# Health Letter

SIDNEY M. WOLFE, M.D., EDITOR

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# Dr. Sidney Wolfe's Testimony before Subcommittee on Health at Hearing on Health Insurance

The following testimony was given by Dr. Sidney M. Wolfe, acting president of Public Citizen and editor of the Health Letter, on June 24, 2009.

hat if you picked up the morning paper tomorrow and saw the following headline: "50 People Died Yesterday thev Lacked Health Because Insurance"? The next day, the same headline - and the next as well. This is the average number of people in the United States who, according to a 2004 report by the Institute of Medicine of the National Academy of Sciences, die each day - more than 18,000 a year - because they lack health insurance. How should we respond to this unacceptable and embarrassing finding?

Not by saying, as President Obama has said that if we were starting now from scratch, we would have a single-payer, but it's too disruptive or, as the health insurance industry recently said, having the public option would be too "devastating". What could be more disruptive and devastating than being one of 45+ million people who are uninsured, from whose ranks come 18,000 people who die each year because of this dangerous status?

The real question is why should we tolerate the fragmented, highly profitable, administratively wasting private health insurance industry any longer? In this regard, the public is way ahead of either President Obama or the Congress in its distrust of the health insurance industry.

A recent national Harris Poll (October, 2008) asked the following question: "Which of these industries do you think are generally honest and trustworthy — so that you normally believe a statement by a company in that industry? "Only one out of 14 people (7 percent) thought that the health insurance industry is honest and trustworthy. The only industries in the survey that were even more distrusted than the health insurance industry were HMO's (7 percent), oil (4 percent) and tobacco (3 percent).

The Congress, on the other hand, trusts the health insurance industry and feels compelled to come up with a "solution" that avoids a big fight with them, not only writing them into the legislation but assuring further growth of that industry. The Congress wants to believe that the health insurance and pharmaceutical industries will be good citizens and voluntarily lower their prices to save

some of the money that is necessary to fund health insurance. Several weeks ago, the collective forces of the health industry promised that they could voluntarily save two trillion dollars over the next 10 years.

But the amount that can be saved over the next ten years by just eliminating the health insurance industry and the \$400 billion of excessive administrative costs it causes each year is \$4 trillion, in one fell swoop. This would be enough to finance health care for all without the additional revenues the Congress and the Administration is desperately seeking.

As an example of administrative waste, over the last 30 plus years there have been maybe two and a half, three times more doctors and nurses, in proportion with the growth in population. But over the same

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interval, there are 30 times more health administrators. These people are not doctors. They're not nurses. They're not pharmacists. They're not

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providing care. Many of them are being paid to deny care. So, they are fighting with the doctors, with the hospitals to see how few bills can be paid. That's how the insurance industry thrives by denying care, paying as little out as it can, getting the healthiest patients.

There is no question

that we have a fragmented health insurance industry. And it thrives on being fragmented, avoiding any kind of serious centralized examination or control. The drug companies make much more money with this insurance fragmentation, because there's no price control. The insurance companies make much more money because they can push away people who aren't going to be profitable, let public programs take care of these patients who are "unprofitable."

What the President and the Congress are really, realistically advocating — since there is absolutely no possibility of having enough money to cover all people in this country as long as the private, for-profit health insurance industry is allowed to exist — is more incremental reform, not National Health Insurance. It is now 44 years since Medicare and Medicaid came into existence. In the interim, there have been many experiments in this country and abroad to try to provide universal health coverage.

Other countries have uniformly rejected the private for-profit insurance industry and have adopted National

Health Insurance. Is everyone else wrong and only the US is right?

A recent study by the international OECD (Organization for Economic Co-operation and Development) provided health insurance data

from its 30 member countries (Europe, Korea, Japan, Mexico, Canada, the United States and others Australia. including New Zealand and The latest Iceland). from those countries showed that 27 of the 30 had health insurance coverage for more than 96 percent of the population, with

only Germany having any non-public coverage (10.3 percent). The other three were Mexico with 60.4 percent covered — all with public coverage, Turkey, with 67.2 percent covered, also with public coverage and the U.S. with 84.9 percent covered 57.5 percent with private and 27.4 percent with public coverage.

In Canada, back in 1970, they were spending the same percentage of their gross national product as we were on health. They also had millions of uninsured people and many of the same insurance companies such as Blue Cross, Blue Shield. They decided to just get rid of the health insurance industry. They had experimented with it in Saskatchewan ten years earlier and it had worked so well, they couldn't wait to do it nationally. So, where there's a will, there's a way. There is no way we are ever going to get to having good health insurance for everyone, as long as there's a health insurance industry, in the way, obstructing care.

Other more recent experiments abroad include Taiwan. In 1995, Taiwan had said, we don't like the

fact that 40 percent of our people are uninsured. They passed, essentially, single-payer plan and within a few years 90-95 percent of the people were covered.

