

Health Letter

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The People Have Spoken: The Drug Industry Doesn't Serve Us Well

The drug industry must be thanking its lucky stars that it doesn't have to get reelected to the job of providing medications to people in the United States. For, if it did face that sort of public accountability, it just got voted out of office.

The Harris Poll, one of the country's most respected polling organizations, has just published its annual poll on public attitudes toward some of the major industries in this country. Each year, Harris surveys about 1,000 people by telephone, asking them whether they generally believe that 15 particular industries are doing "a good or bad job of serving their consumers." Industries other than health care included in the survey were supermarkets, airlines, banks and oil companies.

Among the health care industries inquired about, only hospitals received the endorsement of a majority of those surveyed (70%). Pharmaceutical companies followed with a 44% favorable rating. Health insurance companies fared still worse with a 36% favorable rating and managed care companies ranked last (with the tobacco industry!) at 30%. (In fairness, the tobacco companies had a 60% unfavorable rating compared to 53% for managed care companies, the difference accounted for by people who were not sure or refused to answer.) While the hospital industry ranked seventh, the three remaining health care industries

ranked between 11 and 15.

But any politician worth his or her salt (or campaign contribution) knows that as important as favorable ratings are the trends in those ratings over time. From that perspective, the drug industry is in crisis.

Back in the industry's salad days in 1997, a full 79% of those surveyed professed a favorable attitude toward the drug companies. But since then the industry has experienced a downward spiral, losing support every year but one. The 35% drop in its favorable rating between 1997 and 2004 is a larger drop than every other industry, although the managed care (-21%) and health insurance industries (-19%) were in hot pursuit.

(Interestingly, the industries together lost a median of 8% support over this period, with every industry losing some support, suggesting that something more fundamental in attitudes toward corporations is also occurring.) It appears that this is the first year in which more people had an unfavorable than a favorable attitude toward the drug companies.

It seems that the public is finally getting wise to machinations of drug companies. Years of price-gouging, doctor-bribing and political-power purchasing are taking their toll. If only there were a way to get a drug industry recall petition on the November ballot.

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Boutique Medicine (Concierge Care) Revisited

We have previously discussed with you the growing problem of boutique or concierge medicine wherein doctors, seeking to make as much or more money than they have previously (but see fewer patients) charge an annual “special access” fee to those patients who can afford it in return for special favors from the doctor (see *Health Letter*, October 2003). Of course, many patients, already strapped with gigantic medical expenses, can not afford this extra amount of money — often in excess of one thousand dollars a year — and are forced to seek a different doctor, thus destroying the important continuity of care that comes from going to the same physician.

But aside from the clearly unethical aspects of these practices that have burgeoned in the past five years or so comes evidence that the practices are clearly illegal if the patient is a Medicare patient and the doctor is, in effect, double billing both the government and the patient for the same services. The Inspector General (OIG) of the Department of Health and Human Services, charged with overseeing Federal laws involving programs of the Department, in this case the Center for Medicare and Medicaid Services (CMS), has recently put out a warning about these arguably illegal practices of some U.S. doctors. The following headline preceded the warning:

OIG ALERTS PHYSICIANS ABOUT ADDED CHARGES FOR COVERED SERVICES *Extra Contractual Charges Beyond Medicare’s Deductible, Coinsurance: A Potential Assignment Violation*

The Acting Principal Deputy Inspector General Corrigan alerted Medicare participating physicians of “the potential liabilities posed by billing Medicare patients for services that are already covered by Medicare. Medicare participating providers can charge Medicare beneficiaries extra for items and services that are **not covered** (emphasis added) by Medicare. Participating providers may also, of course, charge beneficiaries for any Medicare deductibles and coinsurance without violating the terms of their assignment agreements. But when participating providers request any other payment for covered services from Medicare patients, they are liable for substantial penalties and exclusion from Medicare and other Federal health care programs.”

Corrigan stated that “We are hearing reports about physicians asking patients to pay additional fees, and we believe this is an ideal time to remind physicians and Medicare patients about this potential liability. Charging extra fees for already covered services abuses the trust of

Medicare patients by making them pay again for services already paid for by Medicare.”

For example, the OIG recently alleged that a physician violated his assignment agreement when he presented to his patients — including Medicare beneficiaries — a “Personal Health Care Medical Care Contract” asking patients to pay an annual fee of \$600. While the physician characterized the services to be provided under the contract as “not covered” by Medicare, the OIG alleged that at least some of these contracted services were already covered and reimbursable by Medicare. Among other services offered under this contract were the “coordination of care with other providers,” “a comprehensive assessment and plan for optimum health,” and “extra time” spent on patient care.” OIG alleged that, based on the specific facts and circumstances of this case, at least some of these contracted services were already covered and reimbursable by Medicare.

