

# Health Letter

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## The Uninsured in the United States: What the Rise to 46.3 Million Means

On September 10, the U.S. Census Bureau released its most recent data on the uninsured, reflecting the situation for the year 2008. The number of uninsured rose from 45.7 million in 2007 to 46.3 million in 2008. This resulted in a slight increase in the percentage without coverage, from 15.3 percent in 2007 to 15.4 percent in 2008.

This year the numbers have greater urgency because they reflect the economic recession and highlight the problem at a time when Congress and the President are focusing on expanding coverage while “bending the curve,” i.e., holding down the rate at which costs are rising. It is not mere coincidence that the new data were made public the day after the President addressed Congress and the nation on the topic of health reform, emphasizing the need for covering more people more thoroughly.

Because employment-based health insurance accounts for the largest share of all coverage (58.5 percent in 2008), there is a clear relationship between jobs and insurance coverage. The expectation is that a 1 percent rise in unemployment results in a decrease of about 1 percentage point in the rate of employer-sponsored insurance for both adults and children. Between 2007 and 2008, however, this expectation was not fully borne out: unemployment rose more than one percent (from 4.6 to 5.7 percent) while the rate of employer-sponsored insurance decreased by only .8

percent (from 59.3 to 58.5 percent) during the same period.

The rise in the total number of uninsured was not more pronounced because government stepped in to cover some of the emerging gaps. The number of people covered by private health insurance decreased by fully one million, and their share dropped from 67.5 percent in 2007 to 66.7 percent in 2008. These declines were more than offset by an increase in the number of those relying on government health insurance, which rose from 83.0 to 87.4 million between 2007 and 2008. As a result, the proportion of those with government-funded coverage rose from 27.8 percent to 29.0 percent during the same period.

Public options — Medicaid, Medicare, military health care, the

Children’s Health Insurance Program (CHIP), and individual state health plans — were instrumental in mitigating a more marked rise in the uninsured. Medicaid beneficiaries, for example, rose by 3 million; in 2008, 9.8 percent had no coverage other than Medicaid for the entire year. Medicare increased by 1.4 million beneficiaries. And CHIP made a definite dent in the number of uninsured children, which went down from 11.0 percent and 8.1 million in 2007 to 9.9 percent and 7.3 million in 2008. This represents a marked improvement in the coverage of children; indeed, the uninsurance rate and the number of uninsured children are the lowest since 1987, the first year comparable health insurance data were collected.

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These data confirm what other economic indicators suggest: a growing proportion of employers are finding it too expensive to offer health coverage to their employees and public financing of care is playing a more prominent role in health coverage. Moreover, even those who have insurance are struggling to meet medical expenses because of higher premiums, less coverage, and heftier deductibles or co-payments.

As in previous years, those who perceive themselves as being at lower risk of illness may opt to go without coverage. As a result, young adults between the ages of 18 and 34 represent the largest proportion of the uninsured, accounting for 40.9 percent of those without coverage.

The breakdown by race and ethnicity shows that the increase in the uninsured was experienced differentially by each demographic group. Among whites, the number of uninsured rose by 800,000 and the percent, from 10.4 to 10.8 percent. Among Hispanics, which are the most likely to lack coverage, the

number of uninsured remained statistically the same, but the percent decreased from 32.1 to 30.7 percent. For Blacks, the rate and number of uninsured was almost the same as the prior year, at 19.1 percent and 7.3 million. For Asians, the uninsurance rate went from 16.8 to 17.6 percent between 2007 and 2008, a slight rise that was not considered statistically different.

The proportion of the uninsured has a marked income gradient: fully 24.5 percent of those with a household income of less than \$25,000 were uninsured, and this proportion declined as income rose. Among those with a household income of \$75,000 or more, 8.2 percent were uninsured.

Because each state has its own characteristics, resources, and ways of addressing health coverage, the percentage of uninsured varies greatly across the country. State-specific rates indicate that Massachusetts has the lowest proportion of uninsured (2.6 percent) while Texas has the highest (28 percent).

The most recent numbers reflect both the results of the status quo as well as the salutary impact of public-sponsored health care. As unemployment rises and more employers are unwilling or unable to offer coverage to their employees, the number of uninsured is likely to rise even further. The 2008 data on the uninsured do not reflect the full impact of a recession which caused the unemployment rate to rise from 5.7 to 9.4 percent between 2008 and 2009. And in many cases the safety net is already overloaded or too frayed to catch those who are not covered. Public Citizen therefore continues to advocate for a single-payer that would cover everyone and pool our resources, using the system's bargaining power to achieve fairer, more efficient delivery of care. The current debate, dispiriting as it often is, is an opportunity to make our voices heard. Public Citizen urges our readers and members to support a single-payer system in which services are based on health need rather than corporate greed. ♦

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## Health Letter

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# Public Citizen Proposes Basic Patient Safety Reforms that Would Save 85,000 Lives and \$35 Billion a Year

A report issued August 6, 2009, by Public Citizen proposes 10 cost-cutting, patient safety measures that would save an estimated 85,000 lives and \$35 billion a year. The report, "Back to Basics," analyzed the results of scientific studies of treatment protocols for chronically recurring, avoidable medical errors.

