

Health Letter

SIDNEY M. WOLFE, M.D., EDITOR

December 2009 ♦ VOL. 25, No. 12

What Happened in Health Care in 2009

2009 ... the year that began with the promise of change! It started with speculation on key political appointments in the health arena and what these would mean. Key among these was the nomination of Tom Daschle as both White House "health czar" and Secretary of the Department of Health and Human Services. Revelations that Daschle had not paid \$128,000 in back taxes forced him to withdraw after 10 days of gossip, delayed hearings, repeated Presidential and Congressional support and editorials from key media.

The rumor that Dr. Sanjay Gupta would be named Surgeon General spread throughout the media, eliciting comments from both supporters (who thought that his TV persona would be perfect for the job) and detractors (who questioned both the relevance of neurosurgery for the role of advocate for the public's health, and the wisdom of some of his judgments). Two months later, Gupta withdrew his name from consideration.

The first food scare of 2009 involved peanut butter produced by the Peanut Corporation of America (PCA). By the third week of January, more than 500 cases of salmonella poisoning and eight deaths had been reported. Two weeks later, the number of sick reached 600. Because the company that manufactured the contaminated

product sold it to more than 400 other companies, the recall also included cookies, other snacks and even pet food. Investigations revealed that the company had been cited a dozen times, and had done nothing to change its processes. Photographs of the plant in which the peanut butter was manufactured showed egregious deficiencies: leaky roofs, insalubrious manufacturing and storage facilities, pests. The pictures could not have been more eloquent. At Congressional hearings, PCA officials invoked their Fifth Amendment right to avoid self-incrimination.

The Food and Drug Administration (FDA) was further placed under a magnifying glass when the Government Accountability Office (GAO) issued a report strongly criticizing the FDA for failing to protect the public by its lax or

minimal testing of medical devices. The conclusions of the report were echoed by a group of nine scientists within the FDA's device division. In a letter to then president-elect Barack Obama and to Congress, the scientists described a corrupt review process in which medical devices are given quick approval following perfunctory testing because manufacturers tell the FDA that their products are "me, too" devices that operate similarly as older devices that have already received agency approval. The scientists subsequently followed up their letter with a memorandum to the FDA pointing out that imaging equipment to detect breast cancer and an orthopedic knee device had been inappropriately approved by the agency. They also charged the FDA with allowing hospitals to wash and reuse surgical devices intended for one-use only.

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Congress approved a \$787.2 billion economic stimulus bill that included a number of health care provisions. These included \$87 billion for state Medicaid programs, an allocation to promote the adoption of electronic health records and federal subsidies to extend the COBRA program.

A federal appeals court upheld the requirement that fast-food restaurants in New York include the calorie count the items on its menus. This was hailed as a victory for consumer advocates and those seeking to control the epidemic of obesity. The case was also important because other states (e.g., California, the city of Philadelphia) were awaiting the decision before adopting similar regulations. Public Citizen's Litigation Group argued this case, winning a significant victory.

Kathleen Sebelius was named Secretary of Health and Human Services. Her prior health-related background included being insurance commissioner in Kansas and governor of Kansas. She was the last of President Obama's cabinet to be confirmed.

The battle over health reform, a perennial issue but one that was back-burnered during the Bush years, gained new energy under the Obama-Biden administration. Unlike previous years, however, there is a growing consensus that the U.S. cannot afford to leave close to 50 million of its inhabitants uncovered. But there are a myriad issues revolving around means rather than ends, with those who want an altogether different health care delivery system pitted against those who just want more money for the inefficiency-ridden, fragmented, costly system we have now. A "Health Reform Summit" conducted in early March brought some of these issues to the fore.

In *Wyeth vs. Levine*, the Supreme Court ruled 6-3 in favor of allowing patients to sue in state court for harmful side effects of drugs that are not properly disclosed even if the drug has been approved by the FDA. The suit arose when Diane Levine sued Wyeth after receiving Phenergan intravenously and losing an arm to gangrene. A New York Times editorial hailed the ruling as "a win for injured patients" and a "wise and surprising decision." The case was also deemed "the most important business case in years." The Public Health Litigation Group was heavily involved in the case.

The desire to diversify their products in a precarious market led to major mergers in the pharmaceutical industry. Roche Holding acquired controlling shares in Genentech; Merck & Co. bought Schering-Plough for \$41.1 billion; and Pfizer acquired Wyeth for \$68 billion.

Citing the need to separate science from policy, President Obama reversed the Bush administration's restrictions on federal financing for stem-cell research. The decision was generally welcomed by researchers but condemned by those who construed it as an assault on life.