Therefore, OIG alleged that each contract presented to this physician’s Medicare patients constituted a request for payment for already covered services—other than the coinsurance and deductible—and was therefore a violation of the physician’s assignment agreement. In

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Product Recalls

June 16 — July 16, 2004

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

DRUGS AND DIETARY SUPPLEMENTS

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

Name of Drug or Supplement; Class of Recall; Problem

Advicor Extended-Release Tablets (Niacin extended release and Lovastatin tablets), 500 mg/20 mg, 90 tablet bottles, Class III; Failed Content Uniformity testing.

Bisacodyl 10mg Laxative Suppositories, each containing 10mg Bisacodyl USP, 12 suppositories; also sold under brand labels: The Magic Bullet, units of 12 and 100, and Qualitest, units of 12; Class III; Stability Failure-Bisacodyl USP.

Collagenase Santyl(r) OINTMENT (derived from Clostridium histolyticum), 250 units per gram, 15 gram tubes, Rx only, Class III; Subpotent: stability.

Contac Cold + Flu Day & Night Caplets in blister packs of 15 count day caplets and 5 count night caplets, over-the-counter; Class III; Mislabeled; product carton does not have pseudoephedrine warning statement directed to hypertensives and diabetics.

Cortisporin — TC Otic Suspension, 10 mL bottle with dropper, Rx Only, Sterile, Class II; Lack of Assurance of Sterility; product cap may not have been adequately tightened when assembled to bottle.

Lot #: Quantity and Distribution; Manufacturer

Lot No. 0303100001 Exp. 1/05; 3,864 bottles distributed nationwide; Kos Pharmaceuticals, Co; Miami, FL

All un-expired Lot Numbers; 70,983 units distributed nationwide; Elge, Inc; Rosenberg, TX

Lot No. 0000059281, Exp. 10/04; Lot 0000093210, Exp. 6/05; 54,333 tubes distributed nationwide and in Puerto Rico; Advance Biofactures Corp.; Lynbrook, NY

Numerous lots; 449,244 units distributed nationwide, in Bahamas and Bermuda; GlaxoSmithKline; Parsippany, NJ

Lot No: 00433M; Exp. 07/04; 26,991 distributed nationwide and in Puerto Rico; King Pharmaceuticals, Inc., Bristol, TN

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BOUTIQUE MEDICINE, from page 2
order to resolve these allegations, the physician agreed to pay a settlement amount to OIG, and to stop offering these contracts to his patients. "If participating physicians decide they want to charge patients additional fees, they should be mindful that they are subject to civil money penalties if they request any payment for already covered services from Medicare patients other than the applicable deductible and coinsurance," Corrigan said.

Note: A participating provider is a provider of Medicare-covered items and services who agrees to accept the Medicare-approved charge for all covered services to Medicare patients. A participating provider "accepts assignment" for all Medicare-payable services. Non-participating providers may also be subject to penalties and exclusion for overcharging beneficiaries for covered services. This is true whether the provider

accepts assignment for a given service or does not, in which case the provider's charge is limited to the "limiting charge."

In addition to the problem of violations of Federal laws governing Medicare, there is some concern that state insurance laws might be violated by doctors who are taking care of patients who are not part of the Medicare program.

DRUGS AND DIETARY SUPPLEMENTS *cont.*

Name of Drug or Supplement; Class of Recall; Problem

Hydrocodone Bitartrate and Acetaminophen Oral Solution, 7.5mg/500mg per 15mL, unit dose cups, For Institutional Use Only, Rx Only; Class III. Stability failure (hydrocodone).

Loxitane Capsules, (Loxapine Succinate) 10 mg base, 100 count bottles, Rx only, Class III. Capsule Defect; split or broken capsules.

Maxifed DM Tablets, Each sustained-release tablet contains: Guaifenesin 580mg, Pseudoephedrine HCl 60mg, Dextromethorphan HBr 30mg, 100 count bottles, Rx Only; Class III. The caplets are embossed as MAXIPHEN DM rather than MAXIFED DM.

Orasept Antiseptic Mouthwash & Gargle (cetylpyridinium HCl 0.05% w/w), 4 fl. oz. (118 mls.) bottles, over-the-counter; Class II; Microbial contamination (yeast and mold).

Phenytoin Oral Suspension USP (125MG/5ML), 8 oz bottles (237mL), Rx only, Class II; Product not manufactured as per approved method (additional unapproved mixing).

PREMARIN (conjugated estrogens tablets USP), 1.25 mg, 1000-count bottles, Rx only, Class III; Dissolution Failure; (18 month stability).

Prozac Pulvules (Fluoxetine Hydrochloride) Equiv. to 20 mg, 2,000 count bottles, Rx Only; Class III; Labeling: missing lot number and/or expiration date.

Zyprexa Tablets, (olanzapine), 15 and 20 mg, 60 count bottle, Rx only; Class II; Counterfeit.

