by the pharmaceutical company. I surveyed 18 of these experts from the United States and Britain about the size of their honoraria, promising them anonymity. The usual amount for British experts was $2,000 for one lecture; for American experts it was more often $3,000. If the expert organized the symposium, the payments went as high as $5,000. Some of the experts were contributing their honoraria to their laboratory research fund; others were keeping it as income. Special cases were described in which the payment could go even higher, especially if the expert presented data that were very favorable to that company's drug (or at least presented data that was not especially favorable in a very favorable light). One American expert had been paid $10,000 last year to fly to Europe to give a single lecture. Another is so well known for his pro-industry presentations that a member of his department told the pharmaceutical representative: "Why don't you just give him a Mercedes all at once rather than piecemeal?"

The pressure by pharmaceutical companies to shape the psychiatric experts' message is not subtle. One European expert told of being sent to Israel to present his research on the use

of antidepressants. After the trip, the company told him that they would also like to send him to South Africa to give the talk but that he first needed to "clarify" his message; he declined to do so. An American expert related how he had given drug company sponsored talks for a brief period but then stopped, he said, "because I felt increasingly like a whore." Such experts are aware that larger honoraria and invitations for future meetings are directly dependent on how they present their data. Emphasizing adverse effects of a drug, for example, may well cost the expert a trip to future congresses, scheduled for venues such as Copenhagen, Buenos Aires, Jerusalem, and Sydney. Some of the psychiatric experts who were sponsored by a pharmaceutical company are also on the company's speakers bureau and/or own stock and thus have a direct financial interest in the success of the company's products. The utilization of influential psychiatrists as, in effect, drug sales representatives is part of a recent trend throughout medicine. The May 2000 edition of *Pharmaceutical Marketing* outlines what it calls the "tricks of the trade" in recruiting "opinion leaders" and then "ensuring your product champions communicate effectively on your behalf."

In addition to the symposia specifically identified as sponsored by pharmaceutical companies, many others included speakers whose expenses and honoraria were provided by pharmaceutical companies, but this was not publicly noted. Symposia and workshops on subjects not directly concerned with drug prescribing had little, if any, industry support. The speaker at one such symposium, which was attended by only a handful of individuals out of the more than 4,000 meeting registrants, said that he "felt like the legitimate act at a Burlesque show, included only to keep the cops out."

The ultimate targets for this pharmaceutical extravaganza, of course, were the practicing psychiatrists who write prescriptions for their patients and who constituted the vast majority of attendees. Although meeting officials were reluctant to provide precise numbers, they acknowledged that more than half of the attendees had been sponsored by pharmaceutical companies. Such sponsorship normally includes tourist class airfare, hotel accommodations, and Congress registration fees as well as special receptions and parties, some complete with dancing girls. Pharmaceutical companies in many countries can now use computerized pharmacy databases (which delete the names of the patients) to ascertain how many prescriptions per month any given physician writes for any given drug. It is thus possible, for example, for Eli Lilly to sponsor Dr. Smith from Detroit or Manchester, send him to Berlin to the Congress, and then monitor his prescribing pattern following the Congress. If his prescriptions for olanzapine (Zyprexa) and fluoxetine (Prozac), Lilly's flagship products, do not increase sufficiently, then a drug representative can remind him how well he was treated in Berlin. And besides, isn't he interested in going to Copenhagen next June? Such scenarios are said to occur increasingly often.

There is clear evidence that attending meetings such as the Berlin meeting does affect the prescribing practices of physicians. In one U.S. study, 10 physicians were invited by a pharmaceutical company to attend "all-expenses paid" symposia at "popular sunbelt vacation sites." The prescribing patterns of the physicians for two drugs being marketed by the company were tracked for 22 months before and 17 months after the symposia. Despite the fact that the physicians had predicted that their attendance at the symposia would not affect their prescribing practices, their prescriptions for one drug increased 87 percent and for the other, 272 percent. Other studies have shown that attending drug sponsored education courses and talking to drug representatives do affect physicians' drug prescribing practices even though the physicians deny that they are so influenced. Indeed, if it were otherwise, why would pharmaceutical companies sponsor such activities?

Does any of this really matter? Isn't this just a classic example of market forces at work in a capitalist society? Pharmaceutical companies should not be criticized for doing what they do, since they are following the accepted rules. If some of their practices seem more in keeping with carnival sideshows, why should we expect loftier behavior?