The appointments of Drs. Margaret Hamburg and Joshua Sharfstein at FDA raised expectations that the agency would assign a higher priority to safety and efficacy and address the agency's weaknesses. Evidence of some of the problems besetting the FDA emerged with the revelation that an 11-year old study linking the schizophrenia drug Seroquel to weight gain and diabetes was never published. Comparisons of Seroquel to the older drug Haldol found not only that patients on Seroquel gained an average of 11 pounds per year, but also that the new drug was not more effective than Haldol in preventing psychotic relapses. AstraZeneca, the

company which produced Seroquel, never published the study results or shared them with physicians. FDA had access to the study, but the agency lacked the authority to publicize the results. AstraZeneca ended up paying the government \$520 million to settle the case later in the year.

The PSA blood test, which has been used for more than 20 years to screen for prostate cancer, was found to save few lives. The test was also found to lead to risky and unnecessary treatments for many men. Two large-scale studies were conducted in the United States and Europe. The European study found that 48 men were told they can prostate cancer and needlessly treated for it for every man whose death was prevented within 10 years having undergoing a PSA. The U.S. study found no reduction in deaths for prostate cancer after the men had been followed for a decade.

The peanut scare was followed by warnings that pistachios were infested with salmonella. The problem was caught early by the firm which grows and markets the nuts. The recall of pistachios involved 31 states, and seems to have averted any outbreak of the disease. In quick succession, alfalfa sprouts were also found to be contaminated with salmonella.

Following a court ruling that the FDA decided not to challenge, the agency allowed selling Plan B (the "morning after" contraceptive) without prescription to persons 17 years old. The prior minimum age requirement was set at 18.

At the end of April, the confirmation of 20 cases of swine flu (more accurately referred to as the H1N1 influenza) spread over 5 states led the U.S. Homeland Security Agency and the Centers for Disease Control and Prevention to declare a public health

state of emergency. In Mexico, where more than one thousand cases and over 100 deaths were reported, the government instituted strict control measures, including distributing surgical masks to the population, closing schools and churches and canceling sports events, and alerting the population concerning signs and symptoms of the disease and how to protect themselves. Because the disease originally appeared to be largely confined to North America, several European countries issued travel alerts against travel to Mexico and the United States; some countries instituted quarantine measures at their borders to monitor the health of incoming visitors. The World Health Organization (WHO) issued periodic alerts ratcheting the level of concern upwards. But the strain of the virus turned out to be less virulent than anticipated, and many felt that it had been more a media than a health event. By the end of May, the U.S. could state that the emergency was over; in President Obama's words, the correct response was one of "concern" rather than "panic." By the end of June, however, more than 127 deaths due to H1N1 flu had been reported in the U.S. The WHO declared the flu a "pandemic" in mid-June. This did not mean that the condition was more lethal, but rather that its spread was considered unstoppable. WHO was motivated to increase the level of concern because of widespread diffusion beyond the region of origin. China, eager to avoid the panic that accompanied its cover-up of the

SARS outbreak (2003), took drastic measures against H1N1, quarantining any person with a temperature and instituting other measures that the CDC considered disproportionate to the threat. International tourists were caught in the dragnet, confined to their hotels or hospitalized.

An unlikely coalition of diverse interests — including labor, the drug and device industries, and health insurance lobbyists — met with the President and other members of the Obama administration and indicated their willingness to control costs voluntarily. The industry groups later hedged on their initial pledge, which was supposed to reduce cost increases by 1.5 per cent per year and save \$2 trillion over 10 years. Instead, they said they had merely agreed to work towards that eventual goal, promising no definite outcome.

The House voted to authorize the FDA to regulate tobacco products. The legislation was passed by the Senate and signed by President Obama. The law allows the agency to regulate the many of the contents of products, requires companies to make public their ingredients, prohibits most flavoring, mandates larger warnings, and controls marketing campaigns, particularly those aimed at youths. The legislation, long in coming, was considered a significant victory for the anti-smoking lobby.

In June, the FDA issued a consumer warning against the use of Zicam, a popular cold remedy, after hundreds of reports that the zinc in the drug destroyed users' sense of smell, a condition called anosmia. Despite the FDA's alert and having had to pay millions to settle lawsuits bought by consumers of the product who suffered damages, the manufacturer did not recall the product.

Summer began without Nestlé's toll house cookies because the cookie dough was contaminated with E. coli. Nestlé's recalled its product after receiving reports of illness from 66 persons in 29 states.

President Obama named Dr. Regina Benjamin as U.S. Surgeon General. Dr. Benjamin, who built and rebuilt a clinic in the bayous of Alabama, is known as a committed advocate for health care as well as a member of the American Medical Association's board of trustees. While the job of Surgeon General is often largely symbolic, some previous SGs have used the position as an effective platform to push for important health issues such as smoking cessation and testing for HIV.

