

Health Letter

SIDNEY M. WOLFE, M.D., EDITOR

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Direct-To-Consumer Advertising—Education or Emotion Promotion?

This article by Health Letter Editor, Dr. Sidney Wolfe is reprinted from the New England Journal of Medicine 2002;346:524-526. Copyright © 2002 Massachusetts Medical Society. All rights reserved.

During the past two decades, there has been an irreversible change in the nature of the doctor-patient relationship. Patients are seeking much more medical information and are actively participating in decisions affecting their health. Intruding into this trend has been the rise of direct-to-consumer promotion, which, in its initial thrust, bypasses primary care doctors and other physicians. Although increased access by patients to accurate, objective information about tests to diagnose and drugs to treat illnesses is an important advance, confusion arises when commercially driven promotional information is represented as educational. Two articles in this issue of the *Journal* address the direct-to-consumer promotion of medical products and services. Rosenthal et al. describe the resources allocated to direct-to-consumer advertising of prescription drugs, as compared with other forms of promotion. Lee and Brennan examine issues arising from the direct-to-consumer marketing of high technology medical screening tests. These articles raise several questions. Is direct-to-consumer advertising educational or emotional? How often is it misleading? Is enforcement by the Food and Drug Administration (FDA) of ad-

vertising regulations adequate? What can be done to neutralize the negative effect of this type of advertising?

In an excellent review of direct-to-consumer promotion, Mintzes stated that "the question is not whether consumers should obtain information about treatment options; the question is whether drug promotion—whose aim is to sell a product—can provide the type of information consumers need."

Addressing the issue of pharmaceutical advertising more generally 30 years ago in the *Journal*, Ingelfinger argued that "advertisements should be overtly recognized for what they are—an unabashed attempt to get someone to buy something, although some useful information may be provided in the

process." He suggested that such advertising should be divested of its "pseudo-educational character."

Serious deficiencies have been documented in the educational value of advertising for prescription drugs. In a survey of 1872 viewers of television advertisements, 70 percent thought they had learned little or nothing more about the health condition requiring treatment, and 59 percent thought they knew little or nothing more about the drug being advertised. Another study found that whereas many advertisements provided information about the name and symptoms of the disease for which the drug was being promoted, few educated the patients about the success rate of the drug, the necessary

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January 11—February 11, 2002

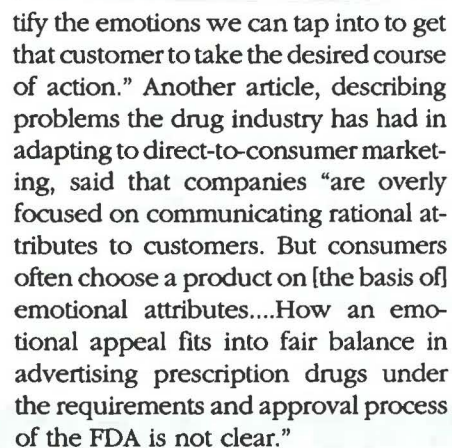
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None of these deficiencies should be surprising in the light of the characterization of advertising by the Canadian economist Stephen Leacock as "the science of arresting the human intelligence long enough to get money from it." Leacock also thought that, for the purpose of selling, advertising "is superior to reality." An advertisement, aimed at the marketers of pharmaceutical products, from an agency that creates drug advertisements, provides some revealing insights about how the process works. The promotional material describes the hippocampus as the "prescription-writing center of the brain"—the part that "processes information by connecting new concepts with the parts of the brain where gut instincts are formed, areas that influence emotional behavior and form memories." The advertising agency asserts that its "communications are focused on making the hippocampus respond positively to your product...[by demonstrating] how your product is superior and unique." An executive of a company that focuses on direct-to-consumer advertising commented that "consumers react emotionally, so you want to know how they feel about your message and what emotional triggers will get them to act.... We want to iden-



correctly believed that only the safest and most effective drugs could be advertised directly to consumers and that the FDA required that it be allowed to review advertisements before they were published. According to another study, consumers rated the safety and appeal of drugs described with an incomplete statement of risks more positively than similar drugs described with a more complete statement of risks.

Defenses of direct-to-consumer advertising by the pharmaceutical industry inevitably mention that the real gatekeeper is the doctor, since only the doctor can write a prescription. Even

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HMOs Try New Approach to Keep Drug Costs Down

PacifiCare Health Systems HMO Covers Generic Drugs Only to Keep Costs Down

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Robert Siegel, Host: From NPR News, this is *All Things Considered*. I'm Robert Siegel.

Noah Adams, Host: And I'm Noah Adams. The federal Medicare program doesn't pay for prescription drugs. Even so, many Medicare patients are able to get drug coverage by joining an HMO. That is changing, though, as more and

more health plans say they can't afford to pay for prescriptions. NPR's Patricia Neighmond reports on a Medicare HMO in California that is trying a new approach to keeping drug costs down.

Patricia Neighmond, Reporter: Sixteen years ago, PacifiCare Health Systems launched a new product. It was aimed at senior citizens who had Medicare health insurance. Medicare pays for basic doctor and hospital care, but not for many things older patients want. Medical director Dr. Sam Ho says the new Medicare HMO paid for many of those things.

Dr. Sam Ho, Medical Director: Prescription drug benefits, comprehen-

sive health improvement programs, preventive services, such as cancer screening programs, health education programs, dental benefits.