In fact it does matter for two reasons. First, patient care suffers when physicians have incomplete information. Psychiatrists trying to decide which antipsychotic to use for a patient with schizophrenia are not told that the psychiatric expert who is minimizing the adverse effects of Zyprexa receives a $10,000 per year retainer from Eli Lilly and also owns substantial company stock. Or that the psychiatric expert claiming that Remeron reverses depression more rapidly in suicidal patients receives $75,000 per year from Organon to support his laboratory. Drug assessments in psychiatry have become so compromised by pharmaceutical company payments to psychiatric experts that I personally do not trust data presented by more than half of my colleagues.

Second, the present arrangement adds to the cost of drugs. Payments to aura interpreters and dancing girls are simply passed on to those who have to buy the drugs. The pharmaceutical company costs for the Berlin Congress were at least $10 million; what that purchased was mostly a good time for psychiatrists, who can afford to pay for it themselves, and the opportunity for drug companies to exert their influence. According to a recent report, in 2000 the 11 pharmaceutical firms in the Fortune 500 "devoted nearly three times as much of their revenue to marketing and administrative costs (30 percent of revenue) as to research and development (12 percent of revenue)."

Several steps could be taken to reverse the present situation. Pharmaceutical companies should be banned from providing gifts and sponsoring lunches for medical students and residents in training; the free pizza from the drug representative may seem trivial, but in fact, it sets a pattern that rationalizes accepting a free trip to Berlin after training is finished. Students and residents should also be made aware of No Free Lunch (www.nofreelunch.org),

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Product Recalls

May 7—June 5, 2002

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 & 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 reasonable probability that the use of or exposure to the product will cause serious adverse health consequences or death. Class II recalls may cause temporary or medically reversible adverse health consequences. A Class III situation is not likely to cause adverse health effects. If you have any of the drugs noted here, label them *Do Not Use* and put them in a secure place until you can return them to the place of purchase for a full refund. You can also contact the manufacturer. If you want to report an adverse drug reaction to the FDA, call (800) FDA-1088. The FDA web site is *www.fda.gov*.

Name of Drug or Supplement; Class of Recall; Problem	*Lot #; Quantity and Distribution; Manufacturer*
Bactroban Ointment, brand of mupirocin, 2% ointment, 22 gram tubes, Rx only, distributed under SmithKline Beecham Pharmaceuticals label; Class II; Microbial contamination; presence of pseudomona fluorescens, burkholderia pickettii or ralstonia paucula	Lot No. EXP date: 50-1B25 11/30/2002 29-1B25 9/30/2002 62-1B25 11/30/2002 84-1B25 2/28/2003 94-1B25 3/31/2003 106-1B25 4/30/2003; 194,580 units distributed nationwide; Glaxo SB Pharmco Puerto Rico, Inc., Cidra, Puerto Rico
Combivent Inhalation Aerosol (ipratropium bromide 18 mcg and albuterol sulfate 103 mcg) 14.7g canister, 200 metered actuations, Rx only; Class II; Defective container; inhaler may not fire properly and patients will not receive their full dose of medication	Lots 165090A, 165092A, EXP 5/03; 192,089 units total distributed nationwide; Boehringer Ingelheim Pharmaceuticals, Inc., Ridgefield, Connecticut
Cortizone 5 and Cortizone Kids Creme, (hydrocortisone) 0.5%, anti-itch creme, 0.5, 0.65, 1, 1.3 and 2 ounce tubes, over-the-counter; Class III; Subpotent for hydrocortisone ingredient (stability)	All lots within expiry; 2,181,859 tubes distributed nationwide and in Puerto Rico; Pfizer Consumer Healthcare, Morris Plains, New Jersey
Hydrochlorothiazide Tablets, 25 mg, 1000-count bottles; Class II; Lot no. 101607A, EXP 10/04; Tablet mixup with Hydrochlorothiazide 50 mg and/or Acyclovir 400 mg tablets	Numerous lots; 17,117 bottles distributed nationwide; Ivax Pharmaceuticals, Inc., Miami, Florida
Junior Strength Motrin Tablets, grape flavored, chewables (Ibuprofen 100 mg) 24 tablets per bottle; Class II; Tablet mix-up; product may contain one or more Women's Tylenol Menstrual Relief Caplets	Lot EBM073 EXP 2/03; 79,968 bottles distributed nationwide; McNeil Consumer & Speciality Pharmaceuticals, Fort Washington, Pennsylvania

BIG PHARMA, *from page 3*

an organization dedicated to "pharmaceutical facts." As one observer summarized it in the *New England Journal of Medicine*: "Medical training should not include acquiring a sense of entitlement to the largesse of drug companies."

Practicing psychiatrists should get their continuing education from objective sources such as the *Medical Letter* and the Cochrane reviews rather than from drug detail persons and industry sponsored talks. For psychiatric experts, standards should be developed that would prohibit experts who are involved in drug trials or giving talks at symposia from owning stock in pharmaceutical companies. The problem in developing such standards is that most of the professional organizations that should be involved, such as the American Psychiatric Association, are themselves so indebted to the pharmaceutical industry that they are reluctant to offend it.