The dog days of summer, the time when "all creatures become languid," proved hostile to the debate on health

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reform, which was characterized more by the stridency of the town hall exchanges than for the clarity of the arguments. Among the major issues that were batted back and forth: whether “advanced directives” implied euthanasia; whether the public option was essential or something to be bargained away in the negotiation process; and whether health coops could replace the public option, achieving some of the same ends without raising as many hackles. In addition, the fact that the President had made major concessions to the pharmaceutical industry — agreeing to forego both leveraging the power of government to bargain for lower drug prices and importing drugs from Canada in exchange for PhRMA’s acquiescence — rankled key members of his own party, who felt that these concessions were premature at best, plain wrong at worst. For the most part, the only option that Public Citizen supports — a Medicare-for-all single payer health insurance system — was kept out of the debate.

The president’s September speech on health care was variously described as a “game changer” by his supporters, but was ineffectual in winning over those opposed to health reform. The immediate audience reflected the existing partisan divide, with cheering and clapping on the part of Democrats and long faces, sour miens, and protests (as well as one memorable heckler) on the part of Republicans.

The data on the number of the uninsured for 2008 showed a rise from the previous year, the result of rising unemployment and a contraction in the number of employers offering coverage. Although there is a rule-of-thumb that a rise of one percent in the unemployment rate will lead to a commensurate increase in the rise of uninsured, the full impact of job losses was temporarily blunted by

an increase in Medicaid and SCHIP beneficiaries.

In September, the FDA admitted that ‘undue influence’ on the part of four New Jersey Congressman and former FDA commissioner Andrew von Eschenbach had led to the approval of ReGen’s Menaflex, a knee implant to treat meniscus tears. The device was not approved by agency scientists, who were over-ruled in the final decision. The agency is therefore reopening the matter and reassessing the device.

A Dutch and a Danish study both found that Yasmin, an oral contraceptive widely used in the U.S., and oral contraceptives containing the progestin desogestrel are both more likely than other, older pills to cause blood clot injury. In many women, this can lead to pulmonary embolisms, wherein blood clots can travel from the legs to the lungs. Drospirenone, a type of progestin, was implicated in the higher risk found with Yasmin.

After appearing to agree to a number of concessions on health reform (e.g., no exclusions for pre-existing conditions, no rescissions), America’s Health Insurance Plan (AHIP), the lobbyist for the health insurance industry, commissioned a report which concluded that the reform would significantly drive up insurance premiums. The costs estimated by PricewaterhouseCoopers for AHIP were premised on the proposed mandate being ineffectual in attracting younger, healthier populations into the insurance pool. The estimates also assumed that taxes on higher-end plans and other health care sectors would be passed on to consumers, thereby raising the price tag on coverage, and that cuts to Medicare would result in fee increases for other patients. While health economists and policy

analysts questioned the accuracy of these assumptions, the report added yet another weapon to the arsenal of scare tactics that have been mustered in the U.S. health debate. Furthermore, the report dashed the Obama administration’s hopes of achieving some sort of accommodation with private insurers, and intensified the debate on having a public option competing with the health insurance companies.

By mid-October, Congressional committees had produced no fewer than five different bills on health reform. All except one included a public option. The attempt on the part of the Democrats to come up with a single bill was hamstrung by the fact that everyone seemed to object to at least part of whatever was proposed. Olympia Snowe emerged as the only Republican willing to incur the wrath of her party in exchange for some type of reform, and she was duly wooed and courted by the Democrats as well as shunned and vilified by her own party.

In a shift from its previous policy and messages, the American Cancer Society adopted a more conservative stance in its advocacy of screening for certain types of cancer. The ACS stated that the advantages of screening had been overstated, especially in the case of breast and prostate cancers, and that screening had led to an over diagnosis of those cancers that did not benefit from early treatment.

After years of downplaying the problem, or even recognizing its existence, the Accreditation Council for Continuing Medical Education (ACCME) took stronger measures to avoid conflicts of interest resulting from the fact that many of the continuing education courses under their aegis are sponsored by drug companies that predictably shape the message to promote their products.

The chief executive of the ACCME completed action on 12 inquiries concerning commercial bias in 2008-2009, and had found only five that were violating the rules. While there is growing consensus on the part of different stakeholders that continuing medical education should be free of industry influence, there is less agreement on what this means for industry funding.

On October 24, President Obama declared the H1N1 outbreak a national emergency. While this did not alter the preparations already in place, it gave states greater flexibility in taking measures to arrest the epidemic and treat those affected. The announcement coincided with the realization that the supply of much-promised H1N1 flu vaccine was going to fall significantly below initial projections, the planned 160 million doses that were promised in July dwindling to a mere 28 million by Halloween. The shortfall was due to snags at different steps in the production process, from the virus not growing as fast as expected in the eggs that culture the vaccine, to difficulties in putting the vaccine into vials and syringes.