Patricia Neighmond: And with all that, PacifiCare won customers easily—in 10 years, over 1 million Medicare beneficiaries. Today it's the largest HMO for senior citizens. But since the beginning of this year the company has taken back one of its most valuable benefits. It no longer pays for brand name prescription drugs. It only pays for generic drugs. So if seniors want the new brand names, they'll have to pay out of their own pockets. Dr. Ho says the new policy results from an unfortu-

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Rosenthal et al. state that doctors will only write a prescription for a drug when they are "familiar with it and comfortable prescribing it." Although it is beyond the scope of this editorial, it is important to examine studies assessing the accuracy of sources of information that physicians use to learn about new drugs or devices. There is evidence that many drug advertisements are not balanced or accurate, and duped gatekeepers may not adequately resist patients' exhortations to write a prescription.

Since a ban on the advertising of pharmaceutical agents is incompatible with the First Amendment, much stricter control by the FDA of misleading advertising is necessary. Although expenditures for the promotion of drugs increased from \$11 billion in 1997 to \$15.7 billion in 2000 (see Figure 1, pg. 2), there is a significant decrease in the number of actions taken by the FDA to enforce advertising regulations—from 139 letters of warning to companies or notices of violation in 1997 to 79 in 2000 and an estimated 73 in 2001. The FDA is grossly understaffed for this important oversight function: the en-

tire Division of Drug Marketing, Advertising, and Communications (DDMAC) has had only 28 to 30 employees since 1997. A further handicap for the FDA is that it lacks the legal authority to impose civil monetary penalties on companies even when they repeatedly violate the law. An editorial in a December 2001 issue of *Business Week* commented that "pharmaceutical company advertising on TV promotes high-priced new drugs with marginal improvement over cheaper generic versions. The FDA should crack down harder on misleading ads." In the realm of screening computed tomographic CT scans analyzed by Lee and Brennan, enforcement is beginning to occur. FDA recently sent a notice of violation to a company, CATscan2000, for illegally promoting screening for heart disease in asymptomatic people: this form of technology has not been approved for use in such screening.

Beyond increased enforcement by the FDA, the issue of better information for patients must be addressed. The irritation felt by many physicians when patients approach them after seeing a direct-to-consumer advertisement may derive from the fact that such advertisements, with their powerful,

emotion-arousing images and frequently unbalanced information on safety and effectiveness, mislead patients into believing that drugs are better than they actually are. There is a hollow ring to the statement by Pharmaceutical Research and Manufacturers of America President Alan Holmer that "direct-to-consumer advertising is an excellent way to meet the growing demand for medical information, empowering consumers by educating them about health conditions and possible treatments."

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 drugs. Public Health Service agencies such as the National Institutes of Health and the FDA, along with medical educators in schools and residency programs, must move much more forcefully to replace tainted drug company "education" with scientifically based, useful information that will stimulate better conversations between doctors and patients and lead to true empowerment.

Rx Needed for Medical Journals

Drug Companies Influence Research; They Also Affect What Gets Published

The following article was reprinted from the January 28, 2002 issue of *The Nation* magazine with their permission. It was written by Sonia Shah a freelance writer based in Storrs, Connecticut. The Nation's website is www.thenation.com.

Why did the esteemed *Journal of the American Medical Association* publish a paper showing that blockbuster anti-arthritis drug Celebrex is superior to a \$7 bottle of ibuprofen, while the FDA maintains it isn't? Because the scientists who wrote the paper—their expenses paid by Celebrex manufacturer, Pharmacia—selectively omitted half their study data to make the boss's drug look good.

The Celebrex case isn't an aberration, according to Public Citizen's Dr. Sidney Wolfe. "People are injured and killed as a result of incomplete data being published and studies being designed in the wrong ways," he says. Corporate researchers attempt to prove marketing claims, not insure public health, critics say, so results are buffed or bullied even if it means impeding doctors' understanding of illness and health.

The problems, however, go beyond eager-to-please scientists and eager-to-earn corporations. Medical journals are themselves reliant on drug industry largesse. As a result, they are ill equipped to exclude unsavory, publicity-seeking corporate research from their public platform.

In September, in an unprecedented joint editorial, editors of 13 leading medical journals, including the *Journal of the American Medical Association* [JAMA] as well as the *New England Journal of Medicine*, *Lancet* and the *Annals of Internal Medicine*, announced a plan to fight back. Along with previously required disclosures about funding, conflicts of interest and scientific contributions, they declared they would also require authors to confirm that their sponsors gave them independent access to data and control

over their publication. (Even the standard disclosures required by hundreds of journals have had limited success. Tufts University's Sheldon Krimsky analyzed the 1997 editions of more than 200 journals, finding that more than half hadn't published a single disclosure, a percentage that is startling given widespread industry support and participation in biomedical research.)

"The pharmaceutical industry has academic clinical investigators in a corner," explains Richard Horton, editor of the *Lancet*. Medical research on human subjects is poorly funded by the federal National Institutes of Health, Horton and others contend, because the agency favors the control and precision of laboratory science in which experimental subjects don't have complicated needs and rights. The result, not surprisingly, is that academic researchers often turn to the drug industry for cash. Corporations now fund 70 percent of all clinical research conducted in this country. Most of this research is "careful, good work," says former editor of the *Annals of Internal Medicine* Frank Davidoff. Even so, company sponsors see the academic work they fund as "marketing primarily, not scientific research," he says.