Excessive use of medical services — often high-tech tests and procedures — has been blamed by many for the nation's galloping health care costs.

But there is a flip side to the allegation that the health care system rewards overuse of expensive procedures: It also fails to encourage some very simple, important measures. The failure of health care professionals to do such things as wash their hands consistently, follow best practices to prevent pressure ulcers, and communicate effectively causes an enormous number of tragic and expensive errors.

This report examines the potential effects of implementing 10 reforms that could prevent more than 85,000 deaths and save more than \$35 billion in treatment costs annually. Because we were unable to estimate the number of lives saved for two of the proposed reforms (a checklist to avoid surgical errors and best practices to prevent patient falls), the total number of avoidable deaths is likely higher.

Additional improvements might save thousands more lives. For example, one study found that improving nurse-to-patient ratios from an average of about 5.5:1 to 4:1 could save an astounding 72,000 lives a year. The authors estimate that doing so would cost up to \$7.3 billion annually — or about three-tenths of 1 percent of the nation's health care bill.

Aside from the tragedy of needless deaths and injuries, the financial toll of failing to follow accepted safety procedures is astounding. Severe pressure ulcers cost an average of

\$70,000 apiece to treat. A catheter infection costs \$45,000. Each instance of ventilator-associated pneumonia costs \$5,800. Collectively, avoidable surgical errors cost an estimated \$20 billion a year, bed sores \$11 billion and preventable adverse drug reactions \$3.5 billion.

"There are many incentives to order expensive tests and procedures and too few rewards for providing basic, sensible care," said David Arkush, director of Public Citizen's Congress Watch division. "As the largest investor in the nation's health care system, the federal government should ensure that fulfilling basic patient safety standards is a condition of receiving federal reimbursements. And the government should pay providers for doing the right thing. It will save money in the long run."

Public Citizen proposes that health care providers:

- Use a checklist to reduce avoidable deaths and injuries resulting from surgical procedures (saves \$20 billion a year);
- Use best practices to prevent ventilator-associated pneumonia (saves 32,000 lives and \$900 million a year);
- Use best practices to prevent pressure ulcers (saves 14,071 lives and \$5.5 billion a year);
- Implement safeguards and quality control measures to reduce medication errors (saves 4,620 lives and \$2.3 billion a year);
- Use best practices to prevent patient falls in health care facilities (saves \$1.5 billion a year);
- Use a checklist to prevent catheter infections (saves 15,680 lives and \$1.3 billion a year);

- Modestly improve nurse staffing ratios (saves 5,000 lives and \$242 million a year);
- Permit standing orders to increase flu and pneumococcal vaccinations in the elderly (saves 9,250 lives and \$545 million a year);
- Use beta-blockers after heart attacks (saves 3,600 lives and \$900,000 a year); and
- Increase use of advanced care planning (saves \$3.2 billion a year). Public Citizen proposes five steps to ensure near-universal adoption of these reforms:
  - The federal government should use its enormous leverage from its \$750 billion annual investment in health care to compel providers to use proven patient safety practices. The Department of Health and Human Services (HHS) has the authority to enact many of reforms proposed in Public Citizen's report through the regulatory process. Congress could ensure rapid adoption by including instructions to HHS in legislation;
  - Congress should require HHS to take responsibility for accrediting providers to receive Medicare reimbursements. At present, the federal government delegates most accrediting authority to the Joint Commission, a private entity that derives its income from the very hospitals it oversees and denies accreditation to less than 1 percent of these hospitals;
  - Congress should make significant financial investments to increase the country's supply of nurses and set federal minimums of acceptable nurse-to-patient ratios. Nurse shortages are often implicated in patient safety

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# A Review of Homeopathy

Each year, Americans shell out almost \$3 billion on homeopathic products — and that number is rising.

In the 2007 National Health Interview Survey conducted by the Centers for Disease Control and Prevention (CDC), researchers found that more than 38 percent of all adults and 11 percent of children use alternative medicine as a form of medical treatment. This includes chiropractic treatment, massage therapy, acupuncture, herbal remedies and homeopathy (4 percent of the surveyed population).

## What is homeopathy?

The term “homeopathy” is derived from the Greek words “homeo-,” meaning similar, and “-pathos,” meaning suffering or disease.

Homeopathy was introduced in the late 1700s by a German physician named Samuel Hahnemann and is intended to treat physical and emotional symptoms, to produce

lifestyle changes and to improve nutritional status.

## How is homeopathy said to work?

Hahnemann formulated the “Law of Similars” which theorizes that “like cures like.” This law claims that a substance that produces a set of symptoms in a healthy person has the ability to cure an ill person who has those same symptoms if it is administered at low doses. The administration of a homeopathic remedy allegedly causes the body to react to the worsening of symptoms induced by the remedy, thus promoting a cure. For example, if a given agent appears to cause a runny nose, that same agent might be effective in treating a runny nose if administered at low doses.

