

Health Letter

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Curbing the Influence of the Drug Industry: A British View

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Britain's House of Commons Health Committee has recently recommended a fundamental realignment of the relationships between the pharmaceutical industry and government, regulators, doctors, the health service, and patients. The committee said that the industry has interdigitated itself into every aspect of health care, and that government and others, including doctors, have taken the easy route of assuming that the interests of the industry and of the health services and patients are the same.

The committee's report makes clear that reducing the influence of the industry would be good for everybody, including — paradoxically — the industry itself, which could concentrate on developing new drugs rather than on corrupting doctors, patient organisations, and others. "It is not in the long term interests of the industry for prescribers and the public to lose faith in it," says the report. "We need an industry which is led by the values

of its scientists not those of its marketing force."

Select Committees:

Rationality before Realpolitik

The Health Committee is one of many select committees of the House of Commons. The committees are comprised of members of parliament and politicians from all parties, and they can choose to examine any subject that raises matters of public importance. They receive written and oral evidence, including from government ministers, and produce reports and recommendations to which the government is required to respond.

The 11-member Health Committee chose to examine the influence of the drug industry because of increasing public concern that this influence is

excessive. The committee was particularly worried by the industry's role in promoting "medicalisation," the idea of a pill for every ill: "What has been described as the 'medicalisation' of society — the belief that every problem requires medical treatment — may also be attributed in part to the activities of the pharmaceutical industry". The committee, whose terms of reference are shown in Box 1, was also worried by the high prevalence of drug side effects. It heard from every interested party, including representatives of the drug companies, patients, doctors, medical journal editors, critics of the industry, and government ministers and officials.

The government does not have to accept the recommendations from

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select committees, and it recently rebuffed recommendations from the same Health Committee encouraging open access to scientific research. Usually, the committees will be much bolder than the government, which is heavily lobbied and pays more attention to realpolitik than to rational argument. Just as the publishing industry pressured the government to ignore recommendations on open access, the pharmaceutical industry will be doing the same now — and the industry is powerful; it is Britain's third most profitable economic activity (after tourism and finance) and employs 83,000 people.

The All-Pervasive and Persistent Influence of the Industry

Although the pharmaceutical industry is now perceived by the public as putting profits ahead of patients' well-being, it is generally, as the committee makes clear, a force for good. Almost all of the drugs that have transformed medicine in the past half century have been developed and manufactured by the industry. "The discovery, development and effective use of drugs," says the committee, "have improved many people's quality of life, reduced the need for surgical intervention and the length of time spent in hospital and saved many lives". And making the industry into a scapegoat for failing to produce drugs for the diseases of the poor is in some ways no more sensible, I believe, than blaming washing machine manufacturers for poor hygiene standards in the developing world. The industry is part of the for-profit sector, and has what many philosophers might call a moral duty to maximise profits. Producing drugs for the poor requires imaginative public-private partnerships.

It's also shallow thinking to view the industry as corrupters and doctors as the corrupted. As a doctor myself, I think that doctors are in many ways to blame for the debased relationship between themselves and the industry. The industry is (mostly) behaving in ways that are "normal" within the commercial sector. It is the

Terms of Reference for the Health Committee Inquiry

"The Health Committee is to undertake an inquiry into the influence of the pharmaceutical industry on health policies, health outcomes and future health priorities and needs. The inquiry will focus, in particular, on the impact of the industry on the following:

- drug innovation
- the conduct of medical research
- the provision of drug information and promotion
- professional and patient education
- regulatory review of drug safety and efficacy
- product evaluation, including assessments of value for money

In doing so, the Committee will examine the influence of the pharmaceutical industry on the NHS; National Institute for Clinical Excellence (NICE); regulatory authorities and advisory and consultative bodies; prescribers, suppliers and providers of medicines; professional, academic and educational institutions; the (professional and lay) press and other media; and patients, consumers, the general public and representative bodies."

doctors who depart from their ethical base when they insist on first-class fares and lavish entertainment from the industry so that they can attend an international conference.

The fundamental problem, says the committee, is that the pharmaceutical industry's influence is too pervasive: "The industry affects every level of healthcare provision, from the drugs that are initially discovered and developed through clinical trials, to the promotion of drugs to the prescriber and the patient groups, to the prescription of medicines and the compilation of clinical guidelines."