In the U.S. we have had experiments as well with seven states having instituted various versions of the public/private combination that this legislation seeks to provide. In none of these states has this worked, once several years had elapsed, despite initial enthusiasm and short-lived decreases in the uninsured.

So as we consider what to do, which experiments do we follow? The ones that were successful, all of which, for all practical purposes, eliminated the private for-profit insurance industry, or the failed U.S. state examples, all of which were built on this industry?

If instead of saying that a single payer program is *not* politically possible, the President and the Congress need to say, "It is not only politically possible, politically feasible, but it's the only practical way national health insurance will ever happen." Anything short of that is essentially throwing tens of billions of dollars at the insurance industry. And if you're afraid of the insurance industry, than you're afraid of doing the right thing: Having everybody in, and nobody out of having health insurance. •

## Dr. Steffie Woolhandler's Testimony before Health Subcommittee at Hearing on Health Insurance

The following testimony was given on June 24, 2009 by Steffie Woolhandler, M.D., M.P.H., cofounder of Physicians for a National Health Program, before the Subcommittee on Health at the House Committee on Energy and Commerce Hearing on Health Insurance.

Chairman, members the Committee. Steffie Woolhandler. I am a primary care doctor in Cambridge, Massachusetts, and associate professor of medicine at Harvard. I also co-founded Physicians for a National Health Program. Our 16,000 physician members support nonprofit, single-payer national health insurance because of overwhelming evidence that lesser reforms - even with a robust public plan option — will fail.

Private insurance is a defective product. Unfortunately, the Tri-Committee health reform plan would keep private insurers in the driver's seat, and, indeed, require Americans to buy their shoddy goods. Once failure to buy health insurance is a federal offense, what's next? A Ford Pinto in every garage? Lead-painted toys for every child? Melamine-laced chow for every puppy?

Even middle-class families with supposedly good coverage are just one serious illness away from financial ruin. My colleagues and I recently found that medical bills and illness contribute to 62 percent of all personal bankruptcies — a 50 percent increase since 2001. Strikingly, three-quarters of the medically bankrupt had insurance — at least when they first got sick.

In case after case, the insurance families bought in good faith failed them when they needed it most. Some were bankrupted by copayments and deductibles, and loopholes that allowed their insurer to deny coverage. Others got too sick to work, leaving them unemployed

and uninsured. And insurance regulations like those proposed in the tri-committee bill cannot fix these problems.

We in Massachusetts have seen in action a plan like the one you're considering. In my state, beating your wife, communicating a terrorist threat and being uninsured all carry \$1,000 fines. Yet despite these steep fines, most of the new coverage in our state has come from expanding Medicaid-like programs at great public expense. According to the state's disclosure to its bondholders, our health reform has cost about \$5,000 annually for each newly insured adult. That's equivalent to over \$200 billion annually to cover all of America's uninsured.

But even such vast expenditures haven't made care affordable for middle-class families in Massachusetts. If I were to lose my Harvard coverage I'd be forced to lay out \$4,800 for a policy with a \$2,000 deductible before it pays for any care, and 20 percent co-payments after that. Skimpy,

overpriced coverage like this left 1 in 6 Massachusetts residents unable to pay their medical bills last year.

Meanwhile, rising costs have forced the Legislature to rob Peter in order to pay Paul. Funding cuts have decimated safety-net hospitals and clinics, and the current budget drops coverage for 28,000 people.

As research I published in the New England Journal of Medicine showed, a single-payer reform could save about \$400 billion annually by shrinking health care bureaucracy enough to cover the uninsured and to provide first dollar coverage for all Americans. A single-payer system would also include effective costcontainment mechanisms like bulk purchasing and global budgeting. As a result, everyone would be covered with no net increase in U.S. health spending. But these savings aren't available unless we go all the way to single payer.

Adding a public insurance plan option can't fix the flaws in Massachusetts-style reform. A public



Physicians come together in Washington, DC to show their support for single-payer at a rally earlier this year.

## Letter to the Editor of the Washington Post Regarding the Coverage of the Recent Congressional Hearing on Single-Payer

The following letter-to-the-editor, written by Public Citizen researcher James Floyd, M.D., appeared in the Washington Post Monday, June 15, 2009. Dr. Floyd attended the hearing discussed in the June 11, 2009, Dana Milbank article.

Dana Milbank's description of the recent congressional hearing on single-payer health care ["It's Healthy to Vent," June 11] was polemical.

First, many attendees were congressional staff members, not single-payer advocates.

Second, to describe the testimony of witnesses, which included Rep. John Conyers Jr., chairman of the House Judiciary Committee, as mere "venting" and "an exercise in blowing off steam" was offensive to the millions of Americans whose views they represent.

Third, Rep. Dennis Kucinich's grilling of the Manhattan Institute's David Gratzer was justified by Mr. Gratzer's selective use of statistics to portray a falsely grim picture of the Canadian single-payer system. Certainly, a national system of health insurance that guarantees comprehensive access to needed care and eliminates profit is anathema to someone who cheerleads the intellectually and morally bankrupt "consumer-driven health care" movement.