On November 9, 2009, the House of Representatives voted 220 to 215 to approve health reform legislation. The 1990-page bill was complicated enough to have something to please and to concern practically everyone. But it did extend health care coverage (though not to everyone), altered some of the rules under which health insurers operate, strengthened primary care, and made a number of tax changes designed to raise revenues. Part of the price of securing the vote on the broader bill was allowing a vote on an amendment to prohibit coverage of abortion by any plan that is that is purchased with the help of federal subsidies through newly created insurance exchanges. As this goes to press, the focus of health reform moves to the Senate, where the process of interest-aggregation will be equally complicated.

By mid-November, the CDC had revised the mortality estimated due to H1N1 upward, estimating that 3,900 cases had resulted in deaths in the U.S., a number still lower than the usual number of deaths from flu at this time of year.

In a major change from previously recommended established practice, the U.S. Task Force on Prevention issued new guidelines for breast cancer screening. The new recommendations raise the recommended age for screening for women from 40 to 50 and the frequency of screening from annual to every two years until age 74. In addition, the Task Force is no longer endorsing breast self-examinations. These changes have caused much debate and controversy among different professional and advocacy organizations, with not all of them falling in line with the new guidelines. ♦



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The Price We Pay for Uninsurance

In the November issue of *Health Letter*, we reported the results of a study by our colleagues at Harvard Medical School, published in the *American Journal of Public Health*, finding that nearly 45,000 deaths a year in the United States are associated with lack of health insurance. At the time of the study, the authors stated that “doctors have many new ways to prevent deaths from hypertension, diabetes and heart disease — but only if patients can get into our offices and afford their medications.”

Since then, three other studies, two by our colleagues Steffie Woolhandler and David Himmelstein and their co-authors, have elaborated on these findings.

The first of these two studies found significant gaps in the care — adequate diagnosis and treatment — for those who are uninsured who have diabetes, high cholesterol or hypertension, leading to an increased risk of costly, disabling and even lethal complications of their disease. The study was based on data collected between 1999 and 2006. The study found that about half of all uninsured people with diabetes (46 percent) or high cholesterol (52 percent) did not know they had these diseases. In contrast, about one-quarter of those with insurance were unaware of their illnesses (23 percent for diabetes, 29.9 percent for high cholesterol).

Under-treatment of disease followed similar patterns, with the uninsured being more likely to be under treated than their insured counterparts: 58.3 percent vs. 51.4 percent had their high blood pressure poorly controlled, and 77.5 percent vs. 60.4 percent had their high cholesterol inadequately treated.

Lead author Dr. Andrew Wilper, who worked at Harvard when the study was done and who now teaches at the University of Washington Medical School, said:

Our study should lay to rest the myth that the uninsured can get the care they need. Millions have

serious chronic conditions and don't even know it. And they're not getting care that would prevent strokes, heart attacks, amputations and kidney failure.

According to Dr. David Himmelstein, associate professor of medicine at Harvard and study co-author:

The Senate Finance Committee's bill would leave 25 million Americans uninsured and unable to get the ongoing, routine care that could save their lives and prevent disability. No other wealthy nation tolerates this, yet Congress is turning its back on tens of millions of Americans.

The second study updated previous estimates of the toll of the lack of insurance on veterans in the U.S., many of whom lack health coverage.

The Harvard researchers say 1.46 million working-age vets lacked health coverage last year, increasing their death rate. The research team estimates 2,266 U.S. military veterans under the age of 65 died last year because they lacked health insurance and thus had reduced access to care. That figure is more than 14 times the number of deaths (155) suffered by U.S. troops in Afghanistan in 2008, and more than twice as many as have died (911 as of Oct. 31) since the war began in 2001.

Using their recently published findings in the *American Journal of Public Health* that show being uninsured raises an individual's odds of dying by 40 percent (causing 44,798 deaths in the United States annually among those aged 17 to 64), they arrived at their estimate of 2,266 preventable deaths of non-elderly veterans in 2008.

“Like other uninsured Americans, most uninsured vets are working people — too poor to afford private

coverage but not poor enough to qualify for Medicaid or means-tested VA care,” said Dr. Steffie Woolhandler, a professor at Harvard Medical School who testified before Congress about uninsured veterans in 2007.

Dr. David Himmelstein, the co-author of the analysis and associate professor of medicine at Harvard, commented, “On this Veterans Day we should not only honor the nearly 500 soldiers who have died this year in Iraq and Afghanistan, but also the more than 2,200 veterans who were killed by our broken health insurance system. That's six preventable deaths a day.”

The third study, done by other researchers at Harvard Medical School, was based on the idea that because of “pervasive evidence of disparities in screening, hospital admission, treatment, and outcomes due to insurance status, a disparity in outcomes in trauma patients (in-hospital death) among the uninsured may exist.”