The committee goes into detail about each of these levels. Regulatory authorities, it says, are too close to the industry, meaning that they do not ensure that the industry works in the public interest. The clinical trials that are the essential evidence base for regulatory and clinical decisions are produced almost entirely by the industry, and the evidence that reaches authorities, doctors, and patients is biased. Guidelines for treating patients are distorted, not only because they must be based on biased evidence, but also because the organisations and people producing them are often in hock to the industry. The organisations may receive millions of British pounds for buildings and activities, while the individuals — particularly key opinion leaders (KOLs, as they are known in the trade) — may receive hundreds of

thousands of pounds for consultancy, speaking fees, travel, research, and articles. "Drug companies are criticised for giving hospitality and recruiting 'key opinion leaders,'" says the committee, "but the prescribers must be equally to blame for accepting the hospitality and some 'key opinion leaders' for lending their names to work they did not produce, often for

Recommendations from the Health Committee Inquiry: Some Highlights

- The process of licensing drugs, and the medicines' regulatory system, should both be more transparent.
- There should be an independent register of clinical trials.
- Clinical trials should focus on using health outcomes that are relevant to patients.
- More research should be undertaken into the adverse effects of drugs and the costs of drug-induced illness.
- The regulator should ensure greater restraint in medicines' promotion.
- Tougher restriction should be placed on the prescribing activities of non-specialists.
- Doctors should be required to declare significant sums or gifts they receive as hospitality.
- The sponsorship of the drug industry should pass from the Department of Health to the Department of Trade and Industry — because the secretary of state for health cannot serve two masters (the public and the industry).

very considerable sums.”

Next in the list of things that concerned the committee comes the industry’s intensive marketing, which is becoming ever more important as the flow of drugs that offer major therapeutic advances (and so need much less marketing) dries up. Britain has some 8 000 drug company representatives, but the industry also spends millions on advertising, sponsorship, meetings, and increasingly, “medical education” — which often means a fine dinner and a lecture from a captive KOL. The report states: “Coupled with company-sponsored information from medical journals and supplements, ‘medical education’ materials, advertisements and sponsorship to attend conferences, workshops and other events, it is little wonder that prescribing practices are affected.” Medical journals, as I’ve argued in *PLoS Medicine*, are in some ways extensions of the marketing arm of the industry, while the free newspapers that overwhelm doctors in the developed world depend 100% on largesse from the industry.

Individual journalists are also captured, the committee heard — and perhaps most troublesome is the way patient organisations have become so dependent on the industry. The committee concluded that “Measures to limit the influence of industry on patient groups are needed.” Currently, in Britain, we see that the “patients” who are trying to convince the British government that it should ignore the advice of the London-based National Institute of Health and Clinical Excellence (NICE) (which says that drugs for Alzheimer’s disease are not sufficiently cost effective) are in many ways agents of the companies that produce those drugs.

The consequences of all of these incestuous relationships, says the committee, are bad decisions on the regulation and prescription of drugs, over-reliance on drugs rather than on other interventions (such as dietary change, exercise, or counselling), and the “medicalisation” of life’s problems, including baldness, shyness, unhappi-

ness, grief, and sexual difficulties.

Recommendations: “Let the Sun Shine In”

The committee came up with 48 conclusions and recommendations, and I have listed some of the highlights in Box 2. The committee’s main recommendation for the problems it identifies is transparency: “let the sun shine in.” It begins by recommending that there be a clinical trials register, “maintained by an independent body” and containing full information. Companies should be required to put the information on the register “at launch as a condition of the marketing licence.” The committee also wants regulatory authorities and ethics committees (the British equivalent of institutional review boards) to help with the design of trials to make sure that they are answering real questions. It didn’t, however, recommend more public funding of trials. I believe that such funding is necessary in order to ensure that trials are addressing the most important questions — including head-to-head comparisons and trials of new drugs against older drugs and non-drug treatments. Advice to companies is unlikely to be effective.

There should be, says the committee, limits on the quantity of marketing materials, particularly in the first six months after launch, and stricter controls on marketing to junior doctors, nurses, and pharmacists. These proposals don’t seem sufficiently thought through: it’s hard to imagine how the proposals would be enforced, and they are patronising to junior doctors, nurses, and pharmacists — many of whom are much better, I suspect, at assessing evidence than burnt out, ageing, high-prescribing general practitioners.

Doctors might come to be seen as the villains rather than the good guys.

The Health Committee would also like to see an independent review of the Medicines and Healthcare Products Regulatory Agency (London, United Kingdom) plus a public inquiry every time a drug is withdrawn from the market on health grounds. It’s hard to see the government implementing

these recommendations, as inquiries are expensive and always create difficulties for government, but if bodies like the Medicines and Healthcare Products Regulatory Agency and NICE are to maintain public confidence they will have to distance themselves from the industry — and be seen to do so. Important first steps will be to make public more of the information they use to make their decisions and to exclude KOLs from their committees (which may be difficult, as KOLs include many prominent doctors and professors of pharmacology and therapeutics).

Doctors’ organisations, says the committee, should produce publicly available registers of doctors’ links with industry. These registers — and this is my recommendation and not the committee’s — should also include information on monetary amounts. Otherwise, it will not be possible to separate the KOLs from the vast numbers of doctors who receive pens, lunches, trips, and other gifts from the pharmaceutical industry. I doubt very much that doctors’ organisations will adopt these recommendations until forced to do so. In Britain, it’s more embarrassing to ask people about money than sex. Plus, doctors might come to be seen as the villains rather than the good guys.