Finally, to decry a national system

of health-care financing that retains the private delivery of health care as socialism simply plays into the propaganda and fear-mongering of the right and the private insurance lobby, which opposes any challenge to its obscene profits.

Make no mistake: Single-payer advocates have much to be upset about, given our near-complete exclusion from the congressional debate on health reform.

But we are the only health-care reform movement with strong and growing grass-roots support, and we will be heard. •

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plan might cut private insurers' profits, which is why they hate it. But their profits account for only about 3

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percent of the money squandered bureaucracy. Far more goes for marketing (to attract healthy, profitable members) demarketing (to avoid the sick). And tens of billions are spent on the armies of insurance administrators who fight over payment and their counterparts hospitals and

doctors offices. All of these would be retained with a public plan option.

And overhead for even the most efficient competitive public plan would be far higher than Medicare's, which automatically enrolls seniors when they turn 65 and disenrolls them only at death, deducts premiums

directly from Social Security checks, and does no marketing.

Unfortunately, competition in health insurance involves a race to the bottom, not the top. Insurers

compete by NOT

paying for care: by denying payment and shifting costs onto patients or other payers. These bad behaviors confer a decisive competitive advantage. A public plan option would either emulate them — becoming a clone of private insurance — or go under. A kinder, gentler public

plan option would quickly fail in the marketplace, saddled with the sickest, most expensive patients, whose high costs would drive premiums to uncompetitive levels.

In contrast, a single-payer reform would radically simplify the payment system and redirect the vast savings to care. Hospitals could be paid like a fire department, receiving a single monthly check for their entire budget, eliminating most billing. Physicians' billing could be similarly simplified.

Eight decades of experience teach that private insurers cannot control costs or provide families with the coverage they need. A government-run clone of private insurers cannot fix these flaws. Only single payer national health insurance can assure all Americans the care they need at a price they can afford.  $\spadesuit$ 

## How Ineffectual Medical Treatments Can Misleadingly Produce "Good" Results

he current critical look at the U.S. health care system has underscored the growing misuse and overuse of certain types of health care. As a result, an ever-expanding number of therapeutic tools are being examined to make sure they work.

Many drugs, devices, and procedures that are found to be ineffectual or even dangerous have seemed to work when initially introduced, or seemed to prove useful for selected populations. Consumers are therefore often puzzled when some therapies that are initially hailed as breakthroughs are later pronounced useless, even hazardous. What are the reasons this occurs?

There are a number of effects at play. These, alone or in combination, can confound the evidence gathered through trials or other types of assessments and make treatments seem better than they really are. Here, we describe some of these.

The placebo effect is defined as a "measurable, observable, or felt improvement in health not attributable to an actual treatment." Placebos (from the Latin "I shall please") are aimed more at pleasing or appeasing patients than at treating them. Yet placebos play an important role in clinical research. When a drug, device, or procedure evaluated, the experimental group which receives the treatment is often compared to a control group which receives a placebo. In double-blind experiments, neither the experimenter nor the subjects of the experiment know who has is getting what. When an active drug is tested against an inert placebo, any significant difference in outcomes is seen as attributable to the drug. Less commonly three-way experiments are conducted in which similar subjects are divided among those receiving a

treatment, those receiving a placebo, and those not receiving anything at all. These also allow comparisons between the latter two groups. Any difference between them can then be attributed to a placebo effect in those with the disease.

"sham" Though based on treatments, the placebo effect is quite real. Because it works through different mechanisms, there is not a single placebo effect but many. The medical literature grows by nearly 100 studies on the placebo effect every year. These studies have found that placebos can assuage pain, and alleviate depression, anxiety, Parkinson's disease, inflammatory disorders and cancer. Placebos have been found to even shrink tumors. And the placebo effect may extend to persons other than those taking them, such as family or friends.

Traditionally, the placebo effect has been explained as the result of a patient's expectations and beliefs affecting the course of the belief. But recent data show that the effect may arise from subconscious associations between recovery and the experience of being treated. Conditioning, in which the patient associates a treatment (or even seeing a doctor, a pill, or a syringe!) with feeling better, can also produce the placebo effect. A placebo can activate physiological processes, including immune responses, the release of hormones and the release of internally-produced pain relievers. These responses are triggered by active processes in the brain, which have been documented in animals and studied through imaging.

A team of German and Swiss scientists documented the placebo effect produced by conditioning in rats. The experimental animals were injected with an immunosuppressive drug (used to prevent the rejection of transplanted organs) at the same

time they were fed sweetened water. The rats associated the two "interventions" to the point where feeding them the sweet drink alone weakened their immune systems. The researchers conclude that these findings "suggest that a placebo effect does not require that a person hope for or believe in a positive outcome." Even more remarkable was the finding that the placebo effect had clinical significance: the conditioned rodents survived transplanted organs longer than their non-conditioned counterparts even when both groups had received the same "active" drug. A similar experiment carried out with a small group of humans found that comparable behavioral conditioning could mimic the immunological effects of an immunosuppressive drug.