For speakers at symposia such as the Berlin meeting, the solution is simple. Prominently displayed next to the speaker's lectern should be a sign for each speaker reading: "For this talk, Dr. Smith is being paid $3,500, business class airfare, and four star hotel accommodations by Eli Lilly and Company." At least then the listeners would have the facts needed to properly evaluate the speaker's presentation.

DRUGS & DIETARY SUPPLEMENTS *cont.*

Name of Drug or Supplement; Class of Recall; Problem	*Lot #; Quantity and Distribution; Manufacturer*
MAXAIR Inhaler With Oral Adapter (pirbuterol acetate) 0.2 mg per actuation, 25.6g inhalation aerosol, 300 metered inhalations, Rx only; Class II; Defective container; inhaler may stick intermittently and patients may not receive the expected puff of medication	Lots 000644 and 000756 August '03, 000947 October '03, 001009 Nov. '03, 001110 and 001111 Dec. '03, 010025 Jan. '04, 010195 and 010283 March '04, 010413 April '04, 010482 and 010414 May '04, 010580 June'04, 010708 and 010709 July '04, 011210 Dec. '04; 737,975 inhalers distributed nationwide; 3M Pharmaceuticals, Inc., St. Paul, Minnesota
Ortho Micronor Oral Contraceptive Tablets (norethindrone) 0.35 mg, 28 tablets in a ring-shaped blister pack, Rx only; Class III; Mislabeling; incorrectly informs user that missing any pills 22-28 will still leave them protected	Lots 11M001 and 11M002 EXP 11/04, 12C003 EXP 01/05, 12C004 EXP 02/05, Physician Sample Lots 11M019 EXP 11/04, Refills: Veridate 12A029 and 12C030 EXP 01/05; 379,656 blisters, 124,704 samples distributed nationwide; Ortho-McNeil Pharmaceutical, Inc., Raritan, New Jersey
Q-Bid DM Sustained Release Tablet (guaifenesin 600 mg/ dextromethorphan 30 mg), 100 tablet bottles, Rx only; Class III; Tablet mix-up; Q-Bid LA tablet containing the active ingredient guaifenesin was found in a bottle of Q-Bid DM	Lot No. 005F1F; 14,150 bottles of 100 tablets distributed nationwide; Vintage Pharmaceuticals, Inc., Huntsville, Alabama
Rocaltrol (calcitriol) Oral Solution, 1 mcg/ml, 15 ml bottles, Rx only; Class III; Subpotent active ingredient calcitriol (18 month stability)	Lot Number: U0005 EXP 2/03; 5,692 bottles distributed nationwide; Hoffmann La Roche, Nutley, New Jersey
Triamcinolone Acetonide Lotion, 0.1%, Rx only, 60 mL plastic bottles; Class III: Subpotent (stability)	Numerous lots; 402,037 bottles distributed nationwide and in Puerto Rico; Thames Pharmacal Co., Inc., Ronkonkoma, New York

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 1-800-FDA-1088. The FDA web site is *http://www.fda.gov.*

Name of Device; Class of Recall; Problem	*Lot #; Quantity and Distribution; Manufacturer*
Amira At Last Brand Blood Glucose Test System; Class II; Alternate site results not reliable when patient blood glucose level is low	All units/lots; 250,000 meters distributed nationwide and in Japan; Amira Medical, Scotts Valley, California. Recalled by Roche Diagnostics Corp., Indianapolis, Indiana

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 1-800-638-2772. The CPSC web site is *www.cpsc.gov.*

Name of Product; Problem	*Lot #; Quantity and Distribution; Manufacturer*
Candles; Pieces of the wick can fall off while burning and it can re-ignite after extinguishing, posing a burn and fire hazard	Single wick surrounded by wax in a brown coconut shell with 20 different scents; 29,000 sold in Hawaii and California from April 2000 through April 2002;.Island Soap & Candle Works, Honolulu, Hawaii (877) 535-5566 www.luxous.com
Cotton Candy Machines, Recall to Repair; Motors on the cotton candy machines can jam and overheat, posing a fire hazard. Additionally, the heating unit can be activated without the spinner in place, presenting a risk of burn	Blue or a purple base and a clear plastic cover. The words "The Real Cotton Candy Machine" are printed in a rainbow of colors on the base of the machine; 188,000 sold nationwide from September 2001 through April 2002; Rose Art Industries Inc., Livingston, New Jersey (888) 262-4474 www.roseart.com