The problems start when expensive, time-consuming clinical trials paid for by the corporations produce negative results that contradict marketing claims. "The academics want to be able to take that information and tease it apart, to look at the good parts and the bad parts too. But the pharmaceutical companies' marketing departments are going to say they don't want to report on the bad stuff," says Dennis DeRosia, chair-elect of the Association of Clinical Research Professionals. In extreme situations, the struggle for control over data resorts to mudslinging and lawsuits. The Immune Response Corporation, for example, slapped a \$10 million lawsuit on scientists it had hired to study its therapeutic vaccine Remune who wanted to publish results showing that Remune was ineffective. "I

spent over \$30 million," the company's president complained to the *Baltimore Sun*. "I would think I have certain rights." The case was eventually settled out of court, and the study was published in the November 1, 2000, *JAMA*.

In such cases, journals' new rules may help scientists negotiate better contracts with their industry sponsors. But there is no antidote to the problem of subtle, pro-industry bias toward positive results when scientists are more than willing to sign on. A case in point is the controversy over the recent study of Celebrex, funded by Pharmacia and Pfizer. "Super-aspirins" such as Celebrex and Merck's Vioxx were developed to improve upon cheaper, over-the-counter remedies like ibuprofen by reducing the incidence of bleeding ulcers and other gastrointestinal side effects. With just a year of aggressive marketing to consumers (later condemned by the FDA as misleading), Celebrex sales leapt to \$1.3 billion, even though FDA-required warning labels on the product stated that its advantage over ibuprofen—which costs about a third of what Celebrex does—was essentially unproven.

In September 1998 Pharmacia and Pfizer launched a study of more than 8,000 patients, overseen by industry scientists and hired academics from eight major universities, seeking to prove to the FDA that Celebrex deserved freedom from the stigmatizing warning labels affixed to competitors ibuprofen and diclofenac. The findings of the study were uninspiring. Celebrex patients developed ulcer complications more than twice as often as researchers expected, and this rate was statistically indistinguishable from the rate for patients taking the comparison drugs. But the study was a huge one, with thousands of patients and reams of data—surely some other conclusion could be made. And indeed, upon closer inspection, the researchers found that they could demonstrate a slight, qualified advantage for Celebrex if they left out the second six months of

the study. A statistical anomaly—the faster dropout rate of susceptible patients in the comparison group—could shore up such a step.

While this move may have made Celebrex look marginally better than its competitors, it also diminished the study's clinical significance. "People aren't on these medications for six months; most are taking them for years on end," says Dr. David Lichtenstein, a gastroenterologist at the Boston University School of Medicine. But what's worse, critics say, is that the team's September 13, 2000, *JAMA* paper on the study neglected to mention that portions of the data had been selectively omitted. Those academics "had full control over the data and publication" of the study, Pharmacia's vice president of medical affairs, Dr. John Fort, assured me. Perhaps so. But they also have industry ties even beyond those they disclosed publicly. What *JAMA* readers did not hear about is that one academic author is an epidemiologist mired in controversy over his claims that the doomed diet drug Redux was safe and effective while he was on the manufacturer's payroll, another is a rheumatologist whose smiling face appears prominently on the Celebrex website, and a third is a partner in a venture capital firm.

A casting glitch raised the curtain on Pharmacia's behind-the-scenes data manipulation. Upon request by *JAMA* editors, Lichtenstein and gastroenterologist Dr. M. Michael Wolfe reviewed Pharmacia's paper and wrote a tepidly favorable editorial to accompany it. But six months later, Wolfe sat on the FDA committee that considered the study in its entirety—a vantage point from which Celebrex's apparent advantage disappeared. He told the *Washington Post* he was "furious. ... I looked like a fool." The FDA rejected the label change application. But the *JAMA* paper had already gone public, and by confirming the marketing hype, "probably had [d] more impact than our labeling," an FDA official told the *Post*.

Sometimes the unseen data are more alarming than the seen. Perhaps the most famous case dates back to 1978, when the *New England Journal of Medicine* reported that Ciba-Geigy's gout drug Anturane had been found to reduce the incidence of fatal heart attacks in people who had suffered at least one previous heart

*Celebrex patients
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expected*

attack. The finding was hailed by the *New York Times* as one of the most important medical advances of the decade—until the FDA alerted journal editors that they were rejecting the new use for the drug. While it did indeed reduce the incidence of cardiac deaths, it increased deaths overall.

Journal editors wring their hands over such debacles, but the reality is that medical journals must curry favor with drug company marketing execs. "If we publish a study that finds positive results, then the industry is delighted and buys lots of reprints," *Lancet* editor Horton confirms. According to insiders, the *Lancet's* parent company, Reed Elsevier, contractually requires Horton to increase the journal's revenues by 10 percent a year. Given flat subscription rates, that means increasing reprint revenues, which now exceed the journal's subscription income, says Davidoff, the former *Annals of Internal Medicine* editor. Most medical journal editors don't muddy their hands with advertising decisions, but

the companies and societies that pay their salaries are not above agitating for a bigger piece of the \$5 billion drug industry advertising pie—and forcing editors to make their pages as industry-friendly as possible. Reed Elsevier's *Excerpta Medica* helps companies place positive articles about their drugs in top tier medical journals, many of which are conveniently owned by Reed Elsevier. Last spring the American Medical Association and the Massachusetts Medical Society, publishers of *JAMA* and the *New England Journal of Medicine*, respectively, funded a study with little clinical application: It showed that ads in their journals' pages more effectively boosted drug sales than expensive television spots aimed at consumers.

