

# Health Letter

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## Medical Journals Are an Extension of the Marketing Arm of Pharmaceutical Companies

By Richard Smith

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“Journals have devolved into information laundering operations for the pharmaceutical industry”, wrote Richard Horton, editor of the *Lancet*, in March 2004. In the same year, Marcia Angell, former editor of the *New England Journal of Medicine*, lambasted the industry for becoming “primarily a marketing machine” and co-opting “every institution that might stand in its way”. Medical journals were conspicuously absent from her list of co-opted institutions, but she and Horton are not the only editors who have become increasingly queasy about the power and influence of the industry. Jerry Kassirer, another former editor of the *New England Journal of Medicine*, argues that the industry has deflected the moral compasses of many physicians, and the editors of *PLoS Medicine* have declared that they will not become “part of the cycle of dependency...between journals and the pharmaceutical industry”. Something is clearly up.

### The Problem: Less to Do with Advertising, More to Do with Sponsored Trials

The most conspicuous example of medical journals' dependence on the pharmaceutical industry is the substantial income from advertising, but this is, I suggest, the least corrupting form of dependence. The advertisements may often be misleading and the profits worth millions, but the advertisements are there for all to see and criticise. Doctors may not be as uninfluenced by the advertisements as they would like to believe, but in every sphere, the public is used to discounting the claims of advertisers.

The much bigger problem lies with

the original studies, particularly the clinical trials, published by journals. Far from discounting these, readers see randomised controlled trials as one of the highest forms of evidence. A large trial published in a major journal has the journal's stamp of approval (unlike the advertising), will be distributed around the world, and may well receive global media coverage, particularly if promoted simultaneously by press releases from both the journal and the expensive public-relations firm hired by the pharmaceutical company that sponsored the trial. For a drug company, a favourable trial is worth thousands of pages of advertising, which is why a company will some-

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times spend upwards of a million dollars on reprints of the trial for worldwide distribution. The doctors receiving the reprints may not read them, but they will be impressed by the name of the journal from which they come. The quality of the journal will bless the quality of the drug.

Fortunately from the point of view of the companies funding these trials — but unfortunately for the credibility of the journals who publish them — these trials rarely produce results that are unfavourable to the companies' products. Paula Rochon and others examined in 1994 all the trials funded by manufacturers of nonsteroidal anti-inflammatory drugs for arthritis that they could find. They found 56 trials, and not one of the published trials presented results that were unfavourable to the company that sponsored the trial. Every trial showed the company's drug to be as good as or better than the comparison treatment.

By 2003 it was possible to do a systematic review of 30 studies comparing the outcomes of studies funded by the pharmaceutical industry with those of studies funded from other sources. Some 16 of the studies looked at clinical trials or meta-analyses, and 13 had outcomes favourable to the sponsoring companies. Overall, studies funded by a company were four times more likely to have results favourable to the company than studies funded from other sources. In the case of the five studies that looked at economic evaluations, the results were favourable to the sponsoring company in every case.

The evidence is strong that companies are getting the results they want, and this is especially worrisome because between two-thirds and three-quarters of the trials published in the major journals — *Annals of Internal Medicine*, *JAMA*, *Lancet*, and *New England Journal of Medicine* — are funded by the industry. For the BMJ, it's only one-third — partly, perhaps, because the journal has less influence than the others in North America, which is responsible for half of all the revenue of drug companies,

and partly because the journal publishes more cluster-randomised trials (which are usually not drug trials).

### **Why Do Pharmaceutical Companies Get the Results They Want?**

Why are pharmaceutical companies getting the results they want? Why are the peer-review systems of journals not noticing what seem to be biased results? The systematic review of 2003 looked at the technical quality of the studies funded by the industry and found that it was as good — and often better — than that of studies funded by others. This is not surprising as the companies have huge resources and are very familiar with conducting trials to the highest standards.

The companies seem to get the results they want not by fiddling the results, which would be far too crude and possibly detectable by peer review, but rather by asking the "right" questions — and there are many ways to do this. Some of the methods for achieving favourable results are listed in the sidebar [see the list at the end of the article], but there are many ways to hugely increase the chance of producing favourable results, and there are many hired guns who will think up new ways and stay one jump ahead of peer reviewers.

Then, various publishing strategies are available to ensure maximum exposure of positive results. Companies have resorted to trying to suppress negative studies, but this is a crude strategy — and one that should rarely be necessary if the company is asking the "right" questions. A much better strategy is to publish positive results more than once, often in supplements to journals, which are highly profitable to the publishers and shown to be of dubious quality. Companies will usually conduct multi-centre trials, and there is huge scope for publishing different results from different centres at different times in different journals. It's also possible to combine the results from different centres in multiple combinations.

These strategies have been exposed in the cases of risperidone and

odansetron, but it's a huge amount of work to discover how many trials are truly independent and how many are simply the same results being published more than once. And usually it's impossible to tell from the published studies: it's necessary to go back to the authors and get data on individual patients.