Name of Product; Problem	*Lot #; Quantity and Distribution; Manufacturer*
Earthquake Gas Shut-Off Valves; Valves could stick in the open position allowing gas to flow freely, which poses a risk of serious injury to consumers from fire and explosion during an earthquake	Northridge 2000; 600 sold in Washington from February through April 2001; Seismic Safety Products Inc., Wenatchee, Washington (800) 948-3782 www.seismic-safety.com
Extension Cords; Cords have reversed polarity, which can present electric shock and electrocution hazards	Black and about one to two feet long. The letters "MSL" are imprinted on the cord's three-pronged plug. The single-receptacle cords have the website, www.ziotek.com, printed on the cord; while the double-receptacle cords have the name "ZIO TEK" printed on the splitter; 12,000 sold in Cyberguys catalogs and on website from January through March 2002; E-filliate Inc., Rancho Cordova, California (800) 327-6703 www.cyberguys.com
Gas Grills, Warning to Consumers; Design allows consumers to light the grill at an air intake tube, instead of at the burner, gas inside the tube ignites. The tube can reach temperatures of up to 750 degrees Fahrenheit and present a burn hazard to consumers. In earlier models, the grill collapsed creating a burn and fire hazard	Red Devil, lid also reads The Portable Outdoor Kitchen; 155,000 sold nationwide from May 1998 through January 1999; e4L Inc. and Quantum North America Inc., Encino, California. Contact the CPSC hotline at (800) 638-2772 for more information
Hammer Drills; The on-off trigger can stick, or the lock-on button can jam, posing a risk of physical injury to consumers	Model HD501; 6,000 sold nationwide from December 2001 through January 2002; Ryobi Technologies, Inc. (RTI), of Anderson, South Carolina (800) 867-9624 www.ryobitools.com
Infant Car Seats/Carriers; When the seat is used as a carrier, plastic handle can unexpectedly release from the carrying position, posing an injury hazard to an unrestrained infant	Safety 1st and Beatrix Potter Designer 22; 26,000 sold nationwide from January through April 2002; Dorel Juvenile Group Inc., Columbus, Indiana (800) 536-1090 www.djgusa.com
Mountain Bicycles; Chainstay that holds the rear wheel in place can fail, causing the rear wheel to separate from the bicycle, which can cause the rider to lose control	16.5-, 18- and 19-inch Slayer and Edge full- suspension; 660 sold nationwide from January 2001 through February 2002; Rocky Mountain Bicycles, Delta, British Columbia, Canada (800) 663-2512 www.bikes.com
Portable Fluorescent Lamps; The ballast (the electrical part located in the arm of the lamp) in these lamps can overheat, short-circuit, and melt the insulating cover of the ballast causing the lamp to fail and posing a burn hazard to consumers	18 watt portable, designed to mount to a desk or sit on a base, Model PS355 and PS360; 18,300 sold nationwide from January 2000 through February 2002; Luxo Corp., Port Chester, New York (800) 222-5896
Power Plus Automotive Chargers; When used under low voltage conditions, the chargers can overheat, posing a fire hazard	Plug into automotive cigarette lighters to charge power tool batteries; 18,000 sold nationwide from March 2000 through April 2002; Milwaukee Electric Tool Corp., Brookfield, Wisconsin (800) 414-6527 www.heavydutytool.com
Speaker Power Adapters; Power cord connector is not grounded, posing a potential shock hazard to consumers	Included in Hewlett-Packard's P1534A External Amplified Speaker sets. There is a label on the bottom of the speakers with the model number "P1534-60001"; 93,000 sold nationwide from October 2000 through April 2002; Philips Electronics, New York, New York (800) 870-7193 www.philips.com/us or www.hp.com
Total Gym Exercise Machines; Handles on these exercise machines can detach during use and the cable attached to the handles can break, resulting in injury to the user	Total Gym(r) 1000 and the Total Gym(r) Pro; 310,000 sold nationwide from June 1997 through October 2001; Fitness Quest Inc., Canton, Ohio (800) 321-9236 www.fitnessquest.com

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Conflict of Interest? Medical Journal Changes Policy of Finding Independent Doctors to Write

The following story was reported on the ABC Evening News on June 12, 2002 by John McKenzie.

Is it a case of, "If you can't beat 'em, join 'em?"

The *New England Journal of Medicine* will announce Thursday that it has given up finding truly independent doctors to write and review articles and editorials for it, as a result of the financial ties physicians have with so many drug companies in the United States. The *Journal* says the drug companies' reach is just too deep.

In 2000, the drug industry sponsored more than 314,000 events for physicians—everything from luncheons to getaway weekends—at a cost of almost $2 billion. On top of that, many doctors accept speaking and consulting fees that link them to drug companies.