The Massachusetts Medical Society, which earns more than three-quarters of its income from journal revenues, pushes editors to be even more amenable to industry dollars, critics say. In a controversial 2000 move, for instance, the society replaced its independent-minded editors with asthma specialist Dr. Jeffrey Drazen, who had ties to more than 20 companies (which he said he would sever before assuming his new post). Drazen's effusive praise for Sepracor's drug levalbuterol, which he was paid to evaluate, was featured in company advertising materials and was later criticized as overstated by the FDA.

Given all this, the journals' new rules are certainly a step in the right direction. But publishing rules alone won't dam the tidal wave of industry dollars sweeping through medical research and publishing, with the very real risk of bias those dollars represent. Ultimately, clinical research must be supported with greater independent funding, and there should be federal rules that ban corporate participation in research the pharmaceutical industry does sponsor. Until then, public health is likely to continue to take second place to private gain.

GENERIC DRUGS, from page 3

nate confluence of events.

Dr. Sam Ho: The costs of drugs have increased approximately 90 percent in the last five years, almost doubled in the last five years.

Patricia Neighmond: And at the same time, the federal government cut back its payments to Medicare HMOs. That means less money for health plans like PacifiCare.

Dr. Sam Ho: We just cut 15 percent of our work force. That was an extremely painful decision, but we've had to live within our means and we had to make ourselves a stronger company in the face of these restricted federal reimbursements.

Patricia Neighmond: Most HMOs, even those serving younger people, have increased what consumers have to pay for prescription drugs. Some have dropped drug benefits altogether. In this context, Dr. Ho says paying only for generics is better than nothing. And as of January, about half of all Medicare HMOs switched to similar policies. For most medications, generic versions are available, but when they're not, patients can face big costs and difficult decisions. Cybil Totten has insurance with PacifiCare. She's 70 years old and has severe rheumatoid arthritis. Until recently, her disease was so debilitating she was nearly bed-ridden.

Ms. Cybil Totten, Patient: It was a struggle to walk around. It was a struggle to do anything. Then when I did do a little something, I would get really tired and have to go and lie down. And then it would affect my back, and so it was hard for me to even straighten up. And then you'd feel like you were walking like an old woman.

Patricia Neighmond: For an active person like Totten, life was miserable. Her doctor tried a number of arthritis drugs. One didn't help, another helped but the side effects made Totten severely ill. Then a new drug came on the market. Its brand name, Enbrel.

Ms. Cybil Totten: After about two doses, right away I started to feel much better. My whole system was better in about two weeks, and I started to play tennis again and be active, and my whole changed and became more normal again.

Patricia Neighmond: But now all of that is threatened. Because Enbrel is a new drug, it's still under patent, so there are no generics available. If Totten wants the drug, she'll have to pay for it herself. It costs over \$1,000 a month.

Ms. Cybil Totten: The only way I think we really could afford it, my husband said, is, 'Well, we could sell the house.' He said he doesn't want me to go without something that really helps me and to live a normal life, and that's what he would be willing to do.

Patricia Neighmond: Totten's doctor, rheumatologist Eileen Schwartz, says that since the first of the year, patients have called her every day saying insurance no longer covers their medications.

Dr. Eileen Schwartz, Rheumatologist: More than ever, I feel like I'm just about being told how to treat my patients. And, you know, I don't have a huge ego, so it's not an ego issue with me. It's that I know what's right morally and ethically. And I do feel that we need to give these patients the best care possible. We've made them live a long time through all of our progress in various areas, and now we need to take care of them.

Patricia Neighmond: The doctors Schwartz works with share similar concerns and worry about their patients getting what Schwartz describes as the latest and greatest in medications. Consumer advocate Dr. Sidney Wolfe directs Public Citizen's Health Research Group. Wolfe says these new diminished drug benefits are simply symptoms of an escalating financial war between two health care giants.

Dr. Sidney Wolfe, Public Citizen's Health Research Group: You've got an insurance industry that is largely increasingly

controlled by stockholders and a pharmaceutical industry which is controlled by their stockholders who want to get as much money as they can. And so the profit margin for the insurance company, on one hand, and the profit margin for the pharmaceutical industry, on the other hand, are really at war with one another.

Patricia Neighmond: Wolfe speculates the war won't end unless something big changes. Either brand name drug prices come down or the federal government decides to include coverage for prescription drugs in Medicare. Congress has been debating that idea for years, but the benefit is very costly and, therefore, controversial. And now, without any federal surplus, it's unlikely to be seriously considered. Patricia Neighmond, NPR News, Los Angeles.

* * *

Some Formulary Restrictions Make Sense

The PacifiCare example cited above is outrageous, because its bottom line is how this for-profit HMO can maximize revenue for its executives and shareholders, patients be damned. But the idea of formularies with restrictions for the benefit of patients is a good one. For example, the not-for-profit Group Health Cooperative of Puget Sound (the Seattle area) never added to its formulary several drugs approved in the late 1990s which eventually were taken off the market because of their dangers combined with the lack of a unique benefit. Therefore, the idea of HMO formulary committees looking at clinical data on safety and effectiveness and concluding that the new drug is no more safe or effective than older ones and might actually be less safe benefits patients using that HMO.

Contrast this with the PacifiCare situation which disregards individual patient clinical needs and bases its decision not to reimburse for any brand name drug, even ones which do not have a generic version, on what is best for those who are financially invested in the HMO.

Product Recalls

January 11–February 11, 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.