Zyprexa Tablets (olanzapine) 5 mg, 1000 count bottles, Rx only; Class III; Labeling: missing lot number and/or expiration date.

Lot #: Quantity and Distribution; Manufacturer

Numerous lots, 1,350, 150 unit dose cups distributed nationwide; Pharmaceutical Associates, Inc; Greenville, SC

Lot No. 49501K02; Exp. 9/2005. 6,480 units distributed nationwide; Watson Laboratories, Inc; Corona, CA

Lot No. 3M05 (no expiration date provided); 2,010 units distributed nationwide; Pharmakon Laboratory, Inc, Tampa, FL

Lot No. 4B45; Exp. 01/06; 9,754 bottles distributed in PA, GA, and CT; Pharmakon Laboratory, Inc.; Tampa, FL

Numerous lots; 317,952 bottles distributed nationwide; Alpharma USPD, Baltimore, MD

Lot Nos. A28811 and A49547, Exp. 05/05; 16,871 bottles distributed nationwide; Richmond Division of Wyeth; Richmond, VA

Lot No. 7AA93P; Exp. 3/1/06; 1,697 bottles distributed nationwide; Eli Lilly & Co.; Indianapolis, IN

Numerous lots; 238 bottles distributed in ME, NH, NY, MA, and VT; Burlington Drug Company; Milton, VT

Lot No. 7AA35S; Exp. 2.1/05; 2,526 bottles distributed nationwide; Eli Lilly & Co.; Indianapolis, IN

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

Baby Strollers. If the stop pins are bent or missing or the seat is not fully attached, the seat can partially detach from the frame during use and the infant occupant can be injured in a fall.

Bamboo Torches. The plastic oil canister can melt when the torch is in use posing a fire hazard.

Lot #: Quantity and Distribution; Manufacturer

COSCO(r) "Rock 'N Roller" Baby Strollers; 300,000 sold nationwide from April 1996 through August 2002; Dorel Juvenile Group USA; Columbus, IN; (800) 711-0402; www.djgusa.com

Bamboo torches stand about five feet tall; bottom has spiked tip to stick in ground; about 36,000 sold at Jo-Ann Stores nationwide from February 2004 through April 2004; Jo-Ann Stores Inc.; Hudson, OH; (877) 527-2677

Name of Product; Problem

Bicycles. The handlebar could unexpectedly loosen causing the rider to lose control of bicycle.

Cell Phone Batteries. Some LG-branded TM-510 batteries may be counterfeit and susceptible to overcharging, especially if used with a non-LG charger. In turn, the counterfeit batteries can overheat, posing a fire and burn hazard to users.

Children's Portable Swings. The swing's carrying handle can fail to stay in place properly and drop or be pushed down, hitting a child in the head. Additionally, the 3-point seatbelt can fail to prevent a child from leaning forward or to either side, posing a risk that the child can fall forward and strike his/her head on the floor or the swing's frame.

Children's Swimsuit Cover-ups. The zipper pull on the cover-up can detach, posing a choking hazard to young children.

Doll Sets. The head and boot of the dolls can detach, posing a choking hazard to young children.

Electric Pressure Washers. These electric pressure washers do not have a ground fault circuit interrupter (GFCI) on the power cord, which poses a serious electrocution hazard if the unit comes into contact with water.

Fire Pit Spark Screens. The fire pit spark screen can catch fire when it comes into direct contact with a flame, posing a burn and fire hazard to consumers.

Fireworks. These fireworks could have a defective fuse that can fail to ignite the device. Consumers who attempt to re-light the fuse could suffer serious injury.

Gas Camping Stoves. Plastic parts in the pump connected to the camping stove can crack or become dislodged. When exposed to extreme temperature change, the blue plastic shrinks around the aluminum parts and has been observed to crack the outer plastic housing. The air tube on some of the pumps can become unglued and dislodged. Both of these failures can permit gas to leak.

Gas-powered Hand Tools. The fuel lines on these tools can develop an "alligator surface" appearance which could develop into a condition that will allow leakage of gasoline and fuel vapor, posing a fire hazard to consumers.