Curiously, the price of a placebo has been found to affect the potency of its effect. In a study published in 2008, 82 healthy paid volunteers were given what they were told was a new opioid and asked to rate its effects on painful electric shocks. Although they were all given the same placebo, some were told it cost \$2.50 a pill while others were told it cost 10 cents a pill. Those who got the more "expensive" pill had significantly greater pain reduction than those who got the "cheaper" pill. The researchers therefore suggest that clinicians harness "quality cues" in the treatment of patients, de-emphasizing factors that may devalue the efficacy of treatments (e.g., its low price, or generic nature) in the patients' eyes. Similar differences between various placebos have been attributed to the size or the color of the pill.

Placebos have also been found to affect not only patients, but their caregivers as well. A recent review of studies of stimulant medications given to children with attention deficit-hyperactive disorder (ADHD) found that, when caregivers believed their ADHD patients were receiving medication, they tended to view the children more favorably and the treatment more positively, whether or not the children were actually receiving the medication. This may have benefits as well as drawbacks. To the extent that this may have led

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to a more positive interaction between patient and caregiver, the effect could be seen as favorable. But some caregivers be misled may into attributing the perceived behavioral changes to the medication, and thus increase its dosage.

The Hawthorne effect gets its name from a series of studies among employees of conducted a telephone-parts factory called the Hawthorne Works, located outside Chicago. The purpose of the studies, which were conducted in 1924, was to learn whether workplace lighting affected workers' productivity. The major finding of the study was that the output increased whenever the lighting increased, but also when it was dimmed. The conclusion was that it was the change, rather than its nature or direction, which produced the effect. The finding was interpreted to mean that it was the workers' awareness that they were being experimented on that altered their behavior. As a result, the fact that behavior tends to change when people know they are being monitored or watched has been called a "Hawthorne effect."

A recent re-analysis of the Hawthorne data has cast doubt on the original interpretation of the findings. It turns out that lighting was always modified on a Sunday, when the plant was closed, and that output was high on Monday and tapered off during the course of the week. Moreover, the fact that productivity decreased when the experimentation ceased has been re-interpreted as a seasonal effect: the experiment ended in the summer, when output fell anyway.

Still, the "Hawthorne effect" has become part of the social science lexicon, and it has been found to actually operate in an array of cases, including medical phenomena.

Patients tend to change their behavior when they know they are under study and

the more intense the scrutiny, the better they are likely to perform. This has been found in patients following prescribed treatments. Thus, for example, closer follow-up has been found to induce or nurture better adherence to medical orders.

The "healthy user" effect has been at play in some significant therapies that were hailed as beneficial before being discarded as ineffectual or misguided. It has also led to the misinterpretation of some previous findings.

A major wake-up call for women and their health providers came in July 2002, when the results of prospective, randomized, Woman's Health Initiative trials overturned findings from many other non-randomized studies. Prior studies had shown that women who had previously taken estrogen and progestin had less heart disease than those who did not. But the WHI study found otherwise: the large (more than 161,000 women) clinical trial found that those who were randomized to take the drugs had slightly more

heart disease, as well as an increased risk of breast cancer. These findings were significant enough to prompt the discontinuation of the trial. The findings of the initial studies were attributed to a "healthy user" effect: women who choose to take any medication for years, regardless of what it is, are different from those who do not. The comparison between users and non-users of estrogen and progestin was therefore inadvertently comparing conscientious, healthsavvy women with women who were less concerned or informed about their health. As pointed out in an article published in the British Medical Journal, "drug treatment may be a surrogate for overall healthy behavior," and those who adhere to healthy lifestyles may possibly "also tend to take care of themselves by greater adherence to prescribed treatments."

The novelty effect refers to the impact of a new treatment or intervention simply because it is unique or new. It is therefore not the treatment itself that brings about a change, but rather its novelty: the person receiving it may be reacting to it solely because it is new and different.

These phenomena can be useful. But they can also play tricks on patients, practitioners, and researchers alike, complicating the evaluation of therapeutic impacts and making it difficult to disentangle causes and effects. As seen in the case of hormonal treatment for the menopause, what was originally thought to be useful and disease-protective drugs turned out to be extremely harmful. •

## **Product Recalls**

June 17, 2009 -July 14, 2009

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. 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. Visit www.recalls.gov for information about FDA recalls and recalls issued by other government agencies.

## Recalls and Field Corrections: Drugs – CLASS I

Indicates a problem that may cause serious injury or death

Name of Drug or Supplemennt: Problem, Recall Information

**ETHEX Dextroamphetamine Sulfate Tablets**, USP, 5 mg, CII, packaged in 100-ct. bottles, RX, 39,230/100-ct. bottles. Some of the tablets are oversized. Lot #: 77946, exp. date 11/2009; Lot #: 81141, exp. date 01/2010; and Lot #: 81142, exp. date 05/2010. Ethex Corporation.