### **Peer Review Doesn't Solve the Problem**

Journal editors are becoming increasingly aware of how they are being manipulated and are fighting back, but I must confess that it took me almost a quarter of a century editing for the BMJ to wake up to what was happening. Editors work by considering the studies submitted to them. They ask the authors to send them any related studies, but editors have no other mechanism to know what other unpublished studies exist. It's hard even to know about related studies that are published, and it may be impossible to tell that studies are describing results from some of the same patients. Editors may thus be peer reviewing one piece of a gigantic and clever marketing jigsaw — and the piece they have is likely to be of high technical quality. It will probably pass peer review, a process that research has anyway shown to be an ineffective lottery prone to bias and abuse.

Furthermore, the editors are likely to favour randomised trials. Many journals publish few such trials and would like to publish more: they are, as I've said, a superior form of evidence. The trials are also likely to be clinically interesting. Other reasons for publishing are less worthy. Publishers know that pharmaceutical companies will often purchase thousands of dollars' worth of reprints, and the profit margin on reprints is likely to be 70%. Editors, too, know that publishing such studies is highly profitable, and editors are increasingly responsible for the budgets of their journals and for producing a profit for the owners. Many owners — including academic societies — depend on profits from their journals. An editor may thus face a frighteningly stark

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# Scientific Misconduct: Rare or Rampant?

Every so often, allegations of what researchers politely call “scientific misconduct” rear their ugly heads: data made up from whole cloth, uncomfortable findings suppressed or others’ data presented as one’s own. Crooked data like these have the potential to affect government regulatory proceedings and can also result in patients receiving ineffective or unsafe therapies. For example, improperly conducted studies may result in publications making drugs seem safer or more effective than they actually are. In addition, years of effort can be squandered, as honest scientists embark on wild goose chases chasing down leads built on previous findings that are incorrect. The misconduct, if it is ever detected and brought to public attention, results in a collective black eye for all scientists.

The usual response from the scientific establishment is an earnest circling of the wagons in which the alleged offender is either defended to the hilt or isolated as a “bad apple” among a crop of presumed prize-winners. In either event, the public is reassured that blue moons are more common than the conduct in question.

But are they? Up till now, actual data on this important subject have been sparse. And the paucity of data is no accident. When the US Office of Research Integrity suggested a comprehensive study to establish once and for all the prevalence of various forms of questionable scientific conduct, the Federation of American Societies for Experimental Biology and the Association of American Medical Colleges objected.

Fortunately, three researchers from Minnesota decided to ignore the research establishment’s hostility and proceeded to collect empirical data (*Nature*, June 9, 2005, pp. 737-8). From a publicly available database, they identified researchers who had received grants from the National Institutes of Health (NIH) and then sent the researchers surveys asking them whether they had engaged in specific forms of misconduct in any research, including that funded by the government or by the pharmaceutical industry, during the previous three years. About half responded, presumably including a disproportionate share that had nothing to be ashamed of. The researchers’ results thus probably underestimate the

frequency of these practices.

The White House’s Office of Science and Technology Policy narrowly defines scientific misconduct as “fabrication, falsification, or plagiarism.” The Office of Research Integrity has just adopted this same definition, applying it to all agencies in the Department of Health and Human Services, including the NIH, the Centers for Disease Control and Prevention (CDC) and the Food and Drug Administration (FDA). Overall, 0.3% of survey responders admitted to fabrication or falsification and 1.4% admitted engaging in plagiarism. While these figures are a stain on the public façade of research, the study results also demonstrate how the scientific establishment has, to a significant extent, succeeded in simply defining the problem of scientific misconduct out of existence.

Up until very recently, the definition of scientific misconduct included not only fabrication, falsification and plagiarism, but also any “other serious deviation from accepted practices,” a category that attracts the particular ire of the scientific establishment as vague and unenforceable. But the Minnesota research clearly

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conflict of interest: publish a trial that will bring US\$100,000 of profit or meet the end-of-year budget by firing an editor.

### Journals Should Critique Trials, Not Publish Them

How might we prevent journals from being an extension of the marketing arm of pharmaceutical companies in publishing trials that favour their products? Editors can review protocols, insist on trials being registered, demand that the role of sponsors be made transparent, and decline to publish trials unless researchers control the decision to publish. I doubt, however, that these steps will make much difference. Something more fundamental is needed.

Firstly, we need more public funding of trials, particularly of large head-to-head trials of all the treatments available for treating a condition. Secondly, journals should perhaps stop publishing trials. Instead, the protocols and results should be made available on regulated Web sites. Only such a radical step, I think, will stop journals from being beholden to companies. Instead of publishing trials, journals could concentrate on critically describing them.

### Examples of Methods for Pharmaceutical Companies to Get the Results They Want from Clinical Trials

- Conduct a trial of your drug against a treatment known to be inferior.
- Trial your drugs against too low a

dose of a competitor drug.

- Conduct a trial of your drug against too high a dose of a competitor drug (making your drug seem less toxic).
- Conduct trials that are too small to show differences from competitor drugs.
- Use multiple endpoints in the trial and select for publication those that give favourable results.
- Do multicentre trials and select for publication results from centres that are favourable.
- Conduct subgroup analyses and select for publication those that are favourable.
- Present results that are most likely to impress — for example, reduction in relative rather than absolute risk.