This theory is based on the premise of extreme dilutions — the “Law of Infinitesimals.” Dilutions are created by taking one part of the original substance and nine parts of liquid,

usually water, and mixing vigorously (“succussion”). This product is then considered to be a 1X solution. Subsequently, one part of the 1X solution is added to another nine parts of water and shaken. This product is then a 2X solution. This process can occur upwards of 400 times in some homeopathic remedies. After 24 dilutions there is only a 60 percent chance that one molecule of the original substance is still present if a standard amount of the substance called one mole was used. By contrast a single 200 mg ibuprofen pill contains almost 600 billion-billion molecules (6 followed by 20 zeros). Advocates of homeopathy believe that, despite the many dilutions, the substance initially present can modify the properties of pure water (“water memory”), thereby creating remedies that may treat illness. We are aware of no credible scientific basis for this assertion.

## Is homeopathy effective?

The idea that no molecule of the

errors. Modest increases would yield significant improvements. A significant increase in the number of nurses could produce dramatic results. One study estimated that increasing the number of nurses by a little more than one-third would save an astounding 72,000 lives annually;

- Congress should require mandatory reporting of adverse events, including requiring hospitals to institute strong internal reporting systems, and creating whistle-blower protections for health care workers. National reporting of the most serious medical errors is largely left to the Joint Commission. However, that organization estimates that it learns of only about one-tenth of 1 percent of serious medical errors despite its stated requirement that doctors disclose all errors to patients. In 1996, the Joint Commission contemplated

requiring mandatory reporting but succumbed to industry pressure and settled for voluntary reporting; and

- Congress should ensure that the requirements for hospitals to report doctor discipline and maintain viable peer review processes are followed. Hospitals have been required since 1990 to report to the federal government cases in which doctors are suspended for more than 30 days. But nearly 50 percent of hospitals have never reported a single disciplinary action. This may be due to hospitals flouting the law, evading the spirit of the law by customizing penalties to sail below the reporting threshold, or failing to carry out warranted doctor discipline altogether because of inadequate peer review processes.

The health care delivery industry is enormous, decentralized and will not

be easily changed. But the federal government has both the authority and an obligation to ensure that no time is lost in putting well-accepted patient safety measures into practice.

*The report was authored by Zachary Gima, Peter Gosselar, Alan Levine, Taylor*

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*Lurie and Dr. Kevin Bowman provided significant guidance for the project.*

Read the full report online at [www.citizen.org/documents/BackToBasics.pdf](http://www.citizen.org/documents/BackToBasics.pdf). ♦

original substance may be present in a homeopathic remedy that is said to work has raised questions about the effectiveness of these remedies. How can something so diluted actually rid people of symptoms or illness?

There have been a number of studies that have reported favorable effects for homeopathy in treating various conditions. However, most of these studies were too small, poorly conducted or conducted by homeopathy advocates. Findings favorable toward homeopathy are more likely to be published in part because homeopathy advocates may not be interested in disseminating information that undermines their claims. We are aware of no condition for which a beneficial effect of homeopathy has been documented and replicated in well-conducted trials.

### **What Attracts People to Homeopathy?**

At some level, it is known that since there is not a very high concentration of active ingredients in these products, they are much safer than traditional prescription or over-the-counter drugs. Their perceived effectiveness, in the absence of any supporting scientific evidence, is based on two factors: Most conditions that homeopathy claims to treat are self-limiting (meaning that they will go away without treatment) and relatively minor. Because these symptoms resolve spontaneously, it is easy to attribute the spontaneous resolution of the illness to the drug's effectiveness. Second, problems such as pain are known to respond to a placebo, which explains why, as mentioned above, homeopathy products do not work better than placebos in randomized trials.

This combination of accurately-perceived safety (assuming the preparations are actually the profoundly diluted solutions that define homeopathy — see FDA actions against Zicam, below) and misperceived effectiveness clearly drives the market for these products.

### **How are homeopathic medicines regulated by the Food and Drug Administration (FDA)?**

According to the 1938 Food, Drug, and Cosmetic Act, homeopathic remedies are regulated as drugs. The 5 percent of homeopathic remedies, that are intended to treat serious conditions such as cancer can be sold only with a prescription, while the other 95 percent, which treat self-limiting conditions, can be sold over-the-counter.

Homeopathic remedies are thus, in theory, subject to regulation of good manufacturing practices, labeling and advertising, that are identical to those required of conventional medications. Whether the FDA enforces these requirements is less certain. Homeopathic remedies are exempt from requirements for expiration dating and determinations of active ingredient identity and strength (presumably because no active ingredient can be detected much of the time). The Federal Trade Commission has jurisdiction over advertising claims by over-the-counter homeopathic remedies but rarely, if ever, takes action.

The main difference between homeopathic and conventional medications is that drugs must be proved safe and effective based on often-rigorously conducted clinical trials, but homeopathic remedies are typically exempt from such important requirements. They are considered safe and effective as long as they are listed in the Homeopathic Pharmacopeia of the United States (HPUS), a publication produced since 1841 by advocates of homeopathy. Currently, there are about 1,300 substances listed in the HPUS, but an overwhelming majority of these were simply “grandfathered” in 1975 and were not subject to any modern clinical testing.