Data were collected from the National Trauma Data Bank from January 1, 2002, through December 31, 2006. The National Trauma Data Bank contains information from 2.7 million patients admitted for traumatic injury to more than 900 US trauma centers, including demographic data, medical history, injury severity, outcomes, and charges.

The authors measured in-hospital deaths after blunt or penetrating traumatic injuries. They found that uninsured patients with traumatic injuries, from car crashes, falls and gunshot wounds, were almost twice as likely to die in the hospital as

“Our study should lay to rest the myth that the uninsured can get the care they need.”

— Dr. Andrew Wilper

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Analysis of USPSTF 2009 Revised Breast Cancer Screening Recommendations

The following analysis was released November 16, 2009 on the website of the National Breast Cancer Coalition. You may visit the National Breast Cancer Coalition online at <http://www.stopbreastcancer.org/>.

In trying to deal with the toll that breast cancer continues to take in our country, the public has followed the lead of public health officials and increasingly put their faith in screening and early detection, though we have never had good evidence that this would have a significant impact. The over-emphasis on the importance of screening, despite a lack of strong evidence, has been elevated to such a degree that some even equate screening with prevention of breast cancer. The National Breast Cancer Coalition hopes that today's release of the U.S. Preventive Services Task Force (USPSTF) revised recommendations will put the brakes on this run-away train and will put screening and its

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limitations into proper perspective.

The revised guidelines¹ were issued by the USPSTF, a government-appointed, independent panel of experts in primary care and prevention that systematically reviews the evidence and develops recommendations for clinical preventive services. Revisions include recommending against universal screening mammography for women aged 40-49, recommending every other year screening for women 50-74, rather than annual screening and recommending against teaching breast self examination.

For over ten years, the National Breast Cancer Coalition has reviewed and analyzed each newly published article looking at the trials of mammography screening. After each analysis, NBCC has continued to take the position that mammography screening has significant limitations and should be a personal choice rather than a public health message. NBCC has also reviewed all articles and studies on breast self examination

and historically informed the public that there was no evidence that monthly breast self examination saved lives. When the evidence from well designed prospective randomized trials in addition to that of other studies showed harm and no benefit from this practice, NBCC changed its message accordingly. We continue to affirm those positions and are gratified that the U.S. Preventive Services Task Force has changed their recommendations to be more in line with the existing evidence.

The issues are not simple, but we believe women can comprehend the complexities of breast cancer and screening for the disease. Women deserve to know the facts and have the right to make informed decisions regarding their health care.

The truth about breast cancer and screening:

- There is no statistically significant evidence that screening women age 40-49 years reduces breast cancer mortality. The USPSTF now recommends against universal screening mammography for women aged 40 to 49 years.¹ The Task Force changed their recommendation based on a systematic review² of randomized clinical trials and on six statistical

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similarly injured patients with health insurance.

Treatment delay, different care (via receipt of fewer diagnostic tests) and decreased health literacy were proposed as possible mechanisms whereby uninsured trauma victims were more likely to die from their injuries.

"This is another drop in a sea of evidence that the uninsured fare

much worse in their health in the United States," said senior author Dr. Atul Gawande, a Harvard surgeon and medical journalist. The study appeared in the November issue of the Archives of Surgery.

Taken altogether, these studies are elaborating important details of how and why 45,000 Americans die each year related to their lack of health insurance. That this occurs in a country that spends more — \$2.5 trillion a year on health care —

than any other so-called developed country is unacceptable. As long as we continue to tolerate a private, for-profit health insurance industry that provides the mechanisms for excluding upwards of 50 million people from having health insurance, these grim realities will continue. A system in which everyone is in and nobody out means eliminating the private health insurance industry. ♦

models of the risks and benefits of mammography screening.³ A major consideration for the change was the addition of recent results from the only clinical trial designed to specifically evaluate mammography in this age group. The Age trial⁴ found no statistically significant difference in breast cancer mortality between those women who were screened during their 40s and those who were not.

- False-positive results and additional imaging as a result of mammography are most prevalent in women aged 40 to 49 years. When screening is started at age 40 years, about 60% more false-positive results have been estimated to occur than if screening is started at age 50 years.³
- The evidence for a benefit of mammography after 50 is not strong. To reduce the harm while still maintaining the small benefit, the USPSTF now recommends biennial (every other year) instead of annual screening mammography for women aged 50 to 74 years.¹ The USPSTF concludes that the benefit of screening mammography is maintained by biennial screening, and changing from annual to biennial screening is likely to reduce the harms of mammography screening by approximately 50%, based on the statistical modeling,³ a systematic review of randomized clinical trials,⁵ a population-wide screening program report,⁶ and on a community-based study.⁷
- Mammography can miss cancers that need treatment, and in some cases find disease that does not need treatment, leading to overtreatment with toxic therapies. Harms for healthy women who do not have cancer can include unnecessary imaging tests and biopsies, unnecessary exposure to x-ray radiation, and psychological trauma and anxiety.