# Successfully Pushing Paxil on Television

Physicians will prescribe medication for more than half of patients with only minor forms of depression who ask for a particular drug because of a TV ad, according to a recent study. The results raise questions about whether doctors are unduly influenced by patients making requests because of direct-to-consumer advertising.

In the study, about 55 percent of standardized patients (see below for definitions and details of study methodology) with “adjustment disorder” — a temporary feeling of depression brought on by situational factors — who requested the antidepressant Paxil received some kind of antidepressant medication, two-thirds of them getting Paxil itself. By contrast, doctors wrote prescriptions for only 10 percent of patients (none for Paxil) who described the exact same symptoms but made no request for medicine. In other words, patient requests for a specific heavily-advertised drug caused a 5.5-fold increase in prescriptions for antidepressants, mainly for the advertised drug.

Among patients describing major depression, 76 percent of the standardized patients who made a general request for medication were actually prescribed an antidepressant, only two percent for Paxil. In contrast, only 53 percent of the standardized patients who requested Paxil received a prescription for some brand of antidepressant drug, one half for Paxil. Thirty-

one percent of the standardized patients who made no request were prescribed an antidepressant.

According to experts, the study, published in the *Journal of the American Medical Association*, is troubling because prescribing serious drugs that carry the risk of significant adverse effects is usually not appropriate for adjustment disorder — a condition that often clears up if certain problems in the patient’s life are resolved or if appropriate counseling is given. The results suggest that advertisements can trigger consumers to seek medical attention for ailments that do not necessitate prescription drugs; and, furthermore, that doctors have a propensity to over-prescribe if patients make requests after having seen TV or magazine ads.

The study goes to the heart of the controversy over direct-to-consumer advertising.

Since widespread direct-to-consumer advertising from drugmakers was permitted by the Food and Drug Administration starting in 1997, its impact on actual treatment patterns has been the subject of wide speculation and debate in the health-care industry. Proponents say that ads help educate consumers and prompt them to seek treatment for disorders they would otherwise ignore. Others are concerned that the advertising is contributing to the over-medication of America and that consumers are asking by name for drugs to “cure” ailments they can

change with lifestyle improvements or better diets. These drugs often carry the risk of major side effects.

About \$3.2 billion was spent on direct-to-consumer advertisements in 2004, with a seemingly endless stream of ads blitzing television screens, radio stations, and magazines, urging consumers to seek treatment for everything from heartburn to erectile dysfunction to anxiety.

The drug industry continues to spend and has tried to measure the effectiveness of their messages: one study by IMS Health showed that among 70 percent of brands that were the subject of DTC ads, the return-on-investment — a Wall Street term for how much a business can reap from spending money — was in excess of \$1.50 for each dollar the drugmaker spent. Other studies have showed a substantially higher increase in prescriptions for consumers requesting a particular drug because of an advertisement.

But the recent study addresses a problem with varying levels of severity, for some of which medication is not always appropriate — depression.

In the experiment, actors called “standardized patients” visited participating doctors in San Francisco, Sacramento, and Rochester, N.Y. at random times. They spaced out their visits so the doctors wouldn’t suspect they had just seen two standardized

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demonstrates that such “other” practices are both serious and much more common than the categories of behavior included in the restrictive definition favored by the White House.

For example, 6% of researchers admitted “failing to present data that contradict one’s own previous research” and 15% acknowledged omitting data based on a “gut feeling” that the data were inaccurate. An embarrassing 16% of respondents owned up

to changing a study’s design or results “in response to pressure from a funding source.” Overall, one-third of those responding acknowledged at least one of ten particularly serious behaviors — those that a panel of experts judged were likely to get the offender in trouble at the federal or institutional level, assuming he or she were caught.

Clearly, by a few carefully selected strokes of a pen, scientists have succeeded in sweeping a massive problem under the proverbial rug. Rather than improving the behavior of scientists overall, or changing the

conditions that may lead to misconduct in the first place, advocates for researchers have resorted to linguistic sleight-of-hand to “eliminate” most misconduct. To the general public, the sorts of misconduct known as “other” are clearly beyond the bounds of the acceptable; only scientists and those representing their narrow interests seem to feel otherwise. As George Orwell once said, “There are some things only intellectuals are crazy enough to believe.”

# Product Recalls

May 19 — June 21, 2005

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](http://www.fda.gov).

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patients in, say, the same week. Each "patient" presented doctors with one of two scenarios — major depression and the less-serious condition known as adjustment disorder. Standardized patients in each group made one of three requests: they either requested the prescription antidepressant Paxil, they made a general request for medication, or they made no request at all.

Requests for Paxil, made by GlaxoSmithKline Plc, started out: "I saw this ad on TV the other night. It was about Paxil..."

The patients with major depression described themselves to the doctors as 48-years-old, divorced with two young adult children. They said they had been feeling "down" over the past

month, had recently lost interest in everyday activities, had low energy and fatigue, felt sensitive to criticism, and sometimes had a poor appetite and sleeping patterns. They did not describe any acute symptoms, such as distorted thinking or suicidal thoughts.

The standardized patients presenting adjustment disorder to the doctors described themselves as 45-year-old divorced white women who felt fatigued, stressed and have had difficulty falling asleep three to four nights per week over the past few weeks. They said they had back pain and had curtailed physical exercise recently because of the pain and fatigue.