For new products to be entered into the HPUS, substances must go through clinical studies to demonstrate safety and effectiveness. These might resemble the randomized, controlled

trials conducted to secure FDA approval for drugs, but it is unclear how many have entered the HPUS on that basis.

Rather, new homeopathic remedies are typically evaluated under a process unique to homeopathy called “proving.” Supporters of homeopathy consider such studies more useful than conventional clinical trials.

In a modern-day proving, a small number of healthy people are given a placebo for a pretrial period followed by a period in which they receive the homeopathic remedy. Participants in the study are asked to self-report symptoms into a diary. At the conclusion of the study, all of the symptoms are compiled and analyzed. If a symptom is more common in the treated than in the placebo period in this healthy population, it is considered a potential treatment for people suffering from that same symptom. Subsequent studies administer the remedy to those suffering from the symptom, but typically are not randomized or controlled.

The lack of adequate testing for safety and efficacy need not be indicated on the labels of these products the way it is for dietary supplements. As a result, many consumers are unaware that, despite being legally considered drugs, homeopathic remedies have not been subject to most of the same level of FDA scrutiny as conventional medications.

### **What are the dangers associated with taking homeopathic remedies?**

Homeopathic remedies are potentially associated with both direct and indirect harms. In a recent commentary in the highly respected medical journal *The Lancet*, Garattini and Bertelé posit the danger of “distracting physicians and patients from effective medicine, and industry from the difficult and costly search for innovative products to a less risky, more profitable market.” In addition, homeopathic remedies

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may include contaminants or even non-homeopathic quantities of pharmacologically active compounds.

Moreover, these products cost between \$5 and \$9 for each retail unit, a cost patients must pay for out of pocket. All of these risks and costs are unacceptable when there is no commensurate evidence of the products' effectiveness.

### What are some examples of homeopathic products?

Some popular homeopathic remedies on sale in major drug stores include Loma Lux AcnePill to treat acne pimples and blemishes; Hyland's Nerve Tonic to relieve nervous tension and stress; oscillococcinum to reduce the severity and shorten the duration of flu symptoms; and Coldcalm to relieve cold symptoms such as sneezing, runny nose, nasal congestion and minor sore throat. Homeopathic remedies are amongst the top 10 best-selling nonprescription drugs for the cough, cold and flu in the United States.

### What actions has the FDA taken against homeopathic products?

Because the FDA is limited in its options for regulating homeopathic remedies, having to defer on the

crucial safety and efficacy questions to the HPUS, and because the potential lack of any active ingredient in homeopathic products reduces their potential dangers, the agency has taken few actions against them.

The usual form of sanction occurs when the product is actually homeopathic, but the company violates the requirements for drugs. For example, on Nov. 22, 2005, the FDA issued a warning letter to NativeRemedies.com regarding its homeopathic product OralFlu Protect. The company claimed that its product could, among other things, protect people against flu. However, the product failed to include the risks, warnings, and contraindications that are required of all drugs. Moreover, the product was sold over the Internet, whereas drugs for the flu require prescriptions.

More recently, there have been hints that the FDA may take a more aggressive stance toward some homeopathic remedies. In June 2009, the agency issued Matrixx Initiatives, the makers of intranasal ZICAM, a warning letter regarding several of their homeopathic nasal cold remedies. While the agency has typically allowed such products to come to market based on their listing in the HPUS, in this case, the agency is requiring a formal application of the kind required for new drugs.

The FDA appears to be particularly interested in this product because actual harm has been demonstrated: More than 130 reports of loss of the sense of smell, some irreversible, have been filed with the FDA. (The documented toxicity of the preparation tends to suggest that the product was not actually homeopathic in that it contained enough active compound — zinc, a known cause of loss of the sense of smell — to produce toxicity.) Since the warning letter, the company has voluntarily removed the questionable products from the market.

### What You Can Do

While homeopathic remedies may appear to provide relief to ill patients, their actual efficacy has not been demonstrated in a convincing fashion and their apparent efficacy is more likely due to symptoms resolving naturally. Given the uncertainties over the actual content of homeopathic remedies and their cost, we recommend that you not use homeopathic remedies to treat symptoms or illness. ♦



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# Product Recalls

August 13, 2009 – September 11, 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](http://www.fda.gov). Visit [www.recalls.gov](http://www.recalls.gov) for information about FDA recalls and recalls issued by other government agencies.

## 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 Supplement, Problem, Recall Information*

**Actavis Twice a Day buPROPion Hydrochloride Extended-Release Tablets**, USP (SR) 150 mg, 60 Tablets NDC 67767-133-60, 13,236 bottles. Failed Impurity Specification: m-chlorobenzoic acid. Lot #: 0805699A; Actavis South Atlantic LLC.

date 06/12; 080846, exp. date 07/11; 081324, exp. date 07/11; 074739, exp. date 03/11; 075164, exp. date 03/11; 072945, exp. date 01/11; 073432, exp. date 01/11; 071711, exp. date 10/10; 071116, exp. date 10/10; 066048, exp. date 06/10; 066443, exp. date 06/10; 068039, exp. date 06/10; 070004, exp. date 06/10;

**Atenolol Tablets** USP, 25 and 50 mg, 1000 count bottles (NDC 0093-0787-10) and 100 count bottles (NDC 0093-0787-01), Rx only, 91,161 bottles. Failed Content Uniformity Specification. Lot #s (25mg): BER28A, exp. date 01/2011; BER29A, exp. date 02/2011; BER30B, exp. date 02/2011; Lot #s (50mg): BER34A, exp. date 02/2011; Teva Pharmaceuticals USA.