- All breast cancers are not equal. Some patients will have fast-growing, aggressive tumors while others will have slower-growing, less aggressive tumors that are less likely to metastasize and, therefore, have a better prognosis. Screening is more likely to identify the slower-growing, less aggressive tumors because of longer asymptomatic periods. This "length-time" bias can make screening appear more beneficial than it is. "Lead-time" bias can also contribute to a misrepresentation of the benefit of mammography. If a lethal cancer is found earlier through screening, the patient would appear to live longer because of "lead time." Screening is not helping patients in these situations live longer, it is only helping them find out about their cancers sooner.

- Breast self-examination (BSE) is ineffective and potentially harmful. Two large, randomized, clinical trials of BSE, both found that women who did BSE were no less likely to die of breast cancer than those who did not do BSE. In both studies, the number of invasive cancers diagnosed in the two groups was about the same, but women in the BSE group had more breast biopsies and more benign lesions diagnosed than did women in the control group. 8, 9 The USPSTF recommends against teaching breast self-examination.²

- The USPSTF concludes that there is insufficient evidence to evaluate the benefit of clinical breast examinations.²

We encourage women to make informed decisions regarding screening based on the actual evidence. To learn more about the myths and truths concerning breast cancer and screening, and to find out how to take action against this disease, visit www.stopbreastcancer.org.

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Product Recalls

October 23, 2009 – November 18, 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 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

Clonazepam Tablets 0.5 mg and 1.0 mg in 100 count bottles (NDC 0093-0832-01 - shipped 120 bottles per case) and 500 count bottles (NDC 0093-0832-05 - shipped 72 bottles per case), Rx Only. Tablets may exceed specifications for weight, thickness and potency. Multiple lots. Teva Pharmaceuticals USA, Inc.

INVEGA (paliperidone) Extended-Release Tablets, 6 mg, 30-count bottle, Rx only, NDC 50458-551-01; 19,668 bottles; CGMP Deviations: One lot of INVEGA 6 mg was coated pink, when the approved color for the 6 mg tablets is beige. Lot #: 9KG024, exp. date 11/2010; Global Supply Pharmaceutical Gr.

OPANA ER (Oxymorphone Hydrochloride) Extended-Release Tablets, 10 mg, 100 count bottles, Rx Only; NDC 63481-674-70. 8,170 bottles. Mislabeled; Bottles labeled as 10 mg tablets actually contain 5 mg tablets. Lot #: 401445NV; Endo Pharmaceutical, Inc.

Temodar (temozolomide) capsules, 5 mg, 5-count bottles, Rx only; NDC 0085-3004-02. 13,141 bottles. Impurities/Degradation Products: This product is being recalled because of an out of specification (OOS) stability result obtained for moisture and total degradation products. Lot #: 7HLO009, exp. date 09/2010; Schering-Plough Products, LLC.

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.

Adventure Playsets Wooden Play Sets. The plastic coated lumber on the horizontal ladder (monkey bar/swing beam) can weaken over time due to rotting of the whitewood (spruce, pine and fir species), resulting in a fall hazard. Adventure Playsets, (877) 840-9068 or www.adventureplaysets.com.

Arctic Cat Snowmobiles. Oil can leak into the engine compartment, posing a fire hazard to consumers. In addition, the fuel tank can come into contact with the engine posing a possibility of wearing through and fuel leakage. Arctic Cat Inc., (800) 279-6851 or www.arctic-cat.com.

Bicycles with EA30 Stems. The bicycle stem can crack and cause the rider to lose control, posing a risk of serious injury if the rider falls. Easton Sports, (866) 892-6059 or www.eastonbike.com.

"Bobby Chupete" Pacifiers. The pacifiers fail to meet federal safety standards. The pacifier mouth guard is too small, posing a choking hazard to infants and toddlers. Grand World Inc., (718) 326-7786 or www.grandworldinc.com.

Dublin Energy Solution 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. Louis Hornick & Co. Inc., (800) 517-3612 or www.hornickindustries.com.

EXO-Tech Safety Harness. The webbing of the waist belt on the safety harness is not routed through the lineman's loop located on the front of the harness near waist level. Since the loops are not

properly anchored to the harness webbing but are attached only through stitching not intended to restrain a user during a fall, they that can pull away from the harness when force is applied, leaving the user unrestrained. In addition, the manufacturer of the harness used a previously untested carabiner connector located at the end of the tether at the back of harness, which is the portion of the tether that attaches to the tree. Gorilla Inc., (877) 685-7817 or www.gorillatreestands.com.

Fall 2009 Newbury Travel Mugs. The travel mugs can become excessively hot to the touch when filled with hot liquids, posing a burn hazard to consumers. The S Group, (888) 339-2987 or www.lifeisgood.com.