Class I Recalls

Name of Drug or Supplement; Class of Recall; Problem

Metabolife Diet & Energy Bar with special Nutrition Formula, contains inulin, green tea extract; Products contain excessive amounts of Vitamin A

Solgar's Digestive Aids packaged in plastic bottles of 100's; Product was manufactured using pepsin that American Laboratories, Inc. recalled due to salmonella contamination

Nature's Plus brand Natural Cleansing Supplements; Products were manufactured using pepsin that American Laboratories, Inc., recalled due to salmonella contamination

Lot #: Quantity and Distribution; Manufacturer

Lemony Lemon (yogurt coated), Downright Chocolate (chocolate flavor coated), Perfectly Peanut (chocolate flavor coated), Outrageous Oatmeal Raisin (yogurt coated). Best buy dates 2/16/02 and earlier; 4,917,216 bars distributed nationwide; Metabolife International, San Diego, California

Lots 31993 and 30957; 754 bottles distributed nationwide, and in the United Kingdom, South Africa, France, Ireland, and Israel; Solgar Vitamin and Herb, Leonia, New Jersey

Numerous product codes; 22,256 bottles distributed nationwide and internationally; Natural Organics, Inc., Melville, New York

Name of Drug or Supplement; Class of Recall; Problem

AK-CIDE brand of Prednisolone Acetate and Sulfacetamide Sodium, ophthalmic ointment-sterile; Class III; Subpotency for sodium sulfacetamide component (stability)

Anti-Aging Wrap Solution, 8 oz., 32 oz. and 36 oz. plastic bottles (conditioned water plus a proprietary blend of sodium magnesium and potassium salts, boron and other naturally occurring trace elements and herbal essences); Class II; Microbial contamination; product is contaminated with *pseudomonas aeruginosa*

Canasa, Mesalamine Suppositories, 500 mg, 30 suppository unit carton, for rectal use only, Rx only; Class II; Dissolution failure (6 month stability station)

Carbamazepine Tablets, Tegretol brand, 200 mg, in bottles of 100 and 1000 tablets; Class II; Dissolution failure (at stability testing)

Lot #: Quantity and Distribution; Manufacturer

Lots 9-AH-1, 9-AH-2 EXP 3/02; 48,000 units distributed in Illinois; Schering-Plough Products, Inc., Manati, Puerto Rico

All codes labeled as "Anti-Aging Wrap" distributed from 10/1/00 through 10/1/01; Unknown quantity distributed nationwide; Pyramid Consulting and Investment Co., Inc., Clearwater, Florida. Recalled by VMM Enterprises, Inc., Clearwater, Florida

Code 1C057 and 1C058; 3,220 boxes of 30 units distributed nationwide; Axcan Pharma, Quebec, California. Recalled by Scandipharm, Inc., Birmingham, Alabama

Lot 124B0093 EXP 4/02, 174D4344 EXP 2/03, 234E9126 EXP 3/04; 88,424 bottles distributed nationwide and in Puerto Rico; Novartis Pharmaceuticals Corp., Suffern, New York

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Name of Drug or Supplement; Class of Recall; Problem

Lot #: Quantity and Distribution; Manufacturer

Clindamycin Phosphate Topical Solution, 1 oz. & 2 oz. bottles, Rx only; Class III; Degradent failure for clindamycin

Lots 23408A, 23408C, 23408E; 11,823 bottles distributed nationwide; Morton Grove Pharmaceuticals, Inc., Morton Grove, Illinois

Clonazepam Tablets, 1 mg, 500 tablet bottles, Rx only; Class III; Misbranding—tablets debossed with incorrect code (93-832 for 0.5mg)

TEVA brand label Lot 356519 EXP 8/03; 1,904 bottles distributed nationwide; Teva Pharmaceuticals USA, North Wales, Pennsylvania

Cortisporin Otic Suspension and Solutions, Sterile (Neomycin and Polymyxin B Sulfates and Hydrocortisone Suspension), 10mL with sterilized dropper, Rx only; Class II; Lack of assurance of sterility (glassware defects)

Lot 0B1436 EXP 3/02, 0I1407 EXP 11/02 and 0D1791 EXP 8/02; 151,992 units distributed nationwide; DSM Catalytica Pharmaceuticals, Greenville, North Carolina. Recalled by King Pharmaceuticals Inc., Bristol, Tennessee

Cortisporin Ophthalmic Suspension Sterile (Neomycin and Polymyxin B Sulfates and Hydrocortisone Ophthalmic Suspension), 7.5 mL Drop Dose, Rx only; Class II; Lack of assurance of sterility

Numerous codes; 693,718 units distributed nationwide; DSM Catalytica Pharmaceuticals, Greenville, North Carolina. Recalled by King Pharmaceuticals Inc., Bristol, Tennessee

Derma-Smoother, Rx only, 4 fl. oz.; Class III; Subpotency for fluocinolone acetoneide

Lots L000099, M000110, B010020, B010026, C010038, D010045, A010004 and C010030; 226,659 bottles distributed nationwide and in Canada; Hill Dermaceuticals, Inc., Sanford, Florida

GenTeal Lubricant Eye Drops, 0.3% hydroxypropyl methylcellulose 0.845 fl.oz. (25mL) bottles; Class II; Non-Sterile-contamination with penicillium sp

Lot No. 96455; 22,272 units distributed nationwide; Novartis Ophthalmics, Inc., Duluth, Georgia

Humalog Injection Kits; Class II; Subpotency (Last dose may deliver less insulin than expected due to breakage of pen internal parts)

Humalog kits lot FF1E79J, Humacart 3/7 kits lots FF1J79J and FF1J79N EXP 05/03, Humacart R kits lots FF1J71K and FFOV67A EXP 5/03 and 9/03; 115,000 pens distributed in Japan; Eli Lilly and Co., Indianapolis, Indiana