No publication in this country influences the way your doctor treats an illness more than the *New England Journal of Medicine*. Since 1812, the *Journal* has scrutinized and published thousands of clinical studies.

These "review" articles on drug therapy can be pivotal. They tell doctors the strengths and weaknesses of new medications for everything from high blood pressure to obesity to cancer. Now, the *Journal* will allow these critical evaluations to be written by people with financial ties to drug companies.

"This change will allow us to recruit the best authors, the people who have experience with new treatments to write these editorials and review articles," said Dr. Jeffrey Drazen, the medical journal's editor-in-chief.

In 2000, the drug industry sponsored more than 314,000 events for physicians.

Under the new policy, doctors writing reviews in the *Journal* can accept up to $10,000 a year from each drug company in speaking fees and consulting fees.

Concerns About Possible Bias

Not everyone thinks this is such a good idea. "So if a doctor is doing that kind of business with four or five companies, he or she can get as much [as] $40 to 50,000 a year and not violate the new *New England Journal* policy," said Dr. Sidney Wolfe, the director of the Public Citizen Health Research Group, one of the country's largest medical consumer groups.

"The bias introduced by drug companies paying writers of review articles a large amount of money can have the consequence of slanting articles and influencing physicians in a way that isn't really in the best interests of their patients," said Wolfe.

The *Journal*, in a letter to its readers, says the policy change is necessary because it simply could not find enough qualified authors who did not already have ties to drug companies. "There are areas where we simply have not published anything because we didn't think we could get a person who was good to write in an area that had absolutely no interaction with a commercial entity," said Drazen.

But Jerome Kassirer, who was the *Journal's* editor between 1991 and 1999, says he had no problem finding independent authors. "There's a lot of depth in academic medicine, sufficient depth, so that it's almost always possible to find a first class person to write an editorial or review article in which they do not have a conflict of interest," said Kassirer, now a professor at the Tufts University School of Medicine.

The Journal is reducing the prestige and influence that it has taken 190 years to build.

Some doctors are concerned that by relaxing conflict-of-interest standards, the *Journal* is reducing the prestige and influence that it has taken 190 years to build.

Nicotine Lollipops: Sweet, Addictive, and Illegal

By Rep. Henry A. Waxman, U.S. House of Representatives (D-CA).

On April 3, 2002, I wrote to Secretary of Health and Human Services Tommy Thompson to express my concern about nicotine lollipops. These products—known by trade names like NicoPop and Likatine—were manufactured and marketed by compounding pharmacies in violation of the federal law. I urged Secretary Thompson to take immediate action to pull these candies from the market. One week later, on April 10, the Food and Drug Administration (FDA) sent warning letters to three pharmacies, halting sales of the lollipops. This was a welcome first step towards increased regulation of the many products on the market containing nicotine and making unproven health claims.

Although I support innovative strategies for smoking cessation, there were three problems with nicotine lollipops. First, these products pose serious risks to children. Nicotine lollipops are new, so there are no studies that examine the use of these products by children. Nevertheless, the potential for use by children is obvious. Just consider the list of available flavors, which include Blueberry, Bubble Gum, Cherry, Cinnamon Apple, Grape, Green Apple, Hawaiian Coconut, Lemon, Lemon-Lime, Licorice, Orange, Orange-Pineapple, Peach, Peppermint, Pina Colada, Pineapple Splash, Raspberry, Root Beer, Strawberry, Strawberry-Banana, Spearmint, Sweet Citrus, Tangerine, Tequila Sunrise, Tropical Punch, Tutti Fruitti, Very Berry, and Watermelon.

Moreover, pharmacists created and marketed the products in ways that might attract children. For example, one Washington State pharmacist said, "We do a good job of flavoring and masking any taste of the drug." And a pharmacy employee in Indiana said, "They taste just like Dum Dum suckers . . . you can't even taste the nicotine at all."

To prevent use by children, an addictive drug should not be masked by sweeteners and sold as a lollipop without a thorough review by the FDA and strict safeguards. Yet no such review had been conducted. Several pharmacies even sold the lollipops over the internet without requiring a prescription.

Second, the active ingredient in nicotine lollipops is a potentially unsafe drug, nicotine salicylate. The salicylate in nicotine salicylate has been associated with a devastating brain and liver disorder in children, Reye's Syndrome. Moreover, unlike the forms of nicotine in FDA-approved nicotine patches and nicotine gums, the safety of nicotine salicylate has not been established by the FDA.

The section of federal law regulating pharmacy compounding permitted pharmacies to produce small quantities of unapproved drugs only if the bulk drug substance is a component of an approved drug, and is found in the *United States Pharmacopeia* or *National Formulary* monograph, or is named by the FDA in a separate list. Nicotine salicylate, however, does not meet any of these criteria.