Lot #: Quantity and Distribution; Manufacturer

Huffy "Cranbrook" Bicycles; 12,000 sold nationwide from April 2004 through May 2004; Huffy Bicycle Company; Springboro, Ohio; (888) 366-3828; www.huffybikes.com

Counterfeit LG-branded TM-510 Cell Phone Batteries; About 50,000 sold from April 2001 through December 2002; Verizon Wireless; Bedminster, NJ; (888) 351-2121; www.vzwshop.com/lgbattery

Travel Lite Swings; 140,000 sold nationwide from June 2003 through June 2004; Graco Children's Products; Exton, PA; (800) 345-4109; www.gracobaby.com

Children's Swimsuit Cover-ups sold under the brand names "Samara" and "Carter's," in sizes ranging from 3 to 24 months; 30,000 sold nationwide from January 2004 through April 2004; Samara Brothers Inc.; Edison, NJ; (866) 448-7758; returns@samara.com

Toddler Doll Family Sets, sold with four figurines, a mom, dad, brother and sister. The 4-inch-tall dolls have a wooden head, arms and feet; about 2,800 sold nationwide from January 2003 through April 2004; Lakeshore Learning Materials; Carson, CA; (800) 428-4414

Turbo Tiger Power Washer; 1,000 sold nationwide from June 2002 through July 2003; Zhejiang Anlu Cleaning Machinery Co. Ltd.; China; (800) 649-2297

Sean Conway Fire Pit Spark Screens; about 430 sold from January 2004 through May 2004; Target Corporation, of Minneapolis, MN; (612) 375-3382

"T6" Titanium 6 Break Artillery Shell Fireworks; About 11,700 units sold from May 2004 through June 2004; American Promotional Events Inc.; Florence, AL; (800) 243-1189; www.TNTFireworks.com

Snow Peak Giga Power White Gas Camping Stove, GS-010; 1,886 sold nationwide from August 2001 through June 2004; Snow Peak USA, Inc.; of Clackamas, OR; 503-697-3330.

Echo-brand grass trimmers, brush cutters, hedge clippers, power blowers and power edgers; about 540,000 sold nationwide from February 2003 to May 2004; Echo Inc.; Lake Zurich, IL; (800) 254-4808; www.echo-usa.com

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<i>Name of Product; Problem</i>	<i>Lot #: Quantity and Distribution; Manufacturer</i>
Girls' Rompers. The crocheted cherry-shape tassels and plastic buttons may pull off, posing a choking hazard to young children.	Basic Editions Infant and Toddler Girls' Rompers; about 20,000 sold exclusively at Kmart stores nationwide from February 2004 through May 2004; Kmart Corporation; Troy, MI; (866) KMART 4U; www.kmart.com
Girls' Straw Cowboy Hats. The straw hat is constructed using a thin wire within a seam. The tip of the wire can break free from the seam, posing a laceration hazard.	Girls Straw Cowboy Hats, sold in pink and natural straw with a flower embroidered on one side and a butterfly embroidered on the other; 5,200 sold nationwide from April 2004 through May 2004; GapKids; San Francisco, CA; (866) 847-0489
Hunting Tree Stands. If the strap mounting bracket loosens or rotates, the strap hook can release, causing the tree stand to detach from the tree. If this occurs, the consumer could fall to the ground.	Big Foot Series and Lite Foot Series hunting tree stands; about 78,000 sold nationwide from January 1998 through July 2001; Rivers Edge/Ardisam, Inc.; Cumberland, WI; (800) 204-7435; www.ardisam.com
Power Adapters for Notebook Computers. Using power cords not intended for these adapters can pose a shock hazard.	Power adapters for Dell notebook computers; about 28,000 units sold nationwide from December 2003 through May 2004; Dell Inc., Round Rock, TX; (888) 245-3844; www.support.dell.com
Power Amplifiers. The amplifier's capacitors can overheat, blow a fuse, and damage the products to which they are connected, presenting a fire hazard.	Linn Power Amplifiers and Linn Melodik Bass Extension Loudspeaker System; about 2,157 units sold throughout the U.S. and Canada from May 1996 through December 2003; Linn Inc.; Jacksonville, FL; (800) 595-6770; www.linninc.com
Ratchet Winch Kits. When the ratchet winch, or hook, is under tension, it can detach and be projected, posing a risk of serious injury or death to user or bystander.	Ratchet winch kits sold as an accessory for the Elite model snowmobile; about 45 sold nationwide from July 2003 through March 2004; JSF Manufacturing Inc.; Hazelnut, GA; (888) 864-2002
Steam Cleaners. Some of the attachments are missing an "O" ring in the handle, allowing hot steam and water to escape, posing a burn hazard to consumers.	Euroflex Monster 55 — 1600 Watt Multisurface Steam Cleaner with Attachments; about 22,000 sold nationwide from February 2004 to March 2004; Euroflex Americas Inc.; New York, NY; (888) 896-8786
Steel Toe Boots. The boots may have been mislabeled to indicate that they are resistant to electrical current, which is incorrect. This may result in a serious shock or electrocution to consumers.	Georgia Boot Steel Toe Logger Boots; about 10,000 pairs sold nationwide from October 2002 through April 2004; Georgia Boot; Franklin, TN; (877) 795-2410; www.georgiaboot.com
Toy Trucks. Components on the trucks could detach, posing a choking and sharp point hazard to young children.	Summerville(tm) Toy Trucks Sets; 25,500 sold at Target stores nationwide from February 2004 through May 2004; Target Corp.; Minneapolis, MN; (800) 440-0680; www.target.com
Wall Plug Ethernet Bridges. The plastic housing on these units can detach, posing a shock hazard.	Wall Plug Ethernet Bridge to extend internet availability; has "NETGEAR" written on top of housing; about 53,500 units sold nationwide from February 2003 through May 2004; NETGEAR Inc.; Santa Clara, CA; (800) 303-5507
Water Coolers. These electric water coolers can overheat and present a fire hazard.	Elkay hot/cold bottled water coolers; 145,000 sold nationwide from 1999 through October 2003; Elkay Manufacturing Company; Oak Brook, IL; (800) 788-2499; www.coolerfix.com