**Nitrofurantoin Monohydrate/Macrocrystals Capsules** USP, 100 mg. (Twice a day Dosage), Urinary Tract Antibacterial, 100 count bottles, Rx only; 263,139 capsules, Failed USP Dissolution Specification. Lot #s: 1769205, exp. date 04/09; 1769797, exp. date 04/09; 177533, exp. date 04/09; 1784346, exp. date 05/09; 1784352, exp. date 05/09; 1799902, exp. date 07/09; 1799904, exp. date 07/09; 1799905, exp. date 07/09; 1809409, exp. date 07/09; 1809411, exp. date 07/09; 1823823, exp. date 09/09; 1823825, exp. date 09/09; 1828044, exp. date 9/09; 1828045, exp. date 9/09; 1828046, exp. date 09/09; 18242193, exp. date 011/09; 1852520, exp. date 012/09; 1852527, exp. date 012/09; 1873962, exp. date 02/10; 1873963, exp. date 02/10; 18880851, exp. date 02/10; 1881355, exp. date 02/10; 1895945, exp. date 03/10; 1902050, exp. date 04/10; 1904599, exp. date 04/10; 1784353, exp. date 5/09; 1852528, exp. date 05/09; 1852528, exp. date 12/09; 1895946, exp. date 05/10; 1895947, exp. date 5/10; Ranbaxy Pharmaceuticals, Inc.

**Cytomel, Liothyronine Sodium Tablets**, 100 Tablets, Rx only, 25 mcg, NDC 60793-116-01; 47,400 units. Subpotent 12 month stability time point. Lot #s: 52215, exp. date 09/2009 and 52216, exp. date 09/2009; King Pharmaceuticals, Inc.

**Fenoglide (fenofibrate) tablets**, 120 mg, 7 tablet Professional Sample bottle, Rx only; NDC 59630-495-07, 58,176 units (7 count bottles). The product may lack efficacy due to the Out of Specification dissolution result at the 9-month stability pull point. Lot # 0802584, exp. date 10/09; Sciele Pharma, Inc.

**Fentanyl Transdermal System**, 100 mcg/hr, Rx only, Packaged as 5 foil pouches per carton, 3214-54, Carton NDC 0591-3214-72; 87,500 cartons. Possibility for leakage of Fentanyl gel from transdermal patches. Lot # 145287A; Recalling Firm: Watson Pharmaceuticals, Inc.

**Potassium Chloride Extended-release Capsules**, USP, 10 mEq (750 mg), 100 Bags of One Capsule Each, Rx only, NDC 58177-001-11 (ETHEX NDC), The products were not manufactured in conformance with cGMP's. Lot #s 080851, exp. date 08/10; 074872, exp. date 03/10; 073305, exp. date 12/09; 072004, exp. date 11/09; 071053, exp. date 10/09; 068333, exp. date 07/09; 066983, exp. date 04/09; American Health Packaging.

**Isosorbide Mononitrate Extended-Release Tablets**, 30 mg, 100 Bags of One Tablet Each, Rx only, (ETHEX NDC) NDC 58177-222-11; The products were not manufactured in conformance with cGMP's. Lot #s 084610, exp. date 06/12; 084741, exp.

**SENNA-TIME (Sennosides) Micro Coated Clear Tablets**, 8.6 mg, 100 Bags of One Tablet Each, NDC 63739-431-10 (McKES-SON NDC), 1,959 units (100 tablets per unit). The tablets may contain undeclared lactose and tartaric acid. Lot #: 080281, exp. date 04/09; Lot # 081067, exp. date 04/09; Lot # 081642, exp. date 04/09; Lot # 081641, exp. date 10/09; Lot # 081808, exp. date 10/09; Lot # 082449, exp. date 10/09; Lot # 082953, exp. date 10/09; Lot # 083730, exp. date 01/10; Lot # 084142, exp. date 01/10; Lot # 084745, exp. date 04/10; Lot # 084965, exp. date 04/10; Lot # 090282, exp. date 04/10; American Health Packaging.

A large recall by Advantage Dose LLC affects approximately 2,635,663 units of 50 different products because these products are not in conformance with current good manufacturing practices (cGMPs).

Call your pharmacist to see if yours is one of the affected lots. For more information, visit the Food and Drug Administration 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](http://www.cpsc.gov). Visit [www.recalls.gov](http://www.recalls.gov) for information about FDA recalls and recalls issued by other government agencies.