The committee also wants patients’ organisations to declare their connections with industry and to make clear when ubiquitous “disease awareness” campaigns are funded by the industry, which is probably very common. I agree with this support for transparency, and while recognising the penury of many patients’ organisations, I think they would do well to resist the lure of the industry’s lucre as much as they can.

Conclusion

In the end, this report will probably be less remembered for its recommendations — most of which will probably be ignored — than for having brought the important debate over the excessive influence of the pharmaceutical industry to a broader public. We all stand to benefit from the reduction of that influence. ■

Product Recalls

Sept 27 — Oct 18, 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.

Name of Drug or Supplement; Class of Recall; Problem

Agua De Alibour (zinc sulfate and copper sulfate) Astringent-Antiseptic liquid, OTC; b) **Alcohol Boricado (Boric Acid Alcohol) liquid**, OTC; c) **Alcohol Mentolado (Mentholated Alcohol) liquid**, OTC; d) **Tincture of Arnica liquid**, OTC; e) **Boric Acid Powder NF Topical Antifungal Agent**, OTC; f) **Eucalyptus Oil Aromatic NF liquid**, OTC; g) **Sodium Bicarbonate USP powder**, OTC; Class III, Misbranding.

a) **Alcohol-free "Baby Wipe"**; b) **Triad "Cleansing Wipes"**, Class III, Mold contamination.

Butorphanol Tartrate Nasal Spray, 10 mg/mL, a schedule C-IV narcotic analgesic, Class III, Degradation products.

Demulen 1/35 — 28 Tablets (Ethinodiol Diacetate & Ethinyl Estradiol), Each Demulen 1/35 tablet contains: ethinodiol diacetate 1mg, ethinyl estradiol 35 mcg, Each Compack contains: 21 Demulen 1/35 (white) tablets 7 placebo (blue) tablets, Rx only, Class II, Subpotent (ethinyl estradiol).

Lot #: Quantity and Distribution; Manufacturer

All lots; 25,682 cases distributed nationwide; Lex, Inc, Medley, FL.

a) Multiple lots; b) Lot numbers 4J59, 4J64, 4K73; 105,348 units distributed nationwide; H & P Industries, Inc., Brookfield, WI.

Lot numbers GN0487, GP4074, GP8357, GP9401, GP9403, GT3173, GT6213, GT6211, GT6215, GV0501, GV0499, GV0503; 160,244 units distributed nationwide; Apotex Corp., Lincolnshire, IL.

Lot # C401110, C400392 and C400827, exp. date 01/31/2007; 32,649 units distributed nationwide; Pfizer Inc., New York, NY.

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DRUGS AND DIETARY SUPPLEMENTS *cont.*

Name of Drug or Supplement; Class of Recall; Problem

Furosemide, 40mg, Rx only, Class II, Mold Growth found on tablets.

Gabapentin Tablets, 600 mg, Rx only, Class II, Dissolution failure at 3 month test point.

Genteal Gel Severe Lubricant Eye Gel. Hypromellose, 0.3%, lubricant, Class III, Defective container, possibility of tubes leaking.

Gladase Papain-Urea Debriding Ointment. Labeled in part as "For topical use only, Store in a cool place." Rx only, Class III, Mislabeling.

Lotrimin AF, Antifungal (Miconazole Nitrate 2%), OTC, Class III, Subpotent.

MESALAMINE RECTAL SUSPENSION, USP, ENEMA, 4g/60 mL, For Rectal Use Only, Rx only, Class III, Container leakage.

Prasco Laboratories T-Tanna DM Suspension, Antihistamine/Decongestant Antitussive, Cotton Candy Flavor, Rx Only, Class II, Superpotent.

Premarin (conjugated estrogens) tablets, USP, 0.9 mg, Rx only, Class III, Dissolution failure.

Sweet Ease — The Sucrose Solution, 24% sucrose and water solution., Class II, Potential risks of infection and other illnesses associated with the presence of mold contamination in a medical food product used for newborns and infants in the clinical setting.

a) **Zonegran® (zonisamide) capsules**, 25mg, Rx only; b) **Zonegran® (zonisamide) capsules**, 50mg, Rx only, Class II, Adulteration: Presence of foreign capsules.

Lot #: Quantity and Distribution; Manufacturer

Lot # T053L04A, exp. date 12/2006; 2,574 bottles distributed in CA; Vintage Pharmaceuticals LLC, Huntsville, AL.

Lot #: G04043, exp. date 01/2007; 6,946 bottles distributed in TN; Teva Pharmaceuticals USA, Sellersville, PA.

Lot Z13322, exp. date 08/2006; 13,056 tubes distributed nationwide; Novartis Pharmaceuticals Corp, East Hanover, NJ.

Lot numbers: S0403 and S0432; 2,916 tubes distributed nationwide; Smith and Nephew, Inc., Wound Management Division, Largo, FL.

Lot numbers: 3B03CC, exp. date 02/2006; 4B09CC, exp. date 02/2007; 4G03CC, exp. date 01/2007; 479,148 units distributed nationwide and internationally; Schering-Plough HealthCare Products, Inc., Memphis, TN.