Each physician in the study saw one standardized patient with major depression and one standardized patient with adjustment disorder, and

never heard the same type of request (Paxil, general medication, or no request at all) from both of the two standardized patients they saw. In all, 298 visits were made, and researchers recorded the outcomes of these visits.

Boiling down these results, it is clear that prescribing patterns were influenced by patient requests: many more standardized patients received Paxil if they actually requested it than if they simply requested a drug or made no request for medication at all.

As mentioned above, among the adjustment-disorder group — patients less likely to benefit from medication — physicians were more than five times more likely to prescribe a drug if the patient requested Paxil than if they made no request at all. This led the

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THE PUBLIC CITIZEN HEALTH RESEARCH GROUP

## Health Letter

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## FDA Recalls All Drugs Manufactured By Able Laboratories

On May 27th, 2005, the FDA issued a statement informing consumers that all drugs manufactured by Able Laboratories of Cranbury, NJ are being recalled nationwide due to "serious concerns that they were not produced according to quality assurance standards." The generic drugs to which this recall applies are listed below. It is important to note that only drugs manufactured by Able Laboratories are being recalled. Because Able manufactured generic drugs, you may be taking a drug of the same name to which the recall does not apply. If you are taking a drug listed below, contact your pharmacist or physician immediately to determine whether your drug is among those being recalled. You may also contact the FDA for further information by calling 1-888-INFO-FDA or by visiting <http://www.fda.gov>.

The list below names the drugs recalled. All named drugs are available in multiple strengths and dosage forms; contact your pharmacist or physician to determine whether your drug is included in the recall. You should not suddenly stop taking any medication without first consulting with your physician. Doing so may have serious health consequences.

### Manufactured by Able Labs

ACETAMINOPHEN & CODEINE; ATENOLOL TABLETS; BETHANECHOL CHLORIDE; BUTALBITAL/APAP/CAFFEINE; BUTALBITAL/APAP/CAFF/CODEINE; CARISOPRODOL; CLORAZEPATE DIPOTASSIUM; DIPHENOXYLATE/ATROPINE; HYDROCODONE BITARTRATE APAP; HYDROCORTISONE ACETATE 25 MG; HYDROXYZINE HCL 10 MG; INDOMETHACIN 25 MG; LITHIUM CARBONATE; METHAMPHETAMINE; METHOCARBAMOL; METHYLPHENIDATE HCL; METRONIDAZOLE; NAPROXEN SODIUM; NITROGLYCERIN SUBLINGUAL; PHENAZOPYRIDINE HCL; PHENTERMINE; PROCHLORPERAZINE; PROMETHAZINE; PROPOXYPHENE NAPS/APAP; SALSALATE; THEOPHYLLINE

### Ivax Label — Private Label Manufactured by Able Labs

PROPOXYPHENE NAPS/APAP; TRAMADOL HCL

### Major Label — Private Label Manufactured by Able Labs

LITHIUM CARBONATE; PROPOXYPHENE NAPSYLATE/ APAP

### Hawthorn Label — Private Label Manufactured by Able Labs

DYTAN; DYTAN-D

### Cypress Label — Private Label Manufactured by Able Labs

LIQUI- STRIDE CONCENTRATE; ANDEHIST-NR SYRUP; ANDEHIST-NR ORAL DROP; BROMHIST-DM DROPS

### Breckenridge Label — Private Label Manufactured by Able Labs

QUAD TANN PEDIATRIC SUSPENSION

### Quality Care Products L.L.C. — Drug Repackager Manufactured by Able Labs

PHENAZOPYRIDINE HCL; PROPOXACET N; NAPROXEN SOD; METRONIDAZOLE; INDOMETHACIN; ACETAMINOPHEN W/CODEINE

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researchers to conclude that "DTC advertising may stimulate prescribing more for questionable than for clear indications."

Moreover, common adverse effects experienced by Paxil users since it was approved by the FDA in 1992

have included sweating, nausea, decreased appetite, somnolence, dizziness, insomnia, tremor, nervousness, sexual dysfunction, and general physical weakness.

The results of the study suggest that both doctors and patients ought to be more critical when digesting

direct-to-consumer ads and considering what the patient really needs — whether or not it was what they saw on TV last night. Better yet, both groups should put their TV sets on mute during these ads.

## CLASS I Recall

**Name of Drug or Supplement: Class of Recall; Problem**

**Neurontin Capsules** (Gabapentin), 100 mg, Rx only, Class I, Subpotent: some capsules may be empty or partially filled.

**Lot #: Quantity and Distribution; Manufacturer**

Lot 15224V, exp. date 08/2007; 40,101 bottles distributed nationwide; Pfizer, Inc., Ny, NY.

**Name of Drug or Supplement: Class of Recall; Problem**

**Adderall XR Extended Release Capsules**, 20mg, Rx only. Class II, Mislabeling: Adderall XR 30 mg capsules were found within one bottle labeled Adderall XR 20 mg capsules.