*Name of Product; Problem; Recall Information*

**10 Speed SRAM Bicycle Chains** with PowerLock connector links. The recalled PowerLock connector links, used on bicycle chains, are brittle and can crack, allowing the chain to separate from the bicycle and posing a fall hazard to the rider. SRAM LLC, (800) 346-2928 or [www.sram.com](http://www.sram.com).

**Baby Jogger City Mini Strollers.** The stroller's restraint buckle could break or unlatch allowing the child or infant to fall out. Baby Jogger LLC, 877-506-2213 or [www.babyjogger.com](http://www.babyjogger.com).

**2007/2008 Felt F1X Cyclocross Bicycles.** The bicycle's fork steerer tube can break, causing the rider to lose control and fall, posing a risk of injury. Felt Bicycles, (866) 433-5887 or [www.feltracing.com](http://www.feltracing.com).

**Bandsaws.** Some of the recalled bandsaws do not have a grounding wire installed, which poses an electric shock hazard to consumers. Grizzly Industrial, (800) 523-4777 or [www.grizzly.com](http://www.grizzly.com).

**2009 d'Lite ST and Solo ST Child Trailers.** The axle assembly's internal sleeve can loosen, causing one wheel to separate from the trailer. This poses a risk of injury to the child occupant or bike rider. Burley Design LLC, (800) 311-5294 or [www.burley.com/STProductRecall](http://www.burley.com/STProductRecall).

**Black & Decker® Thermal Coffeemakers.** The coffeemakers can overheat, posing a burn hazard to consumers. Applia Consumer Products Inc., (866) 699-4595 or [www.acprecall.com](http://www.acprecall.com).

**Amplifiers.** The amplifiers were designed to operate at a temperature warm to the touch. However, a component input device can fail and cause the amplifiers to overheat, posing burn and fire hazards to consumers. Krell Industries LLC, (888) 436-6055 or [www.krellonline.com](http://www.krellonline.com).

**Cannibal Bicycles.** The bicycle stem can crack and cause the rider to lose control, posing a risk of serious injury if the rider falls. Nirve Sports Ltd., (888) 296-4783 or [www.nirve.com](http://www.nirve.com).

**Architect Series® and 850 Series® Casement Windows.** The hinge can break, causing the window sash to fall out, posing a risk of injury to persons beneath the window. Pella Corp., (800) 374-4758 or [www.pella.com](http://www.pella.com).

**Certain Frigidaire and Kenmore Elite Smoothtop Electric Ranges.** Depending on the model, the surface heating elements can: 1) turn on spontaneously without being switched on; 2) fail to turn off after being switched off; or, 3) heat to different temperatures than selected. This poses a fire hazard to consumers. Frigidaire, (800) 449-9812 or [www.smoothtoprangerecall.com](http://www.smoothtoprangerecall.com).

**Children's Animal Masks and Pendants.** The recalled children's animal masks and pendants contain high levels of lead. Lead is toxic if ingested by young children and can cause adverse health effects. Team Work Trading, (213) 680-4489.

## CONSUMER PRODUCTS

**Children's Hooded Fleece Sweatshirts.** The recalled 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 upper garments, such as jackets or sweatshirts. La Jolla Sport USA Inc., (800) 662-7873 or [www.lajollagroup.com](http://www.lajollagroup.com).

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**Durabrand DVD Players.** The DVD players can overheat, posing a fire and burn hazard to consumers. Wal-Mart Stores Inc., (800) 925-6278 or [www.walmartstores.com](http://www.walmartstores.com).

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**eebee's "Have a Ball" Adventures Cloth Books.** A string attaching a ball to the book can become entangled in the basketball hoop element, posing a strangulation hazard to young children. Sterling Publishing Co. Inc., (800) 367-9692 or email [custservice@sterlingpublishing.com](mailto:custservice@sterlingpublishing.com).

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**Force Soldier Playsets, Pirate Expeditions with Parrot, and Pirate Expeditions with Treasure.** The action figure toys have surface paints which contain excessive levels of lead, violating the federal lead paint standard. Liquidation Outlet, Inc., (877) 257-5990 or [info@loidistributing.com](mailto:info@loidistributing.com).

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**Homelite, Husky and Black Max Brand Generators.** The fuel gauge can leak excessive amounts of gasoline, posing a fire hazard to consumers. Homelite Consumer Products Inc., (800) 242-4672 or [www.homelite.com](http://www.homelite.com).

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**Horizontal and Vertical Blinds and Cellular Shades.** Horizontal Blinds: The blinds do not have inner cord stop devices to prevent the accessible inner cords from being pulled out. If an inner cord is pulled out, a child can become entangled in the loop and strangle. Vertical Blinds: Strangulations can occur if a child's neck becomes entangled on the free-standing loop formed by the bead chain or by the cord with a weighted device. Cellular Shades: Strangulations can occur if a child's neck becomes entangled on the shade's free-standing looped cord. Vertical Land Inc., (800) 423-8653.

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**Hungry Figures and Hungry Magnets.** Sewing needles have been found in the stuffing of the Hungry Figures, posing a puncture hazard to consumers. Weight Watchers Intl., (866) 288-3891 or [www.weightwatchers.com](http://www.weightwatchers.com).