104 batches; multiple lot numbers being recalled; 200,000 units distributed nationwide; Clay Park Labs, Inc., Bronx, NY.

Batch # GB952; 1,593 bottles sold in OH; Kiel Laboratories, Inc., Gainesville, GA.

Lot A67610, exp. date 07/2006; 98,260 bottles distributed nationwide; Richmond Division of Wyeth, Richmond, VA.

Lot # 1365, individual containers 2005/11/12-1N; 6,394 cases distributed nationwide and internationally; Respironics, Inc., Murrysville, PA

a) Lot number: 34940 & 34941; b) Lot number: 34943 & 34944; 7,949 units distributed nationwide; Eisai Inc, Research Triangle Park, NC.

CONSUMER PRODUCTS

Contact the Consumer Product Safety Commission (CPSC) for specific instructions or return the item to the place of purchase for a refund. For additional information from the Consumer Product Safety Commission, call their hotline at (800) 638-2772. The CPSC Web site is www.cpsc.gov.

Name of Product; Problem

All-terrain vehicles. The drive pulley inner flange could break resulting in the broken flange fragments becoming a projectile. This situation could cause serious injuries or death to the rider or bystanders.

Lot #: Quantity and Distribution; Manufacturer

Bombardier Outlander 800 H.O. XT ATVs; about 275 sold at Bombardier dealerships nationwide, Jul-Oct 2005; Bombardier Recreational Products Inc., of Valcourt, Providence of Quebec, Canada; (888) 864-2002 or <http://www.brp.com>.

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Type of Product; Problem

Backpack blowers. The fan wheel on these backpack blowers could break, resulting in pieces of plastic flying out of the blower housing. This poses a risk of injury to the user or a bystander.

Bean bag chair and ottoman. The chair and ottoman do not have locking zippers or warning labels. Children have died from suffocation when they unzipped, inhaled and ingested small pellets in similar bean bag furniture.

Candle sets. The decorative covering on the candles can ignite, posing a fire and burn hazard.

Computer batteries. An internal short can cause the battery cells to overheat and melt or char the plastic case, posing a burn and fire hazard.

Cribs. A wooden strip added to the end assemblies of the crib to correct a spacing problem could come loose, creating a space in violation of the federal crib standard and posing a risk of entrapment. In addition, the three pin nails used to hold the strip in place pose a laceration hazard if the wooden strip detaches.

Pencils and sharpeners. The sharpener's razor blade is exposed when the cover is removed. Also, the pencil sharpener hole is large enough to allow a finger to fit inside. This poses a laceration hazard to children and adults.

Pullover/pants sets. The zipper slider and pull on the fleece pullovers can detach, posing a choking hazard to young children.

Refrigerators and freezers. The defrost heater coil can become exposed inside the units, which poses a potential shock hazard to consumers. In some cases the exposed heater wire can also melt, or burn the unit's interior plastic food liner.

Snowmobiles. The fuel tank filler neck on these snowmobiles can crack. A crack in the filler neck area may cause the filler neck to separate from the fuel tank. A crack or filler neck separation may allow fuel or fuel vapors to escape from the fuel tank, posing a fire hazard.

Strollers. Stroller handle-locking clips can unlock during use, causing stroller to collapse.

Ventilation units. LUX 3/8-inch spinlock bolts supplied with these units may not have been properly heat treated, which can result in the

Lot #; Quantity and Distribution; Manufacturer

BR 500 and BR 550 Backpack Blowers; about 6,230 sold by authorized Stihl dealers nationwide, Jan-May 2005; Stihl Inc. of Virginia Beach, Va.; (800) 610-6677 or www.stihlusa.com.

Lily Chair and Lily Ottoman Bean Bag Sets; about 1,100 sets sold at specialty gift and furniture stores nationwide, Jan 2004-Jul 2005; Design Ideas Ltd., of Springfield, Ill.; (800) 426-6394 or www.designideas.net.

Holiday Time(tm) Candle Gift Sets; about 48,000 units sold at Wal-Mart stores nationwide; Sept 2004-Jan 2005; Wal-Mart Stores Inc., of Bentonville, Ark.; (800) 477-8697 or www.walmartstores.com.

HP and Compaq Notebook Computer Battery Packs; about 85,000 units sold at national and regional computer and electronics stores, online stores, hp.com and hpshopping.com, Mar 2004-May 2005; Hewlett-Packard Company, of Palo Alto, Calif.; (888) 404-7398 or www.hp.com/support/BatteryReplacement.

Child Craft Cribs; 155 sold at juvenile furniture stores nationwide, Apr-Oct 2005; Child Craft Industries Inc., of New Salisbury, Ind.; (800) 725-8625 or mprater@childcraftindustries.com.

Jumbo Pencils with Sharpeners; about 176,000 sold at Target Stores nationwide, Jul-Aug 2005; Target Corp., of Minneapolis, Minn.; (800) 440-0680 or www.Target.com.