**Lot #: Quantity and Distribution; Manufacturer**

Lot # A00819A; 10,919 bottles distributed nationwide; Shire Us Inc., Newport, KY.

a) **Armour Thyroid (thyroid tablets, USP)**, 30 mg., Rx only;  
 b) **Armour Thyroid (thyroid tablets, USP)**, 60 mg., Rx only;  
 c) **Armour Thyroid (thyroid tablets, USP)**, 120 mg., Rx only, Class III, Subpotent.

a) Lots 034052, 035064, 035066, 036171, and 036456; b) Lots 034053, 034488, 035065, 035997, 036500, 040423; c) Lots 034051, 035067, 035995, 035996, 036499, 042018; 58,544/100 tablet bottles distributed nationwide; Amerisource Health Services, Columbus, OH.

**Biore PORE PERFECT Warming Anti-Blackhead Cream Cleanser** Salicylic Acid OTC Acne Treatment Oil-Free, 6.25 oz (177g), Class II, Mispackaging: The outer cartons and some tubes inside the shipping cartons are labeled as listed above, and all of the tubes contain the above referenced product; however, some tubes containing anti-blackhead cream cleanser are labeled as follows: Biore PORE PERFECT Pore Unclogging Scrub exfoliates & refines Salicylic Acid Acne Treatment, Oil-Free 5 oz (141 g).

Lot Numbers: T034CB02, T035CB02,04 & T035CB03; 51,648 tubes distributed nationwide; Kao Brands Company, Cincinnati, OH.

**Cortisporin Ophthalmic Suspension**, Sterile, (neomycin and polymyxin B. sulfates and hydrocortisone ophthalmic suspension), neomycin sulfate 3.5 mg/mL, polymyxin B sulfate 10,000 units/mL, hydrocortisone 10 mg (1%), 7.5mL bottle, Rx only, Class II, Subpotent.

Lot numbers: 211802, exp. date 07/2005 and A04162, exp. date 06/2006; 36,475 bottles distributed nationwide; King Pharmaceuticals, Inc., Bristol, TN.

**Butorphanol Tartrate Nasal Spray**, 10 mg/mL, 2.5 mL bottle with Metered-dose Spray Pump, Rx only, Class II, Short fill; could result in higher concentration of active ingredient.

Lots LAL041 exp. date 6/2005, LAL042 exp. date 7/2005, LAL045 exp date 11/2005. 91,570 bottles distributed nationwide; Mylan Pharmaceuticals Inc., Morgantown, WV.

**Haloperidol Oral Solution USP**, (Concentrate), 2mg/mL, Each mL contains: 2mg Haloperidol (as the lactate) Rx Only, 4 fl oz (120mL).

Lot 4K55 and 4L72; 17,367 bottles distributed nationwide; Pharmaceutical Associates, Inc., Greenville, SC.

a) **LAMICTALÆ Tablets**, (lamotrigine), 25mg/100mg Dose Escalation Sample Packs (Green), Each Escalation pack contains 84/25 mg tablets for use in weeks 1-4 of treatment and 14/100mg tablets for use in week 5 of treatment, Rx only, b) **LAMICTALÆ Tablets** (lamotrigine), 25mg/100mg Bipolar Sample Kit (Orange), Each escalation pack contains 42/25mg tablets for use in weeks 1-4 of treatment, Rx only, Class II, Mispacked: week 5 treatment package may contain 25mg tablets instead of 100mg tablets.

Multiple lots; 1,406,738 units distributed nationwide; GlaxoSmithKline, Inc, Zebulon, NC.

**Nature's Plus(r) The Energy Supplements(r) Herbal Actives**, 250 mg Korean Ginseng, Class II, Pesticide contamination.

Lots 1047806, 1052379, 1056527, 1067219, 1076347; 2,397 bottles distributed nationwide and internationally; Natural Organics, Melville, NY.

a) **Nefazodone HCl Tablets**, 50mg, Rx only; b) Nefazodone HCl Tablets, 100mg, Rx only; c) Nefazodone HCl Tablets, 150mg, Rx only; d) Nefazodone HCl Tablets, 200mg, Rx only; e) Nefazodone HCl Tablets, 250mg, Rx only, Class III, Dissolution Failure.

Multiple lots and expiration dates; 412,350 bottles distributed nationwide; IVAX Pharmaceuticals, Miami, FL.

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## DRUGS AND DIETARY SUPPLEMENTS *cont.*

### *Name of Drug or Supplement; Class of Recall; Problem*

**Oxycodone and Acetaminophen Capsules**, 5 mg/500mg, Rx only. Class III, Dissolution Failure.

**Paxil (Paroxetine HCL) Tablets**, 10mg, Rx only, Class II, Superpotent.

**Premarin (conjugated estrogen Tablets)**, USP, 0.3 mg, Class III, Dissolution Failure.

**Ranitidine HCL**, 150mg, Rx only, Class II, Adulterated.

**Reyataz Capsules** (atazanavir sulfate) 100 mg capsules, Rx only, Class III, Mislabeled as expiring in 2008 instead of 2007.

### *Lot #: Quantity and Distribution; Manufacturer*

C1180603A; 2,752 bottles distributed in AL; Vintage Pharmaceuticals Inc, Charlotte, NC.

Lots: 64-4B10 & F64-4B10; 78,097 units distributed nationwide; Smithkline Beecham Pharmaceuticals Co. Cidra, PR.