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**IKEA KARLSTAD sofa-beds.** The mattress and seat cushions intended to be used as a mattress fail to meet the mandatory federal open flame standard for mattresses, posing a fire hazard to consumers. IKEA Home Furnishings, (888) 966-4532 or [www.ikea-usa.com](http://www.ikea-usa.com).

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**Little Tikes™ Workshops Sets and Trucks.** The recalled workshop sets and trucks have oversized, plastic toy nails that can pose a choking hazard to young children. Little Tikes, (800) 791-2737 or [www.littletikes.com](http://www.littletikes.com).

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**Maytag®, Magic Chef®, Performa by Maytag® and Crosley® brand refrigerators.** An electrical failure in the relay, the component that turns on the refrigerator's compressor, can cause overheating and pose a serious fire hazard. Maytag Corp., (866) 533-9817 or [www.repair.maytag.com](http://www.repair.maytag.com).

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**MELINA Roman Blinds.** Strangulations can occur when a child places his/her neck between the exposed inner cord and the fabric on the backside of the blind or when a child pulls the cord out and wraps it around his/her neck. The Roman blind has a continuous looped bead chain that when not attached to the wall or floor, hangs loosely by the blind, posing a strangulation hazard to children. IKEA Home Furnishings, (888) 966-4532 or [www.ikea-usa.com](http://www.ikea-usa.com).

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**Nautilus F3 Chin Dip Stationary Exercise Units.** The footpads on the unit can break, posing a fall hazard to consumers. Nautilus Inc., (800) 935-7313 or [www.nautilus.com](http://www.nautilus.com).

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**Office Max Task Chairs.** The back and the base post of the chair can break while in use, posing a fall hazard to consumers. OfficeMax Inc., (800) 283-7674 or [www.officemax.com](http://www.officemax.com).

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**Oval Roll-up Blinds and Woolrich Roman Shades.** Roll-up Blinds: Strangulations can occur if the lifting loops slide off the side of the blind and a child's neck becomes entangled on the free-standing loop or if a child places his/her neck between the lifting loop and the roll-up blind material. Roman Shades: Strangulations can occur when a child places his/her neck between the exposed inner cord and the fabric on the backside of the blind or when a child pulls the cord out and wraps it around his/her neck. Lewis Hyman Inc., (877) 354-5457 or [www.lewishymaninc.com/recall](http://www.lewishymaninc.com/recall).

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## CONSUMER PRODUCTS

**Pensi Fans.** The internal coupler that connects the down rod assembly to the motor can break and cause the fan to fall from the ceiling, posing an injury hazard to consumers. The Modern Fan Co. Inc., (888) 588-3267 or [www.modernfan.com](http://www.modernfan.com).

**Ridgid 10-inch Table Saws.** The table saw's arbor shaft can fail when used with a stacked blade set (commonly known as a "stacked dado set"), which is used to cut grooves. The stacked blade set can be ejected from the saw, posing a potential laceration hazard to consumers. One World Technologies Inc., (866) 539-1710 or [www.ridgid.com](http://www.ridgid.com).

**Roller Shades.** Strangulations can occur if the shade's looped bead chain is not attached to the wall or the floor and a child's neck becomes entangled on the free-standing loop. Lutron Electronics Co. Inc., (866) 793-4270 or [www.lutron.com/cordedshades](http://www.lutron.com/cordedshades).

**Roman Shades.** Strangulations can occur when a child places his/her neck between the exposed inner cord and the fabric on the backside of the blind or when a child pulls the cord out and wraps it around his/her neck. Pottery Barn Kids/Williams-Sonoma, Inc., (800) 492-1949 or [www.potterybarnkids.com](http://www.potterybarnkids.com).

**Roxy Girl "Very Nice" Cotton Hoodies.** The cotton hoodie has a waist drawstring that could pose an entrapment 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 sweat-shirts. Quiksilver, Inc., (877) 246-7257 or [www.quiksilverinc.com](http://www.quiksilverinc.com).

**Shop Fox Dust Collection Remote Switches.** An incorrectly sized wire inside the remote switch can overheat, posing a fire hazard to consumers. Woodstock International, (800) 840-8420 or [www.Woodstockint.com](http://www.Woodstockint.com).

**Thermal Sailcloth and Matchstick Bamboo Roman Shades.** Strangulations can occur when a child places his/her neck between the exposed inner cord and the fabric on the backside of the blind or when a child pulls the cord out and wraps it around his/her neck. Exposed operating cords can knot or tangle creating a strangulation loop. Victoria Classics, (800) 583-9845 or [www.victoriaclassics.com](http://www.victoriaclassics.com).

**Your Zone Loft Collection Entertainment Stands.** Warning labels sold with the entertainment stands indicate incorrect size and weight limits for televisions used with the stands. A television that is too heavy or wide for the entertainment stand can make the unit unstable, posing a tip-over hazard to consumers. Ameriwood Industries, (877) 732-8252 or [www.ameriwood.com](http://www.ameriwood.com).