Infants' Gas Relief Drops; Class II; Microbial test specification failure

CVS brand Lot 1251 EXP 4/03; 12,210 bottles distributed nationwide; Accumed Inc., Lawrenceville, New Jersey

Infants' Simethicone Drops; Class III; Subpotent for simethicone

Distributed under 52 brand labels, all lots within expiry; 234,473 bottles distributed nationwide, and in Vietnam and the Philippines; Perrigo, Allegan, Michigan

Ketoprofen Extended-Release Capsules, 200 mg., 100 capsules bottles labeled as Mfd. for: Schein Pharmaceutical, Inc., Mfd by: Elan Pharma Ltd., Rx only; Class III; Dissolution failure (at stability testing)

Lot POK0252; 8,646 bottles distributed nationwide; Elan Pharma Ltd. County Westmeath, Ireland. Recalled by Elan Pharmaceuticals Research Corp., Gainesville, Georgia

Levothroid Tablets, Forest Brand (levothyroxine sodium tablets), 25 mcg., Rx only; Class II; Subpotent—prior to labeled expiration date

Lots: 120011 EXP 12/02, 120013 EXP 12/02; 29,054 bottles distributed nationwide; Forest Pharmaceuticals, Inc., St. Louis, Missouri

Neomycin and Polymyxin B Sulfates and Hydrocortisone OTIC Solution, Sterile, 10mL with sterilized dropper, Rx only; Class II; Lack of assurance of sterility (glassware defects)

Lots 0C1782, 0C1783, 0C1784, 0C1785 EXP 7/02 0C1786, 0C1787, 0C1788, 0C1789 EXP 8/02. 0F2139 10/02; 410,154 units distributed in Texas, Nevada and Maryland; DSM Catalytica Pharmaceuticals, Greenville, North Carolina. Recalled by King Pharmaceuticals Inc., Bristol, Tennessee

Neomycin and Polymyxin B Sulfates and Hydrocortisone OTIC Suspension, Sterile, 10 mL with Sterilized Dropper, Rx only; Class II; Lack of assurance of sterility (glassware defects)

Numerous codes; 1,164,571 units distributed in Texas, Nevada and Maryland; DSM Catalytica Pharmaceuticals, Greenville, North Carolina. Recalled by King Pharmaceuticals Inc., Bristol, Tennessee

D R U G S & D I E T A R Y S U P P L E M E N T S *cont.*

Name of Drug or Supplement; Class of Recall; Problem

Neosporin G.U. Irrigant Sterile (Neomycin Sulfate and Polymyxin B Sulfate solution for irrigation), 20mL multiple dose vial, Rx only; Class II; Lack of assurance of sterility (glassware defects)

Otrivin, Pediatric and Adult Nasal Drops (0.05% xylometazoline HCl) nasal decongestant, .83 fl oz (25ml) bottle; Class II; Container closure deficiencies leading to leakage/evaporation and possible higher concentrations of the active ingredient

Pain Relieving Rub, Greaseless, Stainless Analgesic Cream, (Menthol 10%, Methyl Salicylate 15%), 4 oz net weight tube; Class III; Subpotent active ingredient methyl salicylate

Pedlotic Suspension Sterile, 7.5mL with sterilized dropper, (Neomycin and Polymyxin B Sulfates and Hydrocortisone otic Suspension) for use in ears only, Rx only; Class II; Lack of assurance of sterility (glassware defects)

Poly-Tussin Syrup sugar free/alcohol free sorbitol free/sodium free 16 oz bottles, Rx only; Class II; Superpotency

Premarin Tablets, 1.25mg (Conjugated Estrogens Tablets), Rx; Class III; Dissolution failure by manufacturer

Respond First Aid Antiseptic Spray and Respond Burn Relief with Aloe Vera; Class III; Potency: Super-potent Benzocaine in burn spray, Sub-potent Lidocaine in antiseptic spray

Risperdal (Risperidone) Tablets, 0.25mg, bottles of 60 and 500 tablets. Rx only antipsychotic agent; Class III; Dissolution failure

Triple Paste, Medicated Ointment, Zinc Oxide 11.6%; Class II; Misbranding: product used as labeled may cause skin irritations

Lot #: Quantity and Distribution; Manufacturer

Lot 9J2127, EXP 11/03; 13,223 units distributed nationwide; DSM Catalytica Pharmaceuticals, Greenville, North Carolina. Recalled by King Pharmaceuticals Inc., Bristol, Tennessee

Numerous lots; 231,260 bottles distributed nationwide; Patheon Inc., Mississauga, Ontario, Canada. Recalled by Novartis Consumer Health Inc., Summit, New Jersey

Lots 0045-3 EXP 3/02 and 0095-3 EXP 4/02; 18,768 pieces distributed nationwide; G & W Laboratories, South Plainfield, New Jersey.