**Propafenone Hydrochloride Tablets**, 225 mg, 100 Tablet bottles, 6,278 bottles. Some tablets may contain slightly higher levels of the active ingredient than specified. Lot #: 112680A, exp. date 07/31/2010. Watson Laboratories, Inc.

**Digoxin Tablets**, USP, 0.125 mg and 0.25 mg, Rx only; 100 tablets, 639,994 bottles. Some of the tablets are oversized, and some undersized, which will result in the patient not receiving the expected dose. All lot numbers beginning with 61 through 82; expiry 09/30/2009-09/30/2011. Caraco Pharmaceutical Laboratories, Ltd.

The following products have been recalled by **Ethex Corporation** because the products may contain oversized tablets. There are multiple lots, with a total of 5,694,360 affected bottles. Call your pharmacist to see if yours is one of the affected lots.

Dextroamphetamine Sulfate Tablets; Isosorbide Mononitrate Extended-Release Tablets; Morphine Sulfate Extended-release Tablets; Morphine Sulfate Immediate-Release Oral Tablets; Morphine Sulfate Immediate-Release Oral Tablets; Propafenone HCl Tablets.

For more information, visit the Food and Drug Administration Enforcement Report online at http://www.fda.gov/Safety/Recalls/ EnforcementReports/default.htm.

## Recalls and Field Corrections: Drugs – CLASS II

Indicates a problem that may cause temporary or reversible health effects; unlikely to cause serious injury or death

Name of Drug or Supplemennt, Problem, Recall Information

Citalopram Hydrobromide Tablets, USP, 10 mg, 500 tablet bottles, Rx only, 449 bottles. Some of the tablets are oversized or undersized, which will result in the patient not receiving the expected dose. Lot #: 82577A. Caraco Pharmaceutical Laboratories, Ltd.

**Metoprolol Tartrate Tablets**, USP, 25 mg, Rx only; Some of the tablets are oversized or undersized, which will result in the patient not receiving the expected dose. Lot #s: 80658A, exp. date 02/2011; 81739A, exp. date 07/2011; 82695A, exp. date 11/2011; Caraco Pharmaceutical Laboratories.

Clonazepam Tablets, USP, 0.5 mg, CIV, 1000 tablet bottles, Rx only; Some of the tablets are oversized or undersized, which will result in the patient not receiving the expected dose. Lot #: 81529A, exp. date 11/2009; Caraco Pharmaceutical Laboratories.

**Metoprolol Tartrate Tablets**, USP, 50 mg, 1000 tablet bottles. Rx only; Some of the tablets are oversized or undersized, which will result in the patient not receiving the expected dose. Lot #: 80959A, exp. date 03/2011: Caraco Pharmaceutical Laboratories.

Senna Laxative (Standardized Senna Concentrate) sennosides 8.6 mg. per tablet, OTC, packaged under distributor labels: Equaline brand, 50, 100 and 250 tablets; Meijer brand, 100 tablets; Hannaford brand, 100 tablets; Natural brand, 100 tablets; TopCare brand, 100 tablets; GoodSense brand, 100 tablets; CareOne brand, 100 tablets; HyVee brand, 100 tablets; Kroger brand, 100 tablets; Longs brand, 100 tablets; Sunmark brand, 100 tablets; 218,220 bottles. Product contains undeclared anhydrous lactose and tartaric acid. Lot #s: 7JE0529, 7LE0537, 7ME0269, 8AE0404, 8BE0070, 8BE0071, 8BE0087, 8BE0746, 8CE0043, 8CE0501, 8CE0502, 8FE0688, 8GE0279, 8GE0526 and 8GE1213: L Perrigo Co.

**Sulfazine EC, 500 mg (Sulfasalazine Delayed-Release tablets**, USP 500 mg), 300 tablets, Rx only; 884,700 tablets. Out of Specification for dissolution test, at 12 month stability time point. Lot #: C0200108A, exp. date 01/2010. Vintage Pharmaceuticals LLC DBA Qualitest Pharmaceuticals.

**Advantage Dose LLC**. Products involved in three large drug recalls by Advantage Dose LLC affect an unknown quantity of lots. These drugs are all part of a major recall due to the manufacturer's failure to comply with good manufacturing practices (GMP).

The products involved are too numerous to list; if you have any drugs manufactured by Advantage Dose LLC, call your pharmacist to see if yours is one of the affected lots.

For more information, visit the FDA Enforcement Report online at http://www.fda.gov/Safety/Recalls/EnforcementReports/default.htm.

Advent Pharmaceuticals. The following products are involved in a recall by Advent Pharmaceuticals, Inc., which affects multiple lots totaling 171,272 units. These products all contain an unapproved drug. Call your pharmacist to see if yours is one of the affected lots.