Doctor Bribing in Italy

In case people in the United States thought that the bribing of doctors by pharmaceutical companies in order to extract more prescriptions from them was unique to this country (see Health Letter, July, 2004), take a look at Italy.

A recent headline in the British daily newspaper, *The Guardian*, proclaimed: "Over 4,000 doctors face charges in Italian drugs scandal."

In the May 27th issue of the *The Guardian*, reporters John Hooper in Rome and Heather Stewart in the United Kingdom wrote that "One of the biggest inquiries into marketing practices in the drugs industry ended yesterday with Italian police asking for almost 5,000 people to be put on trial, including more than 4,000 doctors and at least 273 employees of the British pharmaceuticals giant, GlaxoSmithKline. Some face up to five years in jail if tried and convicted.

Italy's revenue guard, the Guardia di Finanza, said in a statement that GlaxoSmithKline and its predecessor firm had spent 228m euros [about \$285 million] on "sweeteners" for doctors, chemists and others over four years. The alleged bribes ranged from cameras, computers and holidays to outright cash payments. The Guardia di Finanza said GlaxoSmithKline "should be held responsible for corporate crime as its managers and other employees acted in the company's interest".

A spokesman for GSK said last night it had been "cooperating closely with the authorities to facilitate their investigations. GSK is committed to ensuring that all its business practices are of the highest standards and any breach of that is unacceptable", the spokesman added.

But a British-based pharmaceuticals analyst said yesterday the type of activity the Italian authorities allege to have uncovered is common practice among global drug companies.

"In parts of Europe, these things are absolutely rife," he said. "For

So the desire by multinational pharmaceutical companies to bribe doctors to write more prescriptions for their products seems to be a somewhat universal way of increasing business.

example, doctors may be given 'research grants' — but there are no limits on how they can spend them." He cited cases in which doctors had been offered cars or holidays as inducements to prescribe a particular brand.

Italy's Adnkronos news agency reproduced what it said was a letter written by a GlaxoSmithKline district manager contained in the 10,000 pages of evidence assembled by the Guardia di Finanza.

The letter urged sales representatives to approach specialists directly to get them to prescribe a cancer drug produced by the company. "The initiative can work well with oncologists who have congresses, investments from us ... and who have not given us anything in return," the district manager was quoted as writing. Illicit incentives were said to have been disguised in the firm's accounts under the headings of "field selling", "other promotion" and "medical phase IV".

Of the 4,713 people from all parts of Italy facing charges, 4,440 are doctors. They include more than

2,500 GPs and some 1,700 specialists.

The most serious accusations have been levelled at doctors, pharmacists and sales representatives alleged to have been involved in a programme intended to promote Hycamtin, a drug mainly used in the treatment of lung and ovarian cancers. In some cases, it is claimed, specialists received a pro rata cash payment based on the number of patients treated with the drug.

At a press conference yesterday, a senior revenue guard officer, Giovanni Mainolfi, estimated the investigation was costing GlaxoSmithKline's Italian subsidiary 400m euros [\$500 million] a year in lost sales."

Back in the U.S.A., the saga of another global company, TAP (a joint venture of Takeda of Japan and Abbott of the United States) continues, involving their drug for prostate cancer, leuprolide (LUPRON). Four U.S. physicians pled guilty for violating Federal laws regarding leuprolide and two Florida doctors were convicted of criminal charges for participating in a black market operation that was selling leuprolide.

So the desire by multinational pharmaceutical companies to bribe doctors to write more prescriptions for their products seems to be a somewhat universal way of increasing business. Similarly, the desire to make more money (or get other "sweeteners") seems to be a feature of enough physicians to make it worthwhile and very profitable for drug companies to engage in this behavior. Unless firm criminal prosecution is successfully concluded against the bribing companies as well as against the all-too-willing doctor bribe recipients, these practices — that undermine the doctor-patient relationship by convincing doctors that the safest, most efficacious and least expensive drug is not the best — will continue.

Suicide Risk Added To The Professional Product Labeling For Eight Antidepressants

At the request of the Food and Drug Administration (FDA), eight out of ten manufacturers of newer antidepressants have agreed to add a warning about the possibility of an increased risk of suicide associated with the use of these drugs. The warning will appear in the professional product labeling, or package insert, for these drugs. The package insert is written for pharmacists and physicians and is not routinely distributed to patients or their families unless requested, which we strongly urge you to do.

