

Health Letter

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In Case You Missed It: What Happened in Health in 2008

The 2008 presidential campaign and the election of Barack Obama as president of the United States shaped part of what happened in the health care arena this year. Despite competing issues, particularly politics and the economy, health-related topics grabbed numerous headlines over the past year. Recurring themes included the safety and efficacy of drugs and devices, tainted products and food recalls, conflicts of interest, universal health insurance and how to get it, and health disparities. Here, in approximate chronological order, is a recap of issues that emerged during 2008 and are not likely to go away any time soon.

January marked the publication of the long-delayed findings (divulged 21 months after study completion) of the ENHANCE trial. The study showed that Vytorin (combining Zetia and Lipitor) worked no better than Zocor alone — which costs 1/16 as much in its generic version, simvastatin — in reducing artery plaque that can lead to heart attacks. Vytorin is possibly best remembered for its imaginative advertising campaign featuring colorful foods and look-alike persons with the message that the medication addressed two sources of cholesterol: diet and family history. Because statins are among the most frequently-prescribed drugs, the study elicited unusual attention. ENHANCE did little to enhance the fate of the drug; fallout from the study

findings included confused patients, surprised physicians, disappointed stockholders, an aborted \$100-million ad campaign and half-hearted explanations from the manufacturers. Study findings raised research questions concerning the validity of clinical trials using intermediate or “surrogate markers” (e.g., lowering LDL, low density protein) instead of focusing on outcomes related to heart attacks, strokes or death. The efficacy of the drug was subsequently questioned in July, when the results of another study, known as the SEAS trial, showed that Vytorin does not lower the risk of major cardiovascular events in patients suffering from aortic stenosis, which blocks the flow of blood from the heart. As the year ended, the U.S. Justice Department was looking into whether the promotion of Vytorin prompted false reimbursement claims made to federal health care programs.

In *Riegel vs. Medtronic*, a case argued by Public Citizen attorneys representing the plaintiff, the U.S. Supreme Court ruled that the patients injured by a medical device cannot sue manufacturers. In the words of the *Washington Post*, the ruling leaves the Food and Drug Administration (FDA) as the “first and final arbiter of safety,” limiting the legal recourse available to those harmed by medical devices. A subsequent similar case concerning a drug was decided by a 4-4 vote, which allowed the ruling of the lower court to stand. Public Citizen attorneys also argued that case, which was described as a victory for the 18 plaintiffs, all of whom suffered liver damage by taking the diabetes drug Rezulin, which was later removed from the market.

A California meat company was forced to order the largest

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beef recall in U.S. history. Some 143 million pounds of beef were recalled; of these, 37 million were slated for school lunches or other nutrition programs. The problem was identified and documented by the Humane Society, which filmed the use of "downer" cows (which are unable to walk) in slaughterhouses. The U.S. Department of Agriculture bans the use of these cows for human consumption.

A survey revealed that 59 percent of U.S. physicians favor national health insurance, an increase of 10 percentage points in five years.

The FDA faced additional criticism as a result of problems with imported drugs from China, thereby highlighting the lax oversight that the agency exerts over products made elsewhere. In the words of Janet Woodcock, director of the Center for Drug Evaluation and Research at FDA, the agency "can't be the quality control unit of the world." While the U.S. imports drugs from 714 Chinese establishments, the FDA conducted only 14 inspections in China in 2007. Initially, 19 deaths linked to the blood thinner heparin produced in China were the subject of extensive reporting and investigations, resulting in the identification of a contaminant (a chemically altered form of chondroitin sulfate, a dietary supplement used in treating joint pain). Over time, the total number of deaths was revised to 62 and then to 81. More broadly, the incident revealed the intricate and unmonitored conditions under which the active ingredients of certain drugs are produced, the complexities of the supply chain and the possibility of counterfeit ingredients being deliberately incorporated or otherwise entering the manufacturing process. Baxter International recalled all its heparin products following the revelations. In Europe, Germany, France, Italy and Denmark recalled heparin or its ingredients because of contamination or the suspicion of contamination. The political fallout

from the entire incidents netted the FDA an increase in funds in order to bolster its monitoring activities. Although the incident was repeatedly called a "wake-up call" for the regulatory agency, it underscored the limitations in policing an expanding list of ingredients manufactured outside the U.S.

Bayer took its clotting drug Trasylol off the market after the FDA failed to identify a single population in which the benefits of the drug could outweigh its risks. The drug is used during heart surgery.

The New York City Board of Health reaffirmed its vote to require chain restaurants in the city to list calories on menus and menu boards. Although a previous regulation was blocked by a federal judge who claimed the measure was pre-empted by federal law, the revised regulation was actually broader, covering a larger number of eateries. The regulation affects only 10 percent of NYC restaurants, but it has had an impact on other cities who want to follow suit. Public Citizen's litigation group submitted an amicus brief in favor of the regulation.