### *OUTRAGE from page 12*

This September, for example, drug mega-corporation Pfizer was forced to swallow an all-time U.S. record \$1.2 billion in federal criminal fines for illegally promoting Bextra and other drugs. With civil fines included, Pfizer's settlement reached \$2.3 billion, a decidedly modest sum when set against the company's 2008 net income of \$8.1 billion. The previous criminal fine record holder? Lilly's \$515 million fine in January for its promotion of, you guessed it, Zyprexa.

Lilly's fine was the product of a settlement with the Department of

Justice and more than 30 states. But South Carolina opted out, hoping to fare even better in home-state court. The embarrassing documents were unearthed in that legal proceeding. South Carolina alleges that illegal off-label promotion for uses such as depression, agitation and anger cost the state \$200 million in inappropriate Zyprexa prescriptions.

Indeed, the Lilly rep's unseemly behavior wasn't confined to the golf links. Many doctors like to supplement their already sizable incomes with service on speakers' bureaus. At drug company-sponsored meetings typically held in popular

vacation destinations or high-end restaurants, these physicians present medical information that has been repeatedly demonstrated to favor their sponsors.

Not just anyone can give these talks, in which the docs are often kept on-message by company-produced slides. "If his [prescription] numbers go up, maybe he can talk," said Sullivan, he of the four-par round.

Evidently, the novelist Paul Gallico had it right when he observed that "If there is any larceny in a man, golf will bring it out." ♦

# Health Debate or Health Charade?

With the summer town hall meetings having elicited new concerns and a new vocabulary to express it, the so-called “debate” has become little more than clashing groups venting and ranting, each one with its own script.

Part of the problem can be traced to the concern with ‘framing’ on the part of politicians and stakeholders of every stripe. Both Democrats and Republicans have their own framing experts. These have now placed their skills and strategies at the service of health policy-makers and a range of interest groups.

“Framing” is defined as the employment of narrative, rather than facts, to describe an event or phenomenon. It assumes people react rather than reflect. The Democrat’s

guru, George Lakoff, summarizes the basis for framing: “Rationality resides not in observing and deliberating upon facts but rather in the pictures we have of ourselves and our world.” Thus, a single phrase can conjure up different images. And while two persons may hear the same words, they see different mental pictures and react accordingly. “Framing” is therefore a way sophisticated way to elicit and manipulate what used to be called a knee-jerk response.

The Republicans also have their expert on the matter. He is Frank Luntz, the author of “Words That Work: It’s not what you say, it’s what people hear.” He is perhaps best known for his ten-point memo on how Republicans should talk about health care. This memo, probably

dashed off of the top of Luntz’s head, has nevertheless been greeted as if it had come down from a mountaintop on chiseled tablets. And it has given rise to a set of “talking points” which have apparently been followed by some of the participants in the town hall meetings.

With both sides having their own playbook (and each one being privy to the other’s script), it is not surprising that many of the meetings have rapidly descended into shouting matches and name-calling. While wonkytalk may have a widespread eyes-glazed-over effect among participants, it is still several notches above the strident charade that is now passing for debate. ♦

## The Vocabulary of Health Care

WHAT IS SAID

WHAT IS HEARD

Universal health care.....	Socialized medicine
Health reform .....	Washington takeover
Individual mandate.....	Coerced health insurance
Shared responsibility .....	Higher taxes
Comparative effectiveness .....	Rationing of health care research
Public option .....	Predatory government, unfair competition
Advanced directives .....	Death panels
Health care exchange.....	Restricted choice
Medicare savings.....	Curtailed benefits, higher premiums
Rising numbers of uninsured .....	More “young invincibles”

## Drug Company Inducements to Doctors: Not Par for the Course

Ever get the feeling that, when it comes to the drugs you're prescribed, you're just a small speck (maybe a white, dimpled one) being batted about by forces beyond your control? Turns out that if you lived in certain parts of South Carolina around the turn of the millennium, you just might have been.

Documents recently released in a court proceeding in Spartanburg, SC, reveal the unthinkable: patients' fates (as measured by the drugs they were prescribed) were actually determined by the roll of a golf ball.

Seems that a doctor in South Carolina, out for round with a drug rep for Zyprexa manufacturer Eli Lilly (What's that about, anyway?), entered into a bet. Each time the rep carded a par (for those of you not wearing tartan plus-fours, that

means getting the ball in the hole in a predetermined number of shots), the doctor would agree to start a new patient on Zyprexa. "I got four pars out of nine holes," boasted Lilly rep Vince Sullivan in the court documents. "I said I wanted my four new patients."

The documents do not say whether unsuspecting patients wound up on Zyprexa, a drug for schizophrenia, but they do suggest an alarming pattern of potentially illegal promotion by Lilly.

The court case turns on the notion of off-label promotion. When the FDA approves drugs, it does so for particular conditions. Companies are forbidden to promote the drug for any condition other than the approved one, although doctors are free to prescribe the drug for any

condition they choose. Thus, off-label promotion is illegal, but off-label use is not.

But many a drug company has pushed itself still further into the black by fostering off-label use.

*continued on page 10*



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