The manufacturers who complied with the FDA's request and the antidepressants they produce are:

Bristol-Myers Squibb
Nefazodone (SERZONE)

Forest
Citalopram (CELEXA)
Escitalopram (LEXAPRO)

GlaxoSmithKline
Paroxetine (PAXIL)
Bupropion (WELLBUTRIN)

Lilly
Fluoxetine (PROZAC)

Organon
Mirtazapine (REMERON)

Wyeth
Venlafaxine (EFFEXOR)

Pfizer, Inc. of New York, at the time this was written, was in negotiations with the FDA regarding the exact language that will be used for their antidepressant sertraline (ZOLOFT). Fluvoxamine (LUVOX), produced by Solvay, was withdrawn from the market in 2002 and has not yet been re-approved by the FDA.

Below is the text of the new warning now required in the professional product labeling for paroxetine. The wording in the new warning is simi-

lar for all of the antidepressants listed above.

WARNINGS — Clinical Worsening and Suicide Risk

Patients with major depressive disorder, both adult and pediatric, may experience worsening of their depression and/or the emergence of suicidal ideation and behavior (suicidality), whether or not they are taking antidepressant medications, and this risk may persist until significant remission occurs. Although there has been a longstanding concern that antidepressants may have a role in inducing worsening of depression and the emergence of suicidality in certain patients, a causal role for antidepressants in inducing such behaviors has not been established. Nevertheless, patients being treated with antidepressants should be observed closely for clinical worsening and suicidality, especially at the beginning of a course of drug therapy, or at the time of dose changes, either increases or decreases. Consideration should be given to changing the therapeutic regimen, including possibly discontinuing the medication, in patients whose depression is persistently worse or whose emergent suicidality is severe, abrupt in onset, or was not part of the patient's presenting symptoms.

Because of the possibility of comorbidity between major depressive disorder and other psychiatric and nonpsychiatric disorders, the same precautions observed when treating patients with major depressive disorder should be observed when treating patients with other psychiatric and nonpsychiatric disorders.

The following symptoms, anxiety, agitation, panic attacks, insomnia, irritability, hostility (aggressiveness), impulsivity, akathisia (psychomotor restlessness), hypomania, and mania, have been reported in adult and pediatric patients being treated with anti-

depressants for major depressive disorder as well as for other indications, both psychiatric and nonpsychiatric. Although a causal link between the emergence of such symptoms and either the worsening of depression and/or the emergence of suicidal impulses has not been established, consideration should be given to changing the therapeutic regimen, including possibly discontinuing the medication, in patients for whom such symptoms are severe, abrupt in onset, or were not part of the patient's presenting symptoms.

Families and caregivers of patients being treated with antidepressants for major depressive disorder or other indications, both psychiatric and nonpsychiatric, should be alerted about the need to monitor patients for the emergence of agitation, irritability, and the other symptoms described above, as well as the emergence of suicidality, and to report such symptoms immediately to health care providers. Prescriptions for PAXIL should be written for the smallest quantity of capsules consistent with good patient management, in order to reduce the risk of overdose.

In the group of antidepressants known as selective serotonin reuptake inhibitors (SSRIs) there is a recommendation in their package inserts on how to taper the dose to avoid a withdrawal reaction if the decision is made to stop one of these drugs. The SSRIs, in addition to paroxetine, include citalopram, escitalopram, and fluoxetine. The withdrawal symptoms from these drugs generally start within one to three days after stopping the drug, and generally resolve within one to two weeks after the drug has been discontinued. Withdrawal symptoms may occur even when the dosage of the drug is gradually decreased. The main symp-

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DO NOT USE — Save Your Money

Dextromethorphan (DELSYM or generic) Or Diphenhydramine (BENADRYL or generic) Ineffective For Nighttime Cough In Children

Dextromethorphan and diphenhydramine, both over-the-counter drugs, are sold alone and in combination with other products as cough suppressants for children and adults. We have previously recommended dextromethorphan as a safe and effective cough suppressant for both children and adults. However, the weight of the evidence now suggests that neither dextromethorphan nor diphenhydramine is any more effective than an inactive placebo syrup in suppressing a nighttime cough in children.

The study tipping the balance for us to a DO NOT USE classification for these drugs was published in the July 2004 issue of the journal *Pediatrics* and was conducted by researchers from the Pennsylvania State College of Medicine, Hershey, Pennsylvania.

Sleep quality was used as the measure of effectiveness in the study for the two drugs and the placebo. The study involved 100 children with coughs and their parents, and used a five-question questionnaire to assess sleep quality for both children and their parents. The median age of the

children was 4.5 years and their ages ranged from 2.0 years to 16.5 years. To be eligible to participate in the study, the children had to have an acute cough as a result of an upper respiratory tract infection.