Third, nicotine lollipops were being marketed on the basis of health claims that had not been approved by the FDA or substantiated scientifically. Pharmacies advertised that nicotine lollipops are a treatment for nicotine withdrawal symptoms in the same way as nicotine gum and nicotine patches, two FDA approved products are. One pharmacy tried to convince customers that nicotine lollipops were better than other smoking cessation products. Another pharmacy even claimed nicotine sugar-free lollipops are "ideal for persons with diabetes."

Such health claims are not supported by evidence. In contrast to the many studies establishing the effectiveness of the nicotine patch, gum, and inhaler, I am not aware of a single published study on nicotine lollipops. Unproven claims may deceive consumers and promote a potentially unsafe drug. Under the law, it is simply illegal to market a drug with health claims that have not been approved by the FDA.

At the same time that the FDA issued warning letters to stop the sale of nicotine lollipops, it also barred the sale of nicotine lip balm. According to advertisements, nicotine lip balm "looks like a plastic 'Chapstick' but it contains a dose of nicotine in a sweet flavored base." Each tube allegedly "provides hundreds of small doses—equivalent to approximately 100 cigarette breaks."

Other products not covered by the FDA's recent warning letter also raise similar concerns. Advertisements for nicotine water can still be seen on the internet. Described as a smoking cessation aid and sold as a dietary supplement, this product promises, "all you will taste is the water." I believe the FDA should take the unequivocal position that any product containing nicotine and making health claims must be found safe and effective by the agency before it can be lawfully marketed. The FDA should build on the precedent of its action against nicotine lollipops and bring other products making health claims under its jurisdiction. At the same time, Congress must also take action to bring all tobacco products under the agency's authority to protect the public health.

Cancer.gov

The National Cancer Institute (NCI) has just reorganized its Web site to make accessing information much easier; it is has an address that is easy to remember as well: *http://www.cancer.gov.*

The first thing that pops up is the Home Page which is divided into five major areas of interest: "Research Programs," "Research Funding," "Cancer Information," "Clinical Trials," and "Statistics". Each of these headings has a set of subtopics listed under it. Although the section on research funding would be for those scientists who wish to conduct NCI-sponsored research, all other areas are of general interest.

The Web site organization is a cascade with increasing details as the user progresses from page to page. For example, if on the Home Page, one clicks on the box "Cancer Information," a new page appears with eight new related headings: "Types of cancer," "Treatment," "Prevention," "Screening," "Coping," "Support and Resources," "Literature," and "PDQ" (Physician Data Query). Clicking on "Support and Resources," for example, brings up another new page that in turn has six major topics from which to choose: "General Support Information," "Finances," "Hospice," "Home Care," "Support for Children with Cancer," and "Other Information." Under each of these topics there is again a list of two to seven areas of interest from which one can further narrow the search. Once this choice is made, the next level brings up several pages of text in the area of interest.

There are readily available sources of help on almost every page. At the bottom of most pages are a series of choices (Home, Search, Site Map, Help, etc.) that link the user to other parts of the Web site. The Help function provides an overview of how to use Cancer.gov including an 800 number that can be called and a chat line, "LiveHelp." The latter is reached by clicking the LiveHelp icon located on the bottom right of most pages. A dialog box will come up with "frequently asked questions;" to progress farther, you click the LiveHelp icon a second time. At this point, you type in your question and wait for the answer from the Information Specialist to be typed back. At the end, you have a transcript of your "conversation."

Other sources to be explored include "PDQ," an NCI database, that contains the latest information about cancer treatments, screening, prevention, genetics, and supportive care, plus clinical trials. The "Statistics" site has three general headings: "Understanding Statistics," "Data Sources," and "Statistics by Cancer Type," which provides an alphabetical list of cancer types from which to choose.

Other tools available (on the top right side of the page) include a dictionary to look up medical terms, a site map to get a general orientation of what is available, and a search function, where one can type in a topic of interest. The site map page includes most of what is on the home page plus three additional categories: "About NCI," "Search," and "Espanol" (for Spanish-speaking readers).

To obtain documents from NCI, there is an "NCI's Publications Locator" which has lists of publications that can either be ordered (20 at a time can be ordered free of charge) or that can be viewed at this site. Some publications are available in Spanish. A LiveHelp icon is also available here if one is having difficulties in finding or downloading documents.

There are many cross connections, clear layout, links to related sites, and lots of opportunities to ask questions. Even though we may not agree with all of the philosophies, for example NCI's stand favoring screening mammography for women under 50 (see the January 2002 issue of the *Health Letter*), this is certainly one of the best organized and informative health Web sites around.