Ry-Tann Tablets, Phenylephrine Tannate 25 mg/Chlorpheniramine Tannate 9 mg; D-Tann CT Tablets, Diphenhydramine Tannate 25 mg/Phenylephrine Tannate 10 mg/Carbetapentane Tannate 30 mg; D-Tann CD Suspension, Diphenhydramine Tannate 25 mg/Phenylephrine Tannate 15 mg/Carbetapentane Tannate 30 mg; D-Tann DM Suspension, Diphenhydramine Tannate 25 mg/Phenylephrine Tannate 7.5 mg/Dextromethorphan Tannate 75 mg; B-Vex Suspension, Brompheniramine Tannate ,12 mg; B-Vex D Suspension, Phenylephrine Tannate 20 mg/Brompheniramine Tannate 12 mg; Brom Tann 8mg/DM Tann 60 mg/ PSE Tann 90 mg Suspension, Brompheniramine Tannate/Dextromethorphan Tannate/Pseudoephedrine Tannate, 16 oz; DM Tann 30 mg/PE Tann 25 mg/ Brom Tann 10 mg Suspension, Dextromethorphan Tannate/Phenylephrine Tannate/Brompheniramine Tannate; PE Tann 20 mg/ CP Tann 4 mg Suspension, Phenylephrine Tannate/Chlorpheniramine Tannate, Nasal Decongestant/Antihistamine; D-Tann Suspension, Diphenhydramine Tannate 25 mg/Phenylephrine Tannate 7.5 mg; D-Tann CT Suspension, Diphenhydramine Tannate 25 mg; D-Tann AT Suspension, Diphenhydramine Tannate 25 mg; D-Tann AT Suspension, Diphenhydramine Tannate 25 mg/Carbetapentane Tannate 30 mg.

For more information, visit the FDA Enforcement Report online at http://www.fda.gov/Safety/Recalls/EnforcementReports/default.htm

**Ethex Corporation.** The following products are involved in a large recall by Ethex Corporation which affects 5,694,360 bottles. The products may contain oversized tablets. Call your pharmacist to see if yours is one of the affected lots.

BusPIRone HCI Tablets; Codeine Phosphate and Guaifenesin Tablets; Doxazosin Mesylate Tablets; Guaifenex DM (Guaifenesin/Dextromethorphan HBr), Extended-Release Tablets; Guaifenex PSE 120 (Guaifenesin/Pseudoephedrine HCl), Extended-Release Tablets; Hista-Vent DA Extended-Release Tablets, (Chlorpheniramine Maleate/Phenylephrine Hydrochloride/Methscopolamine Nitrate); Hista-Vent PSE Tablets, (Pseudoephedrine HCl/Chlorpheniramine Maleate/Methscopolamine Nitrate); Hyoscyamine Sulfate Extended-Release Tablets; Hyoscyamine Sulfate Tablets; Hyoscyamine Sulfate Orally Disintegrating Tablets; Hyoscyamine Sulfate Sublingual Tablets; Plaretase 8000 (pancrelipase, USP) Tablets.

For more information, visit the FDA Enforcement Report online at http://www.fda.gov/Safety/Recalls/EnforcementReports/default.htm

#### 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. Visit www.recalls.gov for information about FDA recalls and recalls issued by other government agencies.

Name of Product Problem Recall Information

**18" Kick Body Boards.** The green surface coating of the screened logo "Big Lizard™ body boards" on the underside of the body board contains excessive levels of lead, violating the federal lead standard. JGR Copa LLC, (800) 345-4408 or www.jgrcopa. com.

2009 Polaris Assault model Snowmobiles. Botts on the rear suspension can break causing the rail tip to become dislodged and interfere with the snowmobile's track. This can cause the track to lock up and the rider to lose control of the snowmobile, posing a risk of injury. Polaris Industries Inc., (888) 704-5290 or www.polarisindustries.com.

**BattEQ Battery Equalizers.** The recalled equalizers can overheat, posing a fire and burn hazard to consumers. SmartSpark Energy Systems Inc., (800) 905-6137 or www.batteq.com.

Besea W50 Diving Wings with Poseidon Inner Bladders. The inner bladder located inside the diving wing can break, causing the wing to fail to operate as a floating/buoyancy device. This poses a drowning hazard to divers. Poseidon West, (877) 673-4366 or info@poseidoncentral.com.

Black & Decker® brand Spacemaker™ Coffeemakers. The brew basket can shift out of alignment allowing hot water to overflow. This poses a scalding and burn hazard to consumers. Applica Consumer Products Inc., (866) 668-4442 or www.acprecall.com.

Boys' Hooded Sweatshirts. The hooded sweatshirts have a drawstring through the hood which can pose a strangulation hazard to children. In February 1996, CPSC issued guidelines to help prevent children from strangling or getting entangled on the neck and waist drawstrings in garments, such as jackets or sweatshirts. C-Mrk Inc., (323) 826-6900 or www.oceancurrent.com.