Reebok Children's Fleece Quarter-Zip Pullover/Pant Sets; about 61,000 units sold at Gordmans, Mervyns, JC Penney, Kohl's, The Bon, Fred Meyer, Ross, DD's, Edisons, Macy's, AJ Wright, and Reebok Corporate Headquarters retail store in Canton, Mass., Sept 2004-Feb 2005; Adjmi Apparel Group, of New York, N.Y.; (800) 873-5570 www.Reebok.com.

Automatic Defrost Upright Freezers and All-Refrigerators; about 112,000 units sold at home improvement and appliance stores, Sept 2002-Feb 2005; W.C. Wood Company Inc., of Ottawa, Ohio; (866) 493-3314 or www.freezer-repair.com.

Polaris Snowmobiles; about 16,400 sold at Polaris dealers nationwide, Aug 2004-Sept 2005; Polaris Industries Inc., of Medina, Minn.; (800) 765-2747 or www.polarisindustries.com.

Kelty Speedster Jogging Stroller; 230 units sold at juvenile baby product stores, sporting good stores and Web retailers, May-Jul 2005; Kelty Division of American Recreation Products Inc., of Boulder, Colo.; (800) 535-3589.

Greenheck Sidewall, Rooftop and Centrifugal Inline Ventilation Units; about 4,200 ventilation units sold by independent sales representatives

Saving Money When Buying Prescription Drugs

The following is from the newest edition of our recently published book Worst Pills, Best Pills.

For many people in the United States, the price of prescription drugs is unaffordable. Many drugs cost \$500, \$1,000, \$2,000, or more per drug and many people are taking more than one of them. Although the majority of these drugs have not yet come off patent and generic equivalents are therefore not available, the lack of the kind of price controls that exist in all other developed countries (and in the Department of Defense and the Veteran's Administration in the United States) presents an undue financial burden for too many people.

Five Ways to Save

There are at least five ways you can save money on the high cost of prescription drugs:

- If appropriate, for your condition, ask your doctor to help you try a nondrug treatment first.
- Avoid **Do Not Use** drugs.
- Avoid **Do Not Use until Seven Years after Release** drugs, waiting at least seven years to take any new drug unless it is one of the rare "breakthrough" drugs.
- When you can, buy generic drugs.

- Use caution when purchasing drugs on the Internet and importing drugs from Canada.

In this issue of *Health Letter* we will review the first three categories and, next month, we will finish the review with a discussion of buying generic drugs and cautions about internet purchase of drugs and importing drugs from Canada.

1. Nondrug Treatments

For many conditions, such as mild to moderate high blood pressure, high cholesterol, type-2 diabetes, obesity, and insomnia, changes in lifestyle are just as effective, safer, and less expensive than prescription drugs for many people. In fact, in many instances, nondrug interventions are recommended as the first-line treatment for these conditions before drugs are tried.

It may be easier for you to take pills, but pills may not be the safest or best management for your condition, and they are certainly much more expensive than nondrug treatments.

2. Avoid Do Not Use Drugs

Avoiding drugs listed as **Do Not Use** can both save you money and help you to avoid needless drug-induced injury or death. Most of the

Do Not Use drugs in this book are listed as such because they are more dangerous than a safer alternative. Safer alternatives are listed along with all **Do Not Use** drugs, and many of the alternative drugs are available in a less expensive, generic form. Thus, avoiding such drugs combines reducing risks and, in a large number of cases, saving money as well.

Examples of dangerous **Do Not Use** drugs from previous editions of this book that have subsequently been taken off the market, usually long after we warned against their use in the book and/or our monthly *Worst Pills, Best Pills News*, include the antihistamines Seldane and Hismanal, the heart drugs Posicor and Baycol, the painkillers Duract and Butazolidin, the diabetes drug Rezulin, the heartburn drug Propulsid, the antibiotics Zagam and Raxar, the antidepressant Serzone, and the weight reduction drugs Redux and ephedra.

A much smaller subset of **Do Not Use** drugs are listed as such because — taking advantage of weaknesses in the drug patent laws — they are shameless copies of other drugs already on the market and usually available in a generic form. We discuss examples of this below.

How is such a sleight of hand possible? "Smoke and mirrors" aptly *continued on page 8*

CONSUMER PRODUCTS *cont.*

Type of Product; Problem

bolts breaking. Bolt failure during lifting for rooftop installation or after installation could cause the unit or components to fall and injure bystanders.

Washing machine. If the front-load washer is operated at maximum load capacity, the spinner could malfunction and break apart, posing a safety risk to consumers.

Water heaters. The water heaters can accumulate soot on the burners, posing a fire hazard.

Lot #; Quantity and Distribution; Manufacturer

and original equipment manufacturers, Aug 2004-Jul 2005; Greenheck Fan Corp., of Schofield, Wis; (800) 931-6579 or Kathy.Lenard@greenheck.com.