Lots: 0F2247, 0F2248, 0C1661, 0G2420 EXP 8/02, and 0I1412 EXP 11/02; 110,663 units distributed nationwide; DSM Catalytica Pharmaceuticals, Greenville, North Carolina. Recalled by King Pharmaceuticals Inc., Bristol, Tennessee

Lot 1E04, EXP 05/03; 1,313 bottles distributed in Kentucky; Pharmakon Labs, Inc., Tampa, Florida

Lot #03138, EXP 09/03; 41,545 bottles distributed nationwide; Ayerst Laboratories, Rouses Point, New York. Recalled by Rx Pak, Division of McKesson HBOC, Memphis, Tennessee

Respond Burn Spray, Lot #0011037; Respond Antiseptic Spray, Lot #0003065; 244 cases distributed nationwide; York Pharmaceuticals, Kansas City, Kansas. Recalled by Respond Industries, Inc., Arvada, Colorado

Numerous lots numbers; 537,295 bottles distributed nationwide; Janssen-Cilag S.P.A Latina, Italy. Recalled by Pharmaceutical Sourcing Group Americas (Janssen), Titusville, New Jersey

Lots: 102101 EXP 10/04 and 107011 EXP 11/04. 1 lb size Lots: 102101 EXP 10/04, 107011 EXP 11/04, and 106011 EXP 11/04. Sample size Lot: 102101 EXP 10/04; 25,687 units distributed nationwide; EMS Fort Washington, Pennsylvania. Recalled Summer Laboratories Inc, Collegeville, Pennsylvania

M E D I C A L D E V I C E S

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

First Aid Kits; Class III; Kits contain burn relief spray &/or antiseptic spray recalled by York. Sprays are sub- and super-potent

Lot #: Quantity and Distribution; Manufacturer

Various product codes; 2,994 kits distributed nationwide; Textilease Medique, Wood Dale, Illinois

M E D I C A L D E V I C E S , *cont.*

Name of Drug or Supplement; Class of Recall; Problem

First Aid Kits; Class III; Kits contain burn relief spray &/or antiseptic spray recalled by York. Sprays are sub- and super-potent. Also, leaking containers or loose caps

Latex Condoms; Class II; Failed FDA leak testing

LifeScan Brand One Touch Profile Meter, Blood Glucose Meter; Class II; Meters may develop display problems

Lot #: Quantity and Distribution; Manufacturer

There are no codes applied to the various First Aid Kits affected; Undetermined quantity distributed nationwide and in Canada; Zee Service Inc., Irvine, California

Lubricated, model number 9030, lot number 0661123; 109 cases of 1000 distributed nationwide and in Canada; Alatech Healthcare, LLC Slocumb, Alabama

All codes/serial numbers; 3,000,000 distributed nationwide and internationally; Lifescan Inc., Milpitas, California

C O N S U M E R P R O D U C T S

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 <http://www.cpsc.gov>.

Name of Product; Problem

Baseboard Heaters; Heating element in these baseboard heaters can short circuit and ignite combustible material under the heater, posing fire and burn hazards to consumers

Cordless Electric Lawn Mowers, Recall to Repair; Clips holding the control cable to the handle may be missing, which could cause the blade control device to fail and keep the mower blade running when it should stop

Dehumidifiers; Can overheat, posing a fire hazard

Dried Flower Candles; When burned, the dried flowers in the candle can catch on fire, posing fire and burn hazards to consumers

Electric Pressure Washers; MCM International imported the pressure washers from a manufacturer in China who installed counterfeit ground fault circuit interrupter (GFCI) plugs on some of the units, without MCM's approval

Gas Ranges; Hot air is vented below the small oven and causes the metal surface on the door of this oven to get too hot, presenting a burn hazard to consumers

Lot #: Quantity and Distribution; Manufacturer

Model HZ-514HCP; 450,000 sold nationwide from October 1997 through January 2001; Honeywell Consumer Products Inc., Southborough, Massachusetts (866) 264-9230 www.honeywell.com

Model CMM1000R, date codes between 0043 M.N.D.C. and 0121 M.N.D.C.; 1,300 reconditioned mowers sold at Black and Decker factory stores nationwide from December 2000 through May 2001; Black & Decker (U.S.) Inc., Towson, Maryland (866) 229-5570 www.blackanddecker.com

2 feet high with serial numbers that begin with QG, QH, QJ, QK or QL; 1.4 million sold nationwide from February 1997 through December 2001; Whirlpool Corp., Benton Harbor, Michigan (866) 640-7139 www.whirlpool.com

Botanical uncolored wax with dried yellow, purple and brown flowers in the outer layer; 6,400 sold at Value City and Schottenstein stores nationwide from January through December 2001; Value City and Schottenstein Stores, Columbus, Ohio (888) 278-6370 www.valuecity.com

Black Cat™ All plugs are labeled "WELLONG"; however, the pressure washers with counterfeit "WELLONG" GFCI plugs appear virtually identical to those with genuine "WELLONG" GFCIs. It will require a professional inspection to identify the counterfeit GFCIs; 50,000 sold at Target and Menard's stores nationwide from August through September 2001; MCM International, Eden Prairie, Minnesota (800) 304-1316

Thermador brand 48-inch All-Gas Professional Ranges model numbers PRG484GGUS, PRG486GDUS, and PRG486GLUS and serial number ranges 98020001-98129999, 99010001-99129999, 20010001-20129999 and 81010001-81119999; 2,460 sold nationwide from March 1998 through November 2001; BSH Home Appliances Corp., Huntington Beach, California (800) 735-4328

Name of Product; Problem

Gel Candle Kits; When burned, the gel candle can melt the plastic candleholders included with the kit, posing a fire hazard to consumers

Lunch Bottles; Bottles have a weak seal and can leak hot liquids, which poses a serious burn hazard to consumers

Nightlights; Nightlights can short circuit, posing shock and burn hazards

Power Inverters; The GFCIs on the inverters, which are intended to protect consumers against shock and electrocution, could fail to operate correctly

Ross Root Feeders; The mixing chamber caps on these feeders can detach during use and strike nearby consumers, resulting in injuries

Scuba Diving Devices; Overpressure valve can stick in the open position, posing a drowning hazard to divers