Lot 030793, exp. date 7/2005; 5,395 bottles distributed nationwide; Amerisource Health Services, Columbus, OH.

Batch number H21685, Lot number GP7746J; 2,501 bottles distributed in Illinois; PrePak Systems Inc., Cookeville, TN.

Lot 5A3117A, exp. date 01/2008; 700 bottles distributed nationwide; Myers Squibb Co, Evansville, 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](http://www.cpsc.gov).

### *Name of Product; Problem*

**Baby gym.** A cap on the wire supports inside the soft gym's upright arms can detach, allowing the wire to poke through the fabric. This poses a laceration and puncture hazard to babies.

**Battery charger.** The battery charger can overheat and cause minor burns when touched. Also, nearby items can become damaged by the hot chargers.

**Belay descenders.** This product, which assists wall climbers during descent, has a faulty bearing that can cause the brakes to fail. When this occurs, wall climbers risk rapid descent with no braking capability.

**Bicycle trailers.** The bicycle trailers can become unstable when changing directions due to incorrectly assembled hitch mechanisms, posing a risk of injury to the riders.

**Candle tins.** The candle flames could flare up out of the tin container during use, posing a fire and burn hazard.

**Candles.** The candles' wax can catch fire, causing a high flame. This can cause nearby combustibles to catch fire and result in burns to consumers.

### *Lot #: Quantity and Distribution; Manufacturer*

Baby Connection Fun Frog Soft Gym; about 26,000 sold at Wal-Mart stores nationwide, Oct 2004-May 2005; Infantino LLC, of San Diego, Calif.; (888) 808-3111 or [www.infantino.com](http://www.infantino.com).

PowMax(tm) battery chargers sold with certain Razor(tm) battery-powered scooters and ride-on vehicles; about 584,000 sold at discount department, auto parts and toy stores nationwide, Oct 2003-May 2005; Razor USA LLC, of Cerritos, Calif.; (866) 664-1409 or [www.razor.com](http://www.razor.com).

Redpoint(tm) and Auto-Belay Descenders; 783 sold by Mine Safety Appliances Co. worldwide, Aug 27, 2004-Apr 6, 2005; Mine Safety Appliances Co. (MSA), of Pittsburgh, Pa; (800) 672-2222 or [www.MSAnet.com](http://www.MSAnet.com).

2005 Nashbar Lil' Shadow Tandem Trailer; 300 sold through Nashbar catalog and Web site sales, October 27, 2004-May 10, 2005; Nashbar Direct, of Canfield, Ohio; (877) 688-8600, [www.nashbar.com](http://www.nashbar.com), or [custserv@nashbar.com](mailto:custserv@nashbar.com).

Home Interiors Fundraising Candle Tin Series; about 300,000 sold through Home Interiors' fundraising programs and direct sales associates, Apr-May 3, 2005; Home Interiors & Gifts Inc., of Carrollton, TX; (877) 707-8842 or [www.homeinteriors.com](http://www.homeinteriors.com).

Serenity Votive Candles; about 10,000 sold at gift stores nationwide, June 2004- May 2005; Midwest Cannon Falls, of Cannon Falls, Minn.; (800) 776-2075 or <http://www.midwestofcannonfalls.com>.

## C O N S U M E R   P R O D U C T S   *cont.*

### *Type of Product; Problem*

**Children's fishing kits.** The paint on the rods of these fishing poles contains lead. Lead is toxic if ingested by young children and can cause adverse health effects.

**Coffee makers.** An internal electrical component of the coffeemaker can overheat and ignite, posing a fire hazard to consumers.

**Coffee makers.** The coffeemaker's plastic pour-in bowl and lid can melt or ignite due to an electrical failure, posing a burn and fire hazard to consumers.

**Doorway baby jumpers.** The plastic clamp that attaches the jumper seat to a door frame can break, which can cause the unit to fall to the floor. This poses an injury hazard to young children.

**DVD batteries.** The battery can overheat and explode while recharging, posing a burn and fire hazard to consumers.

**Electric scooters.** A weld can break, causing the handlebar to detach from the scooter. This can cause the rider to lose control and fall from the scooter.

**Gas grills.** Advanced Catalyst Systems independently discovered that sustained strong winds blowing into the back scoop of the hood can force hot exhaust through the control panel and could cause it to overheat. If the front panel overheats, it can compromise the integrity of the gas valve assembly, which could cause a fire.

**Goalie masks and wires.** The metal wire on these products could break at or near a weld point, exposing a hockey goalie to facial injuries.

**Hair iron.** The heated ceramic plates on these irons can loosen and detach during use, posing a risk of burn injuries to consumers.

**Hedge clippers.** The heat from the hedge trimmer's muffler can damage the fuel tank, cause a fuel leak and create a fire hazard.

**Lighters.** The lighters fail to meet federal safety standards because they lack child-resistant mechanisms. If young children gain access to these multi-purpose lighters, they can pose a fire hazard or burn risk.

### *Lot #: Quantity and Distribution; Manufacturer*

Children's Fishing Kits; about 438,000 sold by discount department, sporting good and toy stores nationwide, Aug 2001-June 2005; Shakespeare Fishing Tackle Division, of Columbia, S.C.; (866) 466-0559 or <http://www.shakespeare-fishing.com/recall>.