Maytag Front-Loading Washing Machines; about 5,000 sold at major department and appliance stores nationwide, Apr-May 2005; Maytag Corp., of Newton, Iowa; (800) 462-9267 or www.maytag.com.

75-Gallon Propane Gas Water Heaters; about 5,000 units installed by independent contractors and plumbers nationwide, Jan 2004-Jul 2005; A.O. Smith Water Products Co., of Ashland City, Tenn.; (866) 880-4661 or <http://www.hotwater.com>.

SAVING ON DRUGS, from page 7
describes the technique. The smoke consists of phony “breakthrough” advertising, and the mirrors are represented by a chemical gimmick involving isomers.

We all know what advertising is, but what is an isomer? It is, chemically speaking, a molecule containing identical atoms to another molecule but differently arranged: a mirror image, to be precise. So it is with many pharmaceuticals. Many exist as equal parts of a chemically identical compound that are mirror images of each other. All of the atoms in the drug molecule are the same, only their spatial orientation is different. Separating these mirror images and selling only a single mirror image as a “new” drug is a successful business scheme, not a strategy to improve public health. This may be likened to selling one glove and claiming that it is as good as or better than two.

This low-class “research” activity by the pharmaceutical industry is almost always done because the patent on the first drug is about to expire and the company wants the “new” drug to compete with lower-price generic versions of the original drug. The examples that follow include several pairs of drugs, one of each pair having been approved in the United States since the mid-1990s. The older drug of the pair is the original mix of mirror images, while the new drug is only one of the mirror images. In each case, the single mirror image has never been shown to be therapeutically superior to the original mixture of mirror images.

Esomeprazole (NEXIUM) and Omeprazole (PRILOSEC)

The “new purple pill” esomeprazole is really only one of the two mirror images that make up the “old purple pill” omeprazole. Despite the fact that esomeprazole was only approved by the FDA in February 2001, due to clever marketing and uncritical physicians, this drug was dispensed almost 4 million times in U.S. pharmacies by the end of 2001. The FDA physician who reviewed the data on the two drugs stated that “the sponsor’s conclusion

that H 199/18 [esomeprazole] has been shown to provide a significant clinical advance over omeprazole in the first-line treatment of patients with acid-related disorders is not supported by data.” [emphasis added] Esomeprazole and omeprazole are both produced by the same company, AstraZeneca Pharmaceuticals, based in Wilmington, Delaware.

Escitalopram (LEXAPRO) and Citalopram (CELEXA)

Escitalopram was approved by the FDA in August 2002, bringing to six the number of selective serotonin reuptake inhibitor (SSRI) antidepressants now on the U.S. market. It is the most recent member of the mirror-image marketing rage, being one-half of the mixture that constitutes citalopram. The other SSRIs currently available are fluoxetine (PROZAC, SARAFEM), fluvoxamine (LUVOX), paroxetine (PAXIL), and sertraline (ZOLOFT).

Both escitalopram and citalopram are produced by Forest Laboratories, Inc., of St. Louis.

The editors of *The Medical Letter on Drugs and Therapeutics* concluded in their September 30, 2002, review of the drug: “Escitalopram (LEXAPRO), the active enantiomer [one of the two mirror images] of citalopram (CELEXA), is effective for treatment of depression, but it has not been shown to be more effective, more rapid-acting or less likely to cause adverse effects, including sexual dysfunction, than citalopram or any other SSRI.”

We have also listed escitalopram as a **DO NOT USE** drug because for practical purposes, it is the same drug as citalopram and it has no therapeutic or safety advantage over citalopram or other SSRI antidepressants.

Dexmethylphenidate (FOCALIN) and Methylphenidate (RITALIN)

Dexmethylphenidate (FOCALIN), approved by the FDA in November 2001 for attention deficit hyperactivity disorder (ADHD), is simply one-half of the chemically identical mixture of mirror images that makes up the 40-year-old drug methylphenidate

(RITALIN).

Both dexmethylphenidate and methylphenidate are produced by Novartis Pharmaceuticals of New Jersey.

Dexmethylphenidate was reviewed in the August 2002 issue of *Worst Pills, Best Pills News*. Novartis’s “spin” to sell its old product as a new and better drug was to claim that “the duration of activity [of dexmethylphenidate] was statistically significantly longer...than methylphenidate.” Unfortunately, this strategy works with many health professionals and patients. But the FDA medical officer who reviewed Novartis’s data wasn’t fooled, saying, “This statement is misleading for several reasons.”

We agreed with the conclusion of the editors of *The Medical Letter on Drugs and Therapeutics* in their May 13, 2002, review of dexmethylphenidate: “There is no evidence that dexmethylphenidate (FOCALIN) offers an advantage over any other formulation of methylphenidate (RITALIN and others). Older drugs with better established dosages and longer safety records are preferred.”