The questionnaire was administered on two consecutive days. On the first day no medication had been given the previous night and on the second day it was administered after the drugs or the placebo had been given the previous night.

The study concluded that dextromethorphan and diphenhydramine were not superior to the placebo in providing nighttime symptomatic relief for children with a cough and sleep difficulty as a result of an upper respiratory tract infection. In addition, the use of these drugs did not result in improved sleep quality for the children's parents. In other words, neither drug had any effect on the natural course of cough improvement over a 24-hour period.

Dr. Ian Paul, the study's lead investigator, on July 6 was quoted on *ABC News*, saying that, "The kids that got the medicines in the study, they didn't cough any less, they didn't cough any less severely or sleep any better than the kids that got the sugar water."

Older research on the value of these drugs as cough suppressants was conflicting. Recently, a type of statistical summary of multiple studies known as a meta-analysis published in the February 9, 2002 *British Medical Journal* concluded "Over the counter cough medicines for acute cough cannot be recommended because there is no good

evidence for their effectiveness."

The American Academy of Pediatrics' Committee on Drugs has not supported the use of dextromethorphan or codeine primarily because there is a lack of proven benefit, and some potential for toxicity and overdose.

Even ineffective drugs have the potential to cause adverse effects. In usual doses, dextromethorphan has been associated with loss of muscle tone, severe allergic reactions and the proliferation of a type of cell called mast cells that may appear as a blister. Overdose of dextromethorphan may result in psychosis, mania, or hallucinations. Deaths have been reported from an overdose of this drug.

Diphenhydramine is also commonly used as an antihistamine (for which it is effective) and shares the adverse effects of this family of drugs. These include drowsiness, occasional restlessness, nervousness, and insomnia in usual doses. Death can result from an overdose with diphenhydramine.

Parents and health professionals have a strong urge to "do something" to ease symptoms in children even in a mild, self-limiting illness such as an upper respiratory tract infection. The lesson from this study is that it is sometimes better to do nothing because the medications have no therapeutic benefit, but do carry a known risk of potentially serious adverse reactions.

What You Can Do

You should not use dextromethorphan or diphenhydramine for cough suppression. Neither drug is effective and each has its own risks.

ANTIDEPRESSANTS, from page 8

ptoms of this reaction are: dizziness, vertigo, uncoordination, nausea and vomiting, and flu-like symptoms that include fatigue, lethargy, muscle pain and chills.

What You Can Do

You should be monitored closely if you start treatment with one of the antidepressants listed in this article or if your dose of one of these drugs is increased.

As a physician and consumer advocate who has monitored the pharmaceutical industry for more than 30 years in Washington, I strongly urge you to reject this programming. This is a blatant violation of accepted journalistic tenets. Your viewers will undoubtedly be deceived into believing this content is a product of the normal newsgathering process, which is supposed to be objective and non-biased — not driven by an economic agenda or marketing considerations. If you use this content, you not only will be doing a disservice to your viewers, but you will be actively participating in the purveying of propaganda and, more seriously, the erosion of journalistic standards that distinguish a free and open democracy. The line between editorial content and advertising should be clear and bright. As you blur this line with products such as this, you will undermine your credibility as well as that of American journalism in general.

Recently, major journalistic institutions such as *The New York Times* and *USA Today* have experienced embarrassing scandals that eroded public confidence in the reliability of journalists. And several recent examples of “fake news” used by TV stations have resulted in well-deserved criticism from experts in journalistic ethics and others.

For example, the U.S. General Accounting Office earlier this year determined that the Bush administration’s use of video news releases to trumpet the 2003 Medicare law was a form of “covert propaganda” and violated federal law. These segments, which featured an actor posing as a journalist, were used by TV stations across the country and aired as news

segments.

WFLA in Tampa, Fla., was criticized in *The Washington Post* and elsewhere in 2003 for its decision to sell segments in its morning show to guests who want to promote products and services. For \$2,500, guests could tout their wares for four to six minutes. The station insisted the practice was aboveboard, but after the Society of Professional Journalists denounced it, the station began identifying the segments as paid advertising.

On its web site, the Poynter Institute, a prestigious journalism school, addressed its concerns about the use of MediZine’s “Headline Health” videos with a reminder of the Radio and Television News Directors Association (RTNDA) guidelines for balancing business pressures and journalism values: *“Professional electronic journalists should gather and report news without fear or favor and vigorously resist undue influence from any outside forces, including advertisers, sources, story subjects, powerful individuals and special-interest groups.”*

Poynter also cautions that “News operations should use press releases and video news releases very selectively and only when journalistically justified. Journalists should clearly inform viewers/listeners when corporations, public relations agencies, news release services, advertisers or others who are not journalists provide any material you are using in a news story.”