Faux Suede Roman Shades. Strangulations occur when a child places his/her neck between the exposed inner cord and the fabric on the backside or when a child pulls the cord out and wraps it around his/her neck. Hanover Direct Inc., (also known as Domestications), (800) 524-0597 or www.domestications.com.

Gehl's HOT TOP2 Nacho Cheese and Chili Sauce Dispensers. The dispenser's fan blade can come into contact with the heater coil, posing fire and burn hazards to consumers. Gehl Foods Inc., (877) 440-4008 or www.gehls.com.

Halloween Flashlights. The flashlights can overheat and melt, posing a burn hazard to consumers. Target, (800) 440-0680 or www.target.com.

Hang-On Fixed Position Treestands. The clasp may open unexpectedly if the strap is fastened incorrectly, causing the tree-stand and user to fall to the ground. Gander Mountain Company, (888)-542-6337 or www.gandermountain.com.

Homelite Backpack Blowers. The fuel tank can leak gasoline, posing a fire hazard to consumers. Homelite Consumer Products Inc., (800) 242-4672 or www.homelite.com.

ISDANS, TUPPLUR, and ENJE Roller Blinds. Strangulations can occur if the blind's looped bead chain is not attached to the wall or the floor with the tension device provided and a child's neck becomes entangled in the free-standing loop. IKEA Home Furnishings, (888) 966-4532 or www.ikea-usa.com.

Maclaren Strollers. The stroller's hinge mechanism poses a fingertip amputation and laceration hazard to the child when the

consumer is unfolding/opening the stroller. Maclaren USA, Inc., (877) 688-2326 or www.maclaren.us/recall.

Power Adapters with IBM RDX Back Up Hard Disk Drives. A plastic weld on the power adapters can fail and allow two parts to separate, exposing live electrical contacts. This poses a shock hazard. IBM, (800) 426-7378 or www.ibm.com/storage.

Rechargeable Batteries sold with MVP 5000 Series Wireless Touch Panels. Touch panels left uncharged for more than three months can fail, causing the battery to rupture. This poses a fire hazard to consumers. AMX, (800) 222-0193 or www.amx.com.

Samsung Over-the-Range Microwave Ovens. If an installation bolt comes in contact with an electrical component inside the unit and the microwave is plugged into an ungrounded outlet, it could create a shock hazard. Samsung Electronics America Inc., (888) 402-6974 or www.samsung.com/otrecall.

Sony VAIO Computer AC Adapters. Insulation inside the AC adapter can fail over time, posing an electrical shock hazard to consumers. Sony Electronics Inc., (877) 361-4481 or esupport.sony.com/ac19adapter.

SurgeMaster™ Surge Protectors. The molding of the plastic rotating plug, which allows for easy cord movement, can crack or detach from the plug assembly, posing a shock hazard. Belkin International Inc., 800-952-1465 or www.belkin.com/recall.

Yayita Baby Hammocks. The hammock can flip over, posing a serious fall hazard and strangulation hazard to infants who become entrapped in the restraint straps while upside down. Three Sisters Toys Inc., (888) 537-9293 or www.threesisterstoys.com.

Young Artist Easels. The chalkboard surface coating contains high levels of lead, violating the federal lead standard. MacPherson's, (866) 319-5335 or www.art-alternatives.com/recall.

Youth Hooded Sweatshirts and Jackets. The 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. Century 21 Promotions, (800) 935-2100.

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uses, the companies do studies to publish the alleged new benefits of drugs.

The legal case against Neurontin uncovered some of the strategies that Pfizer and Parke-Davis employed to offset or otherwise scuttle publication of unfavorable findings. The deceptive tactics that were first revealed to the public in 2008 included delaying reports that found no evidence of the drug's efficacy, "spinning" or reinterpreting negative data, and bundling negative findings with positive studies to neutralize results. In some cases, legitimate researchers saw their findings rewritten and recast to, in the words of one of company's medical writer, "make [the overall picture] sound better than it looks on the graphs."

A recent study published in the *New England Journal of Medicine*, based a more comprehensive analysis of these same documents, found that published results of randomized clinical trials on off-label uses of Neurontin conducted by Pfizer and Parke-Davis were skewed to show efficacy, and that the data were manipulated to support the desired findings. This practice, called "selective outcome reporting," used two techniques: non-reporting of negative outcomes, and changing the outcomes of the trials to produce the desired results.

The latter practice entails modifying the purposes of the research after it has been conducted. Most drug trials include primary and secondary

outcomes. Primary outcomes are, by definition, more important than secondary ones. For example, the primary outcome may be reducing the incidence of a particular condition, while a secondary outcome may be mitigating some of the symptoms.