Clarinet and Claritin: A New Twist — Patenting Metabolites

In addition to the “smoke and mirrors” schemes described above, another patent-ending avoidance scam involves metabolites. For example, when you swallow loratadine (CLARITIN), your body metabolizes it to desloratadine, which is actually the active form of the drug. As Schering-Plough started feeling the despair of the end of the patent on their big-selling, heavily advertised drug Claritin, the business heads there arranged for the testing and ultimate FDA approval of the main metabolite, desloratadine, and came up with the sound-alike name of Clarinet.

Not surprisingly, there is no evidence that Clarinet is any better than Claritin because Clarinet is exactly the same substance as what your body turns Claritin into when you swallow it.

A former drug company executive, who also was a physician, noted while testifying before the U.S. Senate that

Public Citizen Writes of Drug Company Deception in *Lancet* Medical Journal

In 1996, GlaxoSmithKline halted a clinical trial involving the drug salmeterol (SEREVENT) because preliminary data from that trial indicated an increased risk of asthma-related death in users of the drug. In 2003, the company submitted data from the trial to the FDA. But, as Public Citizen researchers argue in a recent issue of the British medical journal The Lancet, the company deceived the FDA, physicians, and consumers when it did so. Our comments on the trial and the Lancet article follow.

GlaxoSmithKline presented misleading results to the Food and Drug Administration (FDA) from a study of the popular asthma drug salmeterol (Serevent, known as Advair when combined with the steroid fluticasone), Public Citizen writes in a letter in this week's issue of *The Lancet*.

In 1996, the Salmeterol Multicenter Asthma Research Trial was initiated to study tens of thousands of asthma patients who received either salmeterol or a placebo. The study lasted 28 weeks and showed an increased risk of asthma-related death for those

taking salmeterol. The results have never been published, although GlaxoSmithKline presented the interim results to the FDA in July 2003, when the drug came up for review before the FDA's Pulmonary-Allergy Drugs Advisory Committee. The company submitted final study data to the FDA on August 29, 2003.

However, that data included adverse events that were reported six months after the trial ended and were not to be included, according to the original study protocol. The inclusion

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the pharmaceutical industry is "unique in that it can make exploitation appear a noble purpose." The testimony was given over 40 years ago and is as true today as it was then. Capitalizing on their decades-old charade of nobility, the pharmaceutical industry is increasingly selling expensive "new" patented drugs that are chemically identical or nearly identical to the old drugs they replace. Remarkably, physicians prescribe them and patients pay exorbitant prices, both groups somehow believing, while being exploited, that an old drug with a new name is a therapeutic breakthrough.

3. Avoid "Do Not Use Until Seven Years After Release" Drugs, Waiting at Least Seven Years to Take Any New Drug Unless It Is One of the Rare "Breakthrough" Drugs

In addition to abusing the drug patent laws by gaining patents on the optimal isomers or metabolites of other drugs as described above, the industry is also quite prone to modifying just a few atoms in a complicated molecule and getting a patent on a so-called me-too drug.

The alternatives (the molecules from which they made the modification) to many of these new drugs are

The Health Research Group's Seven-Year Rule

You should wait at least seven years from the date of release to take any new drug unless it is one of those rare "breakthrough" drugs that offers you a documented therapeutic advantage over older proven drugs. New drugs are tested in a relatively small number of people before being released, and serious adverse effects or life-threatening drug interactions may not be detected until the new drug has been taken by hundreds of thousands of people. A number of new drugs have been withdrawn within their first seven years after release. Also, warnings about serious new adverse reactions have been added to the labeling of a number of drugs, or new drug interactions have been detected, usually within the first seven years after a drug's release.

increasingly generically available and will therefore be less expensive; in addition, the decision not to use these drugs will also have a safety benefit in many instances.

For many years, we have warned patients not to use newly approved drugs unless they are one of the decided minority of new drugs with evidence that they are a breakthrough beyond existing treatments. A study involving Dr. Sidney Wolfe as one of the authors provides clear evidence why this caution of waiting seven years is well founded. A total of 548 new chemical entities were approved in 1975-1999. By 1999, 45 drugs (8.2%) acquired one or more black-box warnings and 16 (2.9%) were withdrawn

from the market. **The estimated probability of acquiring a new black-box warning or being withdrawn from the market over a period of 25 years was 20%. Half of these black-box warning changes occurred within 7 years of drug introduction; half of the withdrawals occurred within 2 years.** The article concluded that serious adverse drug reactions commonly emerge after FDA approval. The safety of new agents cannot be known with certainty until a drug has been on the market for many years. This study, as mentioned above, confirms the basis for our "Seven-Year Rule" concerning newly marketed drugs that are not therapeutic breakthroughs. ■

FDA Reverses Course on Needle Sticks, Shows Profound Indifference to Worker Health

A primary activity of Public Citizen's Health Research Group is holding government accountable to the people who depend on it for protection — in this case, health care workers who depend on government regulation to protect them from dangerous medical devices. Unfortunately, the FDA has once again bowed in response to industry pressure and exposed thousands of workers to needless risks in the process. The statement of Health Research Group Deputy Director Peter Lurie is reprinted below.