Campbell Hausfeld Air Compressors. The compressor's thermal overload, which shuts the unit off when it overheats, can fail. This can lead to overheating, melting of parts and a risk of fire. Campbell Hausfeld, (800) 241-0448 or www.chpower.com.

"Chelsea's" Necklace and Bracelet Sets. Small parts can detach from the necklace and bracelet when the elastic string break, posing a choking hazard to young children. D&D Distributing-Wholesale Inc., (800) 262-9435 or www.dddist.com.

**Copco Harmony Tea Kettles.** The lid on the tea kettle can come loose during handling, posing a burn hazard to the consumer. Wilton Industries Inc., (800) 794-5866 or www.copco.com.

**Craftsman Lawn Tractors.** The tractor's parking brake can fail posing a loss of control hazard. Husqvarna Consumer Outdoor Products N.A. Inc., (800) 978-7615 or www.sears.com.

Crane Bath Tubs With A Whirlpool. The drain covers in the tubs can entangle a bather's hair in the openings, causing the bather's head to be held under water, which can result in drowning. Crane Plumbing LLC, (866) 876-3632 or www.craneplumbing.com.

**DesignWare Sport Balls.** The surface coating on the basketball contains excessive levels of lead, in violation of the federal lead paint standard. American Greetings Corp., (800) 777-4891 or www.ag.com.

**DEWALT D51825 and D51850 Framing Nailers.** The bump action trigger on the framing nailers could have been incorrectly assembled during production, which would allow the nailer to eject a fastener unexpectedly or cause the trigger lock-off not to function. This can pose a serious injury hazard to the user or bystander. DEWALT Industrial Tool (877) 437-7181 or www.DEWALT.com.

Dragonfly II Mosquito Traps and NightWatch Bed Bug Monitors. Carbon dioxide (CO2) pressure sensors inside these products can crack and leak or burst causing the release of CO2. This could cause cracks with sharp edges that could cut a consumer's hand, or direct CO2 discharge could cause a frostbite-like burn to a consumer's hand. BioSensory, Inc., Dragonfly II: 1-800-537-8484; NightWatch: (800) 261-2659 or http://www.biosensory.com.

#### CONSUMER PRODUCTS

Epic Threads and Greendog Hooded Sweatshirts. The sweatshirts have a drawstring sewn at the base of the hood which can pose a strangulation hazard to children. In February 1996, CPSC issued guidelines to help prevent children from strangling or getting entangled on the neck and waist drawstrings in upper garments, such as jackets or sweatshirts. Macy's Merchandising Group Inc., (888) 257-5949 or www.macys.com.

**Gas-Fired Wall-Hung Boilers.** An electrical connector can overheat, posing a fire hazard to consumers. Bosch Thermotechnology, (800) 283-3787 or www.buderus.net.

Hard Tail girl's hooded jackets and pullover sweatshirts. The jackets and pullovers have a drawstring through the hood or waist which can pose a strangulation hazard to children. In February 1996, CPSC issued guidelines to help prevent children from strangling or getting entangled on the neck and waist drawstrings in upper garments, such as jackets or sweatshirts. Hard Tail, (888) 942-7382 or www.hardtailforever.com.

**Heat Guns.** An electrical component failure inside the heat guns can cause them to continue to produce heat after the power switch is turned off. This can melt the heat gun's plastic exterior, causing a burn if the heat gun is touched and ignite nearby combustibles, posing fire and burn hazards. Wagner Spray Tech Corp., (888) 925-6244 or www.wagnerspraytech.com.

Inflatable Baby Floats. The leg straps in the seat of the float can tear, causing children to unexpectedly fall into or under the water, posing a risk of drowning. Aqua-Leisure Industries, (866) 807-3998 or www.aqualeisure.com.

Intermatic Model ST01 and El600 In-wall Electronic Timers. When consumers trying to replace the timer's battery place a metal object through the battery tray slot, the object can reach internal metal contacts, posing a shock hazard to consumers. Intermatic Inc., (877) 417-4316 or www.intermatic.com.

lonic Salt Lamps. The lamps overheat causing the vinyl coating on the cord to burst and melt, posing a fire hazard to consumers. LTD Commodities LLC, (866) 736-3654 or www.ltdcommodities. com; ABC Distributing of Bannockburn, Ill., (866) 736-3654 or www.abcdistributing.com; Lakeside Collection, (866) 847-4327 or www.lakeside.com.

**Jaloma Pacifiers.** The pacifier mouth guard and the ventilation holes are too small and fail to meet federal safety standards. The pacifier could pose a choking and aspiration hazard to young children. Gromex Inc., (973) 458-9399.

Kidde Model Pl2000 Dual Sensor Smoke Alarms. An electrostatic discharge can damage the unit, causing it not to warn consumers of a fire. Walter Kidde Portable Equipment Inc., (877) 524-2086 or www.kidde.com.

Kolcraft, Carter's, Sesame Street, Jeep, Contours, Care Bear and Eric Carle Play Yards. The play yard's side rail can fail to latch properly and when a child pushes against the rail it can unlatch unexpectedly, posing a fall hazard to children. Kolcraft Enterprises Inc. (866) 594-4208 or www.kolcraft.com.