THE PUBLIC CITIZEN HEALTH RESEARCH GROUP
Health Letter

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

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

Ten Years Ago Today

The Suppressed Democratic Study Group's "Stealth" Survey Surfaces

The following article was in the July 1992 Health Letter. *Unfortunately, not much has changed.*

Surprise! 70 Percent of DSG Poll Respondents Demand Comprehensive Overhaul of Health Care System.

The Democratic Study Group (DSG), a Capitol Hill think tank organized in the 1950s to inform its congressional members about legislation coming to the floor of the House and occasionally to push a particular policy, recently published results of a survey of 98 House Democrats on the subject of health care reform. To everyone's apparent surprise, including that of the polltakers, 70 percent of the respondents believed that "we should work to pass a *comprehensive overhaul* of the nation's health care system." (Emphasis added)

The level of opposition to "play or pay" employer based plans, in which insurance companies would continue to play a dominant role, and the level of support for a national single payer health plan on the Canadian model was surprising. First choice (among five options) of 43 percent of those surveyed and second choice of 11 percent (54 percent total) was "creating single payer national health insurance by establishing a new public program to cover the entire population." Only 15 percent said they were likely to vote against a single payer health reform plan.

In contrast, a mere 27 percent picked "play or pay" as first or second choice among the five approaches, while 36 percent said they were likely to vote against any reform proposal based on "play or pay." While "play or pay" has been touted as a more "moderate" reform approach, the polltakers were surprised at how poorly it fared among Democratic moderates. Southerners, for example, opposed "play or pay" more strongly than members from any other region, with 54 percent saying they would vote against any legislation containing such a provision. When asked whether they would vote against a single payer plan, 73 percent replied they would not.

	Would Favor (%)	Would Oppose (%)
Single payer	54	15
Play or pay	27	36

This is in direct contrast to the conventional wisdom, promoted by the Senate Democratic leadership (including Majority Leader George Mitchell (ME), health committee Chairman Edward M. Kennedy (MA), Jay Rockefeller (WV) and others) which holds that single payer Canadian-style national health insurance will never pass the Congress.

Despite the fact that 60 percent of those polled in the DSG survey said it is "extremely important that we bring health care reform to the Floor," the survey was not released until May 11th, four months after it was completed. When *Health Letter* recently questioned Scott Lilly, executive director of the DSG, about the timing of the release, he replied that "the health care agenda was not moving earlier in the year," and that the DSG has "limited resources and large responsibilities."

Contrary to Mr. Lilly's recollection, a series of Democratic "town meetings" on health care was held with great fanfare in December; Senator Kennedy's Labor and Human Resources Committee reported out its "play or pay" bill during the last week in January; and President Bush introduced his so-called "health plan" on February 7, and for the next two weeks the country was deluged with print and electronic discussions of health care reform measures including the Russo Bill, the closest thing to a single payer bill in the House—but not a word about the DSG poll, which by that time was well in hand, but under wraps.

We agree that the DSG has "large responsibilities," but first among these is to play straight with its members and with the public that those members represent. Perhaps some powerful Democrats and their deep-pocketed PAC friends in the insurance industry were so alarmed by the DSG survey that they did not want it circulated as part of the 1992 health care debate and conspired to silence the report. Far better for everyone to think that true health reform will "never pass the House." This is a year, however, when the smart players are betting on the unconventional wisdom.

What You Can Do

Call on your state's two senators to support a single payer bill (S. 2320) introduced in the Senate last March by Sen. Paul Wellstone (D-MN) and urge your representative to introduce or support companion legislation in the House.

OUTRAGE, *from page 12*

tension for ephedra than for all other dietary supplements combined (the petition is available at *http://www.citizen.org/publications/release.cfm?ID=7053* or by writing us at 1600 20th Street, NW, Washington, DC 20009).

The dangers of these products, combined with the attractiveness of products that allegedly improve fitness and strength, have led to a number of deaths and serious damage in people in the armed services. According to Navy Surgeon General Richard Nelson, "All three military services have documented medical cases where significant adverse events and deaths have occurred among active duty service members taking certain dietary supplements, specifically preparations containing ephedrine alkaloids." This led to a Navy ban of the sale of ephedrine-containing dietary supplements from stores at Pearl Harbor and the Marine base at Kaneohe Bay.

According to a May 13 "Fatality" bulletin from Fort Hood, Texas—an army base—there have been two deaths in soldiers at that facility from using ephedrine. At Fort Jackson, in South Carolina, two soldiers died after taking ephedra, and, in a statement issued by Moncrief Army Community Hospital, "We recommend that you don't take ephedra at all. The bottom line: Ephedra is a very dangerous herb that can kill."