Today's withdrawal of a rulemaking initiated to protect health care workers from accidental needle sticks shows a profound indifference to the safety of workers and is yet another example of the Food and Drug Administration's (FDA) failure to do its job.

In 2000, Public Citizen and the Service Employees International Union (SEIU) petitioned the FDA to ban a variety of unsafe devices used by health care workers, including certain intravenous (IV) catheters, blood collection devices, blood collection needle sets ("butterfly syringes"), glass capillary tubes and IV infusion equip-

ment. The problem is significant: Each year, U.S. health care workers sustain 590,000 needle sticks, according to the

Again, the agency [FDA] is eschewing its responsibility to ensure the safety of the products it regulates.

University of Virginia, and thousands have contracted HIV and hepatitis B or C after being accidentally stuck by infected needles while on the job. Many have died. These deaths and injuries were unnecessary because devices that are equally effective, yet have safety features such as retractable needles, self-blunting needles and protective shields, exist.

In response to the petition, the FDA issued an advance notice of proposed rulemaking, in which the agency acknowledged the dangers associated

with needles and began the process of addressing them. Now, the agency has retreated in the face of industry pressure. The agency claims that not enough detailed data exist to warrant action. However, an extensive body of research documents the ability of the safer devices to reduce needle sticks. As the American Medical Association concluded in 2001, "Scientific data now indicate that the appropriate use of needlestick prevention devices, especially in comprehensive prevention programs, significantly reduces the incidence of needlestick injuries."

The FDA has increasingly come under fire for its refusal to ensure that prescription drugs are safe before being placed on the market. In most cases where unsafe drugs have had to be removed from the market, safer, equally effective alternatives have existed. Here, again, the agency is eschewing its responsibility to ensure the safety of the products it regulates. By allowing considerably more dangerous devices to stay on the market when equally effective, safer alternatives are available, the FDA has endangered the lives of hundreds of thousands of health care workers in this country. ■

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of the post-study data reduced the apparent dangers of salmeterol with respect to four critical study outcomes, including asthma-related death.

GlaxoSmithKline did not clearly inform the FDA that the final study included data from six months after the trial had concluded until the FDA inquired about the results in April 2004. The FDA had presumed the data were only from the 28-week trial itself, since that was the "period of interest," according to the FDA.

Since learning of the suspicious

reporting of the study results, the FDA's Pulmonary-Allergy Drugs Advisory Committee on July 13, 2005, recommended strengthening the warning on the labels for both Serevent and Advair, but the agency has yet to make a final decision. Public Citizen learned of the misleading data presentation from materials provided to the advisory committee.

"The behavior of GlaxoSmithKline in submitting these faulty data is deplorable," said Dr. Peter Lurie, deputy director of Public Citizen's Health Research Group and co-

author of the letter. "Absent greater transparency at the FDA, we will never know how often this kind of self-serving data analysis occurs."

Public Citizen listed Serevent as a "Do Not Use" drug in its *Worst Pills, Best Pills* newsletter (www.worstpills.org) in March 2003 because of the interim study results.

Salmeterol was dispensed more than 2.1 million times in U.S. pharmacies in 2004. The combination product, Advair, was dispensed more than 16.1 million times in U.S. pharmacies that year. ■

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Helping Drug Reps Serve You Better: National Healthcare Census

Several weeks ago I received an envelope in the mail, addressed to Sidney M. Wolfe, M.D., with a return address of National Healthcare Census. Being curious — especially since 46 million Americans lack health insurance and thinking that maybe someone is asking doctors about this embarrassing state of affairs in a country currently spending almost 1.9 trillion dollars on health services and supplies — I opened the envelope.


Was I surprised! Rather than seeking any information from me about patients for a healthcare census, the survey questions were preceded by a revealing statement urging me to “help the healthcare industry better serve you”. It went on to say that “By answering the attached survey, you

will provide insight into your practice and in turn you will receive better service from pharmaceutical representatives.” For 28 different categories of drugs, I was being asked whether I recommend or prescribe drugs in that category and, if I did, how many times per week. They then asked about the use of COX-2 drugs and, finally, what I thought about the influence of Direct-to-Consumer (DTC) advertising on my prescribing practices. Before the actual end of the six-page questionnaire, I was asked if I would like to participate in on-line surveys of my prescribing practices and, if so, would I provide my e-mail address.

On the front page of the survey, nestled between “help the healthcare industry better serve you” and the

questions, was a personal check for \$5, made out to me to help induce me to help the industry. There was, in the interest of full disclosure, an option to donate the money to a medical charity. By way of further enticement to get me to cooperate, I was told that this survey has already raised “more than \$250,000 for worthy charitable organizations”, i.e., 50,000 doctors have already filled out the questionnaire.

I decided, because of profound disappointment with what this “healthcare census” had turned out to be, not to fill out the questionnaire, a decision further supported by the fact that a number of the products were ones we list as **DO NOT USE** in our book, *Worst Pills, Best Pills*. ■

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