**Loyal Bedding Mattress Sets** (Mattresses and Mattresses with Foundations). The mattresses sets fail to meet the mandatory federal open flame standard for mattresses, posing a fire hazard to consumers. Guaynabo Industrial Inc., (877) 888-2552 or www.guaynaboindustrial.com.

Orangatang Skateboard Wheels. The recalled skateboard wheel's core can shear and blow-out causing the wheel to separate from the skateboard truck's axle and bearings. This poses a risk of serious injury to riders. Loaded Boards Inc., (877) 855-0708 or www.loadedboards.com.

**PowerPlus Generators.** The 220-volt receptacle can fail to produce power correctly and cause power surges that can damage appliances. This poses a risk of fire and possible injury to consumers. Big Muddy Sports, (800) 678-3607 or www.bigmuddymotorsports.com.

Simplicity Drop Side Cribs. The crib's plastic hardware can break or deform, causing the drop side to detach. When the drop side detaches, it creates space between the drop side and the crib mattress. Infants and toddlers can roll into this space and become entrapped which can lead to suffocation. Simplicity Inc. and SFCA Inc. Consumers should immediately stop using the recalled cribs and find an alternative, safe sleeping environment for their baby. Consumers should immediately return the crib to the place of purchase for a refund, replacement or store credit.

Starbucks Barista® Blade Grinders and Seattle's Best Coffee® Blade Grinders. The grinder can fail to turn off or can turn on unexpectedly, posing a laceration hazard to consumers. Starbucks Coffee Co., (866) 276-2950 or www.starbucks.com.

**Women's Sample Shoes.** The heel of the recalled shoes can detach, posing a fall hazard to consumers. Charles David; Sold exclusively at Nordstrom, (800) 804-0806 or www.nordstrom.com.

**Tabletop Rope Cutters.** The recalled rope cutters can overheat, posing fire and burn hazards. MarineTech Products Inc., (800) 634-7838 or www.marinetech.info.

#### OUTRAGE from page 12

a multi-national company, Elsevier, described as "the world's largest publisher of medical and scientific literature." This Amsterdam-based company, founded in 1880, publishes 2,000 journals, and has published 17,000 books.

According to an article about this scam in the British Medical Journal, Elsevier said that "the email did not reflect company policy" and that it had been the "mistake" of an Elsevier employee.

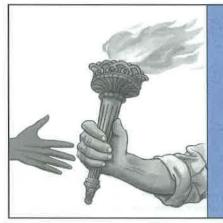
However, in its defense, Elsevier stated that:

Encouraging interested parties to post book reviews isn't outside the norm in scholarly publishing; nor is it wrong to offer to nominally compensate people for their time, some of these books are quite large. But in all instances the request should be unbiased, with no incentives for a positive review [such as a 5-star], and that's where this particular email went too far.

But alas, the attempted bribe backfired. The only review for the new book Clinical Psychology found on the Amazon.com site gave it only one star, not five, explaining the low rating as follows:

"Elsevier publishing's marketing department offered financial compensation in exchange for 5 star reviews of this book. Please be wary of reviews posted for this book."

According to Amazon.com, "27 of 27 people found [this] review helpful." ◆



## PASS THE TORCH

For Public Citizen to maintain its momentum, we not only need your continuing support, but we must grow. That's why we are launching a gift membership campaign called Pass the Torch. If you know of socially conscious people who care about our democracy and want to help strengthen it, please give them a gift membership to Public Citizen today.

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 Health Letter

Acting Public Citizen President Sidney M. Wolfe, MD

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#### OUTRAGE OF THE MONTH

### Medical Publisher Offers Bribes for Writing Favorable Book Reviews

e have often wondered about the legitimacy of the Amazon.com reviews of books, especially when they are mostly five-star reviews that appear to have been "planted" to increase the books' sales on the ecommerce Web site, Amazon.com.

Thus, when a book publisher sends the following e-mail to contributors to a book with the following message, these concerns are significantly heightened:

Now that the book [Clinical Psychology: Assessment, Treatment, and Research] is published, we need your help to get some 5 star reviews posted to both Amazon and Barnes & Noble to help support and promote it. As you know, these online reviews are extremely persuasive when customers are

considering a purchase. For your time, we would like to compensate you with a copy of the book under review as well as a \$25 Amazon gift card.

The e-mail continued:

If you have colleagues or students who would be willing to post positive reviews, please feel free to forward this e-mail to them to participate. We share the common goal of wanting Clinical Psychology to sell and succeed. The tactics defined above have proven to dramatically increase exposure and boost sales. I hope we can work together to make a strong and profitable impact through our online bookselling channels.

One of the most surprising things

about this was that the attempted bribe did not come from a small publisher whose financial success hinged on the big sales for the book.

Instead, the buyoff offer came from

continued on page 11



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