The Guardian describes the practice of modifying the outcomes as follows:

You might do a trial on a blood pressure pill, for example, stating that you will look to see if it can reduce heart attacks, but find that it doesn't. Then you might retrospectively change the purpose of the study, ignore heart attacks, pretend it was only ever about blood pressure, and glowingly report a reduction in blood pressure as if this was what you were always interested in.

This is tantamount to embarking on a cross-country trip between Los Angeles and Washington, DC, but deciding that you have arrived when you reach Wichita, Kansas, and declaring that is was your destination all along!

The researchers examining the research protocols for Neurontin identified 20 clinical trials, of which 12 were reported in publications. In eight of these 12 published trials, the primary outcomes defined in the report were different from those in the original research protocol. The discrepancies included introducing a new primary outcome, failing to distinguish between primary and secondary outcomes, and failing

to report on one or more primary outcomes. Of the 21 primary outcomes in the research protocols, six were not reported at all and four were reported as secondary outcomes. And of the 28 primary outcomes in the published reports, 12 were newly introduced. And these changes were not neutral, but rather led to a more favorable presentation of Neurontin's efficacy for unapproved indications.

While there may be legitimate reasons for modifying primary and secondary research outcomes, these changes need to be documented in the research protocol and in the statistical analysis to which findings are subjected, and should be included in any published report on the clinical trials. This was not consistently done in the Neurontin trials. The authors of the study therefore express their concern that "the reporting practices observed in [their] analysis do not meet the ethical standards for clinical research or maintain the integrity of scientific knowledge."

These practices undermine the trust we place on science and published studies and make a mockery of the systems that generate evidence for decision-making purposes. While reliable data on clinical trials may seem arcane, they are at the core of much of what we do and don't do in health care. To quote *The Guardian*: "Our failure to ensure full, undistorted publication of all trial data is the single most important issue in medicine today, because this is the only way we can know whether a treatment does good, or harm." ♦

Editor.....Sidney M. Wolfe, MD
Managing Editor.....Kate Resnevic
Contributors.....
Annette B. Ramirez deArellano, DrPH
Sidney M. Wolfe, MD
Proofreader..... Kate Resnevic

THE PUBLIC CITIZEN HEALTH RESEARCH GROUP

Health Letter

Public Citizen President
Robert Weissman

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Published Monthly by
Public Citizen Health Research Group
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The Health Research Group was co-founded in 1971 by Ralph Nader and Sidney Wolfe in Washington, D.C. to fight for the public's health, and to give consumers more control over decisions that affect their health.

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Annual subscription price is \$18.00 (12 issues). Mail subscriptions and address changes to Health Letter, Circulation Department, 1600 20th St., NW, Washington, D.C., 20009. Our Web site address is www.citizen.org/hrg.

The Case of Neurontin: Skewed Research in the Service of Selling

When pharmaceuticals are intent on proving that one of their products is safe and effective, they may engage in practices that are professionally suspect and morally unethical. The recent news on Neurontin is a case in point.

Neurontin, manufactured by Pfizer and Parke-Davis, is the brand name for the drug gabapentin. It is approved to treat epilepsy and post-herpetic neuralgia but may also be used off-label, i.e., for uses not approved by the Food and Drug Administration (FDA). The latter include the treatment of migraines, bipolar disorder, and restless leg syndrome.

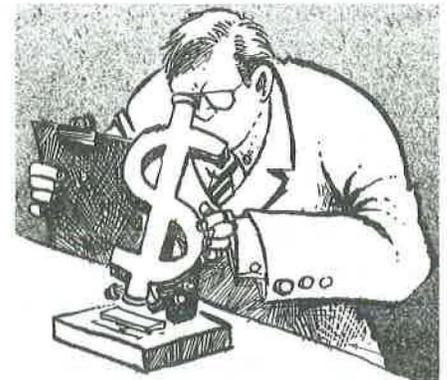
In addition, some physicians prescribe Neurontin off-label for a wider range of higher-prevalence conditions, including hot flashes,

insomnia, and certain types of tinnitus (ringing in the ears). Over time, off-label uses have exceeded approved uses, so they are an increasingly important share of the market. In 2004, sales of the drug peaked at \$2.7 billion. But that same year Pfizer was found to be urging physicians to prescribe Neurontin for off-label uses, which is illegal. As a result, the company had to pay \$430 million in criminal fines and civilian penalties. But this was not the end of the Neurontin saga.

Because companies have a vested interest in having the FDA approve some of the off-label uses, they conduct research to see if the drug works for some of these other conditions. If they can convince the federal regulators that there is adequate evidence of safety and

efficacy, FDA can then extend its approval for these additional uses, thereby broadening the drug's market. Otherwise, advertising or promoting these uses is prohibited. Sometimes, not even intending to submit studies to the FDA to extend the approved

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