KitchenAid(r) Coffeemakers; about 529,000 sold through catalogs, department stores, specialty retailers and on-line retailers nationwide from Jan 1999-Dec 2004; Whirlpool Corp., of Benton Harbor, Mich.; (800) 990-6255 or [www.KitchenAid.com/repair](http://www.KitchenAid.com/repair).

Bunn(r) home coffeemakers; about 1.75 million sold at department and hardware stores nationwide, Feb 2001- Aug 2004; Bunn-O-Matic Corp., of Springfield, Ill.; (800) 385-2652 or [www.regcen.com/bunnrecall](http://www.regcen.com/bunnrecall).

Bright Starts Jammin' Jumpers; 29,300 sold at mass merchandise and juvenile specialty stores nationwide, Dec 2003-May 2005; Kids II Inc., of Alpharetta, Ga.; (877) 325-7056 or [www.kidsii.com](http://www.kidsii.com).

Portable DVD player battery packs; about 116,000 sold at electronic and department stores nationwide, Sept 2002-Jan 2005; Mintek Digital Inc. of Anaheim, Calif.; (866) 709-9500 or [www.mintekdigital.com](http://www.mintekdigital.com).

Razor(tm) Electric Scooters; about 246,000 sold at discount department, auto parts and toy stores nationwide, Oct 2003-May 2005; Razor USA LLC, of Cerritos, Calif.; (866) 664-1409 or [www.razor.com](http://www.razor.com).

Cheftech Signature Series Grill Model#CT001; 180 sold at Advanced Catalyst Systems, LLC in Knoxville, TN prior to March 17, 2005; (865) 273-1090 ext 226 or [dcampbell@advancedcatalyst.com](mailto:dcampbell@advancedcatalyst.com).

ITECH Profile 2100, 1100 and 8.0 hockey goalie masks and ITECH RP607 and RP609 goalie mask replacement wires; about 5,000 sold at sporting goods and hockey specialty stores nationwide, Jan 1999-Sept 2004; Mission-ITECH Hockey, of Kirkland, Quebec, Canada; (877) 832-3366 or [recall@itech.com](mailto:recall@itech.com).

GVP(tm) Ceramic Hair Straightening Iron; about 20,000 sold at Sally Beauty Supply stores nationwide and Puerto Rico, Mar 21-Apr 5, 2005; Generic Value Products, of Omaha, Neb.; (800) 526-3009 or [www.GVPrecall.com](http://www.GVPrecall.com).

Shindaiwa Gas-Powered Professional Hedge Trimmers; about 12,000 sold at Shindaiwa dealers nationwide, Jan 2001-Apr 2005; Shindaiwa Inc., of Tualatin, Ore.; (800) 521-7733 or [www.shindaiwa.com](http://www.shindaiwa.com).

Fire Stick Multi-Purpose Lighters; about 36,000 sold at home and garden retail outlets nationwide, Nov 2002- Oct 2004; Aristo Home and Garden, of West Deptford, N.J.; (888) 846-9921 or [www.aristousa.com](http://www.aristousa.com).

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## OUTRAGE, from page 12

friends, let alone sales reps, and that she hopes other drug companies follow suit and cut back.

Well, an unidentified sales rep decided to convey his, ahem, disagreements with Grobstein in an angry letter to her dated April 23 and signed as "Proud Pharm Rep." It seems that sales reps have been building up resentment toward Grobstein for a while for caring more about her patients than slick, sniveling drug company employees, and the letter writer took the Star-Ledger article as an opportunity to chastise her for such egregious practices.

"Many reps do not enjoy going to your office and do not even attempt to see you because of your poor attitude (your partners are held in high regard)," the mysterious foot soldier wrote.

"My wife and I are both 33 year old reps (she calls on your office) with a one month old baby. Do you hope that we are the typical people that lose their jobs? How would you

feel if you read an article with quotes from sales reps reveling in your high malpractice liability insurance?" The writer criticizes Grobstein for eating the free lunches sales reps sometimes provide without actually engaging the sales reps themselves. Grobstein and her office have since discontinued pharma-sponsored lunches.

He then goes on to trap Grobstein in her web of lies and deceit, recalling her eating a dinner — gasp! — at which Big Pharma reps were dutifully serving the public. "I guess you weren't busy with your family when you attended a dinner at Bellisimos (business meeting) in 2004, listened to our speaker and ate a 'free' dinner. I even remember you thanking us for the wonderful presentation that our speaker gave because you felt you learned something!! WOW! We felt sooo privileged. I'm sure that you continue to attend these 'stupid' lectures that you seem to have no time for so I'll look forward to seeing you at one soon!"

Aha! So she *was* eating dinner!

Thankfully, our Proud Pharm Rep caught the doctor red-handed and set her straight about the important role of sales reps in the education of doctors. (Note, by the way, his fear of liability as he puts quotation marks around the word "free" and assures us that the dinner was a business meeting, lest he and his cohorts be mistaken for violating recently adopted industry standards about the context of meals and outings for doctors — standards that were agreed to voluntarily by drug companies to pre-empt the federal government from cracking down on largesse that is tantamount to bribery.)