Toasters; Heating element in these toasters can continue to operate after use, posing a fire hazard

Lot #: Quantity and Distribution; Manufacturer

Kits include bags of gel chips and candle supplies, models 3041 or 3042; 2,300 sold at Value City and Schottenstein stores nationwide from January through December 2001; Value City and Schottenstein Stores, Columbus, Ohio (888) 278-6370 www.valuecity.com

Wide Mouth 32 oz stainless steel; 4,000 sold at Eddie Bauer outlet stores nationwide from September through November 2001; Eddie Bauer Outlet Stores, Redmond, Washington (800) 426-6253 www.eddiebaueroutlet.com

Electroluminescent models GN 172 and GN165; 156,000 sold nationwide from January 1999 through December 2001; Intermatic Inc., Spring Grove, Illinois (800) 391-4555

Numerous models. Check CPSC website or hotline; 1,600 sold nationwide from November 1999 through November 2001; Vector Manufacturing Ltd., Fort Lauderdale, Florida (866) 584-5504

30 inches tall, model 1200C; 345,000 sold nationwide from October 1994 through January 2002; Easy Gardener Inc., Waco, Texas (800) 621-4769 www.rosscap.com

Jacket and wings style with brand names Diving Unlimited International (DUI), International Divers, Ocean Management Systems, Rip Tide and Steam Machines; 7,700 sold nationwide from October 2000 through November 2001; Custom Buoyancy Inc., Torrance, California (766) 790-5099 www.custombuoyancy.com

Black & Decker® brand model number T1200, T1250, T1400 or T1450; 2.1 million sold nationwide from June 1999 through January 2002; Applica Consumer Products Inc., Miami Lakes, Florida (866) 264-9230 www.householdproductsinc.com

PHYAMERICA, from page 12

signed to see 35,000 patients per year but currently sees almost twice that number.

PhyAmerica has a history of some rather unusual bill-collecting practices: *The Wall Street Journal* reported that the company sent letters to patients in Florida threatening to "employ the attorney general" if they failed to cough up their fees. According to one lawsuit brought against the company, this was a violation of the Florida Consumer Collection Practices Act, since, as attorneys general do not collect debts, creditors may not assert legal rights that they don't have. Although the penalty per violation is only \$500, because the company sent out between 150,000 and 190,000 letters, total penalties would

be in the millions of dollars. *The Journal* reported that in the court brief, PhyAmerica argued, that if the case were to be successfully prosecuted, the company would be faced with "ruinous damages," which would "far outweigh any harm caused by the alleged violations."

Additionally, in 1993 the company was the subject of a *60 Minutes* report, which accused it of hiring doctors who had been disciplined or sued for malpractice. The company disputed this claim.

Nevertheless, the company has reportedly told St. Joseph's officials that it has mended its old ways and is turning itself around. *The Record* reports that the company plans to save money by restructuring its debt, as well

as buy back its stock and become a private company—a move that would protect it from further public scrutiny.

St. Joseph's isn't the only institution supporting this "rehabilitated" company: PhyAmerica Government Services recently won a \$568,767 contract from the U.S. Department of Veteran Affairs for the Department's Fresno, California facility. It is not clear whether the VA was fully aware of the precarious situation of PhyAmerica when it signed this contract.

We wish St. Joseph's in Paterson, New Jersey and the Fresno VA well in their pacts with PhyAmerica but are very concerned that the troubled past of this company might be a prologue to more troubles.

We Wish this Hospital Well

Imagine a health care company which:

- in the five years ending in 2000, lost \$328 million, according to the company's annual report;
- has dropped from \$40 a share in 1994 to 13 cents as of February, this year and which was delisted by the New York Stock Exchange in 1998;
- last year alone lost 10 hospital contracts and settled a lawsuit alleging mismanagement and fraud;
- was sued for attempting to pressure patients in Florida to pay their bills by threatening to employ "the office of the Attorney General." (Attorneys general, in fact, do not collect debts.)

Would you want this company running your emergency department?

St. Joseph Hospital in Paterson, New Jersey does.

According to the *Bergen Record*, the

medical center, which was founded in 1867 by the Sisters of Charity of St. Elizabeth, recently signed a three year contract with PhyAmerica, commencing in January 2002. In doing so, the hospital and St. Joe's emergency physicians join over 200 emergency rooms and about 3,000 physicians nationwide as part of the PhyAmerica family. The company oversees patient flow, staff scheduling, and patient billing at St. Joseph's, which has been dedicated to caring for the poor since its founding, and, according to *The Record*, receives minimal or no payment from a third of the patients seen in its ER. The hospital hopes that the company, which according to *The Record* is so far in debt that its interest payments alone were \$18 million in 2000, can help it out of its own financial difficulties. St. Joseph's, Paterson's largest employer, has a budget gap of \$30 million, and in October 2001 laid off 120 employees, cut 60

unfilled positions, and has also cut salaries in order to save millions of dollars.

The management company, which in 1999 changed its name from Coastal Physician Group to PhyAmerica in hopes of burying its past, intends to improve the hospital's financial footing in part by providing pay incentives to physicians for seeing more patients, a move that concerns some patient advocates and physicians alike. Defending this practice, *The Record* quotes a regional president of PhyAmerica, Mark Rosenberg, a physician himself, as saying "... whether it's a Wal-Mart or anything else, the more people you see, the more sales you make, the more money you have." He added that without pay incentives, doctors have a "blue collar mentality" and "don't care if they see one patient in 12 hours." According to *The Record*, the emergency room at St. Joseph's is de-

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