In a Web article called “Ethics in Television News” (May 18, 2004, at http://poynteronline.org/content/content_view.asp?id=65894) RTNDA President Barbara Cochran told Poynter Institute media ethics

expert Bob Steele: “Stations are trying to maximize their profits and the sales departments can come up with some ingenious schemes to generate revenues that may involve the news department. The best test for such plans is how it would look if it were exposed on the front page of the local newspaper. If it would be embarrassing, it’s probably not a good idea. Stations that ignored that test have had to change their plans. The cost in credibility is huge compared to the dollars earned in revenue.”

A solid line between news and advertising is needed now more than ever as drug companies have developed increasingly deceptive and unscrupulous tactics to sell their products in a cut-throat market. Drug companies have been criticized for making false or misleading claims in drug ads that directly target consumers, having excessive influence over what doctors prescribe, influencing the outcome of medical research, suppressing research that reflects negatively on drugs, and even ghostwriting research papers and opinion pieces.

Just last month, Warner-Lambert, a division of the drug giant Pfizer, agreed to pay more than \$430 million to settle criminal and civil charges that the company engaged in a widespread, methodical effort to encourage physicians to prescribe the anti-seizure drug Neurontin for unapproved uses. A Pfizer subsidiary (Parke-Davis) executive reportedly instructed the sales staff, “We need to be holding their hand and whispering in their ear: Neurontin for pain, Neurontin for everything.” An *NBC News* report aired recordings of the executive responding to employee concerns about off-label use of the drug, telling

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them, "Don't give me any of that safety crap."

And in early June, New York Attorney General Eliot Spitzer sued GlaxoSmithKline for consumer fraud, charging that the company covered up negative data about its popular anti-depressant Paxil. The company allegedly failed to inform physicians that studies showed the drug not only did not work in adolescents but in some cases could cause suicidal tendencies.

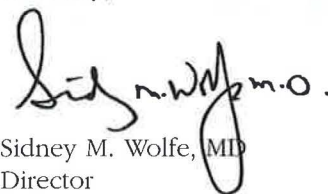
Meanwhile, drug companies have dramatically ramped up marketing efforts since the government relaxed rules on direct-to-consumer advertising in 1997. A 2002 Harvard-MIT study ("Trends in Direct-to-Consumer Advertising of Prescription Drugs") found that direct-to-consumer advertising by the industry increased from \$791 million in 1996 to roughly \$2.5 billion in 2000. Add to this scenario the fact that the drug ad watchdog — the U.S. Food and Drug Administration (FDA) — is no longer watching closely to see whether drug companies are violating advertising laws. This is evidenced by an 85 percent decrease in FDA enforcement actions against prescription drug advertising violations between 1998 and 2003. If the FDA isn't watching television, it certainly won't be monitoring MediZine's pseudo-news stories that promote drugs.

The education of patients — or physicians — is too important to be left to the pharmaceutical industry, with its pseudo-educational campaigns designed, first

and foremost, to promote prescription drugs. It remains a responsibility of the journalism gatekeepers to prevent the airing of this covert propaganda.

We ask you and other broadcast journalists to protect the integrity of the news by barring MediZine's advertorial health features and any similar type of sponsored "education" from your station's air waves. This will help ensure that viewers see fair, accurate and balanced coverage of medical topics.

Sincerely,



Sidney M. Wolfe, MD
Director
Public Citizen's Health Research Group

cc [news director name]
Fairness and Accuracy in Reporting (FAIR)

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Medizine: Drug Ads Masquerading as News

In December, 1990 as part of a Senate hearing chaired by Senator Ted Kennedy, a former employee of an advertising company that made video news releases for pharmaceutical companies testified. He explained how these slanted messages favoring the drug whose company paid for the "news release" were surreptitiously inserted into TV programming in a way that made them appear to be unbiased news, rather than the advertisements they actually were.

It appears that this form of misleading advertising is about to be re-launched this summer. We sent this letter to 258 local television station general managers and news directors in the country's top-30 television markets.

Mr./Ms.
July 9, 2004
General Manager, TV Station
Street Address
City, State Zip

Dear Mr./Ms.:

This summer, health information publisher MediZine Inc. and syndicated news programmer Daily Health Feed (DHF) will begin offering a series of health-related features to TV stations in major U.S. markets. This will be in addition to the DHF health news feeds that already are carried by stations in 39 markets. According to MediaDailyNews, these segments will be bought

and paid for by major pharmaceutical marketers and offered free of charge to local stations.

This programming, although disguised as "news," is nothing more than veiled advertising for pharmaceutical companies, which will use the free access to news programming to promote consumer demand for their products. According to news reports, the "Headline Health" segments will feature specific drugs, new medical procedures, medical organizations and even information about specific clinical trials.

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