As long as the FDA delays the inevitable ban of these products, cases such as the following three (extracted from medical records and being forwarded to the FDA) will continue to occur (note that two of the three occurred since our petition to ban):

1) A 35-year-old previously perfectly healthy African-American man using ephedra, well until the morning of 12/25/01. Complained of severe occipital headache, went back to bed, found by his wife blue and not breathing; on arrival of emergency squad, immediately intubated and had a bounding pulse (indicative of hypertension); brought to the hospital in coma. Diagnosis of cerebellar bleed and died on 12/31; autopsy showed no circle of Willis aneurysm or other pre-existing anatomic explanation for bleed/death.

By now, there have been well over 100 deaths reported to the FDA in people using ephedra containing products

2) A 37-year-old woman with no past medical history suddenly collapsed 4/02; no abnormal autopsy finding and was thus assumed to have died of a cardiac arrhythmia. At autopsy, no evidence of a heart attack, atherosclerosis or arteriosclerosis; non-lethal (therapeutic) levels of ephedrine and pseudoephedrine found in the blood. She was 5'3", 110 pounds and was using a natural herbal energizer/diet supplement for weight loss.

3) A 36-year-old male athlete (all his life) involved in bodybuilding, without a prior cardiac history, using ephedra and exercising (8/01) and developed acute onset of chest pain while sitting up: blood pressure 181/88, pulse 98; occasional multifocal PVCs (an arrhythmia known to be caused by ephedra). According to the medical record, "ephedra use exacerbated aortic outflow shear [sic] force and contributed to aortic root dissection" also rupture into the pericardium; Aortic insufficiency (damaged aortic valve) related to the root dissection. Fortunately, with emergency surgery, this man survived.

In summary, it should not require further deaths or strokes in soldiers or anyone else in this country for the FDA and HHS to abandon their cowardly position and ban ephedra alkaloids. If officials in those agencies do not believe that these products "present a significant or unreasonable risk of illness or injury" (the legal standard for banning a dietary supplement when there is evidence of harm at the recommended dose), they are dangerously misinformed, medically and legally.

CONSUMER PRODUCTS *cont.*

Name of Product; Problem	*Lot #; Quantity and Distribution; Manufacturer*
Toy Planes; Plastic air intake chamber of the air-powered toy planes can burst, throwing plastic pieces, posing a laceration, bruise and abrasion hazard	Firestormer and Skyblazer; 137,000 sold nationwide from January through May 2002; Spin Master Toys, Toronto, Ontario (800) 622-8339 www.spinmaster.com
Toy Steering Wheel Attachments; Steering wheel can break away from its base, allowing the small plastic turn signal and horn pieces to come off, posing a choking hazard to young children	Sold on Jeep Cherokee stroller model 55120; 17,000 sold nationwide from January through February 2001; Kolcraft Enterprises, Inc., Chicago, Illinois (800) 453-7673 www.kolcraft.com

Department of Health and Human Services Fails to Ban Ephedra or Issue Adequate Warnings

The following is a statement by Health Letter *Editor, Dr. Sidney Wolfe in response to this decision.*

Today's announcement by the Department of Health and Human Services (HHS), which not only fails to ban ephedra dietary supplements but also fails to seriously warn against the use of these products, should result in the firing of all officials in HHS and the Food and Drug Administration (FDA) who are responsible for this dangerous cowardice. The idea that more studies are needed and that the more than 100 deaths and hundreds of other cases of serious damage to users of these products—many of which are extremely well-documented and have occurred at recommended doses—is not enough for a ban is in sharp contrast to what has usually occurred with the removal of dangerous prescription drugs from the market. Almost all of these bans or withdrawals were based on well-documented case reports in which the only plausible explanation for the deaths or damage was the drug, as is the case with ephedra. The idea of all but encouraging the use of dangerous ephedra products and urging discontinuance only in case of chest pain, irregular heartbeat, loss of consciousness or other symptoms pending, or actual heart attacks or strokes, is a cruel abdication of even the responsibility to warn.

One year ago today, the Canadian government warned Canadians "not to use products containing the herb Ephedra" because such products "may cause serious, possibly fatal, adverse effects." On January 9 of this year, Health Canada requested a recall of all ephedra products "with labeled or implied claims for appetite suppression, weight loss promotion, metabolic enhancement, increased exercise tolerance, body-building effects, euphoria, increased energy or wakefulness, or other stimulant effects."

By now, there have been well over 100 deaths reported to the FDA in people using ephedra containing products and, as described in our September 5, 2001 petition to ban these products, there are more reports of death, stroke, arrhythmia, heart attacks, chest pain, seizures and hyper-

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