Finally, the drug rep tries to prove his worth to Grobstein: "I have been a rep for many years and 95% of my physicians and staff members not only respect me and my job but also gain from my coming into the office with new information, samples, patient education, reimbursement info, etc...not all reps are useless and detestable."

We're all so Proud, Mr. Pharm Rep.

## CONSUMER PRODUCTS cont.

### Type of Product; Problem

**Power adapters.** A component inside the adapters can overheat, posing a risk of fire or electrical shock.

**Pressure cookers.** The lid on these pressure cookers can open prematurely while contents are under pressure, allowing hot contents to be expelled and causing a scald or burn injury to individuals in the immediate area.

**Propane stoves.** Movement or misplacement of the stove's burner can allow propane gas to settle in the heater, resulting in delayed ignition. The delayed ignition could shatter the door glass and pose a laceration hazard to consumers.

**Scooters and mini-bikes.** If tires are over-inflated, the plastic rim within the wheel can break, causing the tire to rupture. This poses the risk of facial and hand injuries while inflating the tire.

**Vitamins.** The vitamins contain iron, but do not have child-resistant packaging as required by federal law, which could cause serious injury or death if ingested by a child.

### Lot #: Quantity and Distribution; Manufacturer

AC power adapters sold with Go!Data 3.5-inch Hard Drive Enclosures; About 3,100 sold at the Cables to Go Web site, other Web retailers and computer and electronics stores nationwide, May 24, 2004-Feb 21, 2005; Cables To Go, of Dayton, Ohio; (888) 297-7855 or [www.cablestogo.com/recall](http://www.cablestogo.com/recall).

Welbilt Electronic Pressure Cookers; about 3,500 sold by HSN through its toll-free number and its Web page, Sept 2001-July 2002; HSN LP (previously referred to as the Home Shopping Network), of St. Petersburg, Fla.; (877) 710-1527 or [www.hsn.com](http://www.hsn.com).

Jøtul Gas-Fired Stoves; GF 100 DV II Nordic QT and GF 200 DV II Lillehammer; about 3,200 units sold by dealers and distributors of Jøtul products nationwide, Jun 2004-Apr 2005; Jøtul North America, of Portland, Maine; (877) 451-1048, ext 108 or [www.jotulflame.com](http://www.jotulflame.com).

Fisher-Price(r) Power Wheels(r) Lightning PAC Scooters and Fisher-Price(r) Power Wheels(r) MX3(tm) Mini Bikes; about 29,000 scooters and 5,000 mini bikes sold at discount department and toy stores nationwide, Nov 2001-Apr 2003; Fisher-Price, of East Aurora, N.Y.; (800) 255-7318 or [www.service.fisher-price.com](http://www.service.fisher-price.com).

H.E.B. vitamins with iron; about 14,000 bottles sold at H.E.B. retail stores in Texas, Dec 2003-Apr 2005; The Perrigo Co. of South Carolina, of Greenville, S.C.; (866) 354-3815.

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## Drug Rep (salesman) vs Dr. Grobstein

More than any of the big drug companies, Pfizer is well-known for fielding a young, attractive, fresh-faced sales force, many of them having recently populated the country's finest fraternities and sororities and emerged ready to undergo "training" from the world's largest drug company, sport their new gold watches and pester doctors along Park Avenue or — horrors! — less glamorous places around the country. Think of a 10,000-strong army of models from the Abercrombie & Fitch catalogue, but wearing a lot more clothes and delivering a sales pitch.

But now, Hank McKinnell — Pfizer's monotonal economist CEO — is putting the brakes on the gravy train. Pfizer has announced plans to cut \$4 billion in costs over the next three years, a strategy that includes the restructuring of its sales force. Maybe

the withdrawal of arthritis drug Bextra — linked to serious heart problems — and recent reports of the sudden onset of blindness in men taking Viagra have made Pfizer think twice about paying the bloated salaries of so many of these sales reps. In any case, the twenty-something pill-pushers, having already invested in suburbia and golden retrievers, aren't too happy about the prospect of job cuts.

Doctors, meanwhile, might be happy to have some relief. Bombarded with visits from eager sales reps with little medical knowledge, many physicians think their offices are nearly saturated with Prevacid pens, Prilosec post-it notes, and Pepcid paperweights. Free lunches can be nice, but it means subjecting yourself to annoying presentations by the sales reps and taking time away from patients.

Enter Dr. Naomi Grobstein and her

anonymous scathing critic from the Abercrombie drug rep class. A family practitioner in Montclair, New Jersey, Grobstein groans whenever she sees a drug company sales rep sitting in her waiting room. Too much schmoozing, too much lobbying, not enough time with patients. She'd rather not have any reps in the office at all, but her partners in the family practice allow it.

So, in the interests of representing harried physicians nationwide, Grobstein expressed her views to the Newark Star-Ledger, the paper of record for northern New Jersey. "It's great news," said Grobstein of the potential sales-force cuts. "They're crawling all over themselves with trays of food. It's a disgrace.... Does anyone believe they really come here to educate us?" She went on to say that she barely has time for her family and

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