A survey revealed that 59 percent of U.S. physicians favor national health insurance, an increase of 10 percentage points in five years. More than half of all respondents from every medical specialty supported national health legislation, with the exception of surgical specialists, anesthesiologists, and radiologists. Support was particularly high among psychiatrists (83 percent), pediatric physicians (71 percent) and those in emergency medicine (65 percent).

BPA (bisphenol A) became yet another acronym that made headlines. This is a widely used compound found in hard plastic food containers, including baby bottles and the linings of baby formula cans. Amidst growing concern that BPA could cause neurologic and behavioral effects in fetuses, infants, and children, the FDA was forced to convene a task force to develop recommendations with regard to FDA-regulated products containing BPA. The issue was further exacerbated by the revelation that a contractor drafting a report on BPA risks for the National Toxicology Program also worked for the chemical industry, and that some of the previous studies on BPA had been sponsored by industry. In May, Canada banned the use of BPA in baby bottles. In the U.S., action was not as prompt. In August, the FDA released its draft reporting upholding the prevailing safety standard for BPA in food. The agency based its decision on two studies sponsored by the plastics industry. The following month marked the publication of a study showing that exposure to BPA was associated with higher rates of heart disease, diabetes and liver abnormalities. At the end of October, a panel of outside scientists chastised the FDA for ignoring crucial studies and using flawed methods in drawing conclusions about BPA.

National mortality data broken down by county revealed that there are certain U.S. counties in which life expectancy declined between 1983 and 1999. While no county had a statistically significant reduction in this indicator from 1961 to 1983, after that date life expectancy decreased an average of 1.3 years in 11 counties for men and in 180 counties for women. The decline among women was attributed to increases in diabetes and lung cancer. Among men, the decrease was explained by rises in HIV infection and homicide. Geographical differences were consistent with trends in smoking, hypertension and obesity. In the

words of one researcher, widening disparities indicated “the worsening of the worst off,” thereby revealing the backsliding that can result from neglect and persistent, cumulative inequities.

In late spring, tainted tomatoes emerged as yet another focus of concern for the FDA and consumers. By mid-July outbreaks of salmonella poisoning had affected more than 1,200 individuals in 43 states, D.C. and Canada, making this is largest food-related outbreak in a decade. The list of suspects, which initially included Roma, plum, and standard red tomatoes, was later widened to include cilantro, and jalapeño and serrano peppers, creating a veritable salsa of shunned products before authorities finally zeroed in on jalapeños as the source of the outbreak. As the investigation lengthened, it also became more difficult, as victims were unable to recall what they had eaten, and most of the perishable products were discarded. The vulnerabilities of the existing monitoring system were thus exposed: while the U.S. Department of Agriculture is responsible for the conditions under which the products are grown and the FDA is in charge of overseeing the quality of produce, much can happen in between field and table.

In July, Congress voted to give the FDA authority over the regulation of tobacco products. This legislation, which was predictably opposed by tobacco companies except for Philip Morris, also banned certain flavorings in cigarettes. The ban excluded menthol additives, which are most often in cigarettes targeted at younger and African-American smokers, thereby igniting a debate concerning who should be protected and how. This resulted in a bill calling for a scientific review of menthol.

After years of mounting criticism for using experts with potential conflicts of interest, the FDA tightened its guidelines to limit these conflicts among members of their advisory committee members. Under the new rules, medical experts with more than a \$50,000 financial interest in companies cannot serve on committees during meetings that review their products or those of their competitors. Those with a financial interest under that amount can serve, but the FDA must consider their participation necessary and issue a waiver. The FDA may also intervene to prohibit the participation of those who may have a conflict even if they meet the financial guideline. Additionally, voting on decisions will be simultaneous rather than sequential. This precludes having some advisors be swayed by the votes of others.

Usual standards and practices on screening for prostate cancer were significantly altered when the U.S. Preventive Services Task Force, which issues guidelines on prevention, recommended that physicians stop screening men over the age of 75 for prostate cancer. The prostate-specific antigen (PSA) test, which has been in use for more than 20 years, was found to be more harmful than beneficial in those older than 75. The harms included anxiety as well as unnecessary biopsies, and surgical costs and complications. The task force also concluded that there is inadequate evidence to determine whether prostate cancer screening in younger men improves treatment outcomes compared with clinical detection of the disease.

In September, tainted infant formula caused several deaths and over tens of thousands cases of illness, including serious kidney problems, in children in China. The formula was found to be contaminated with melamine, an industrial chemical used to artificially increase the protein content of the

product, and 700 tons of the products were initially recalled. While the initial focus was on a single company, the investigation later expanded to more than 20. In addition, the European Union and its constituent countries took action to ban or recall such products because milk products from China are in cookies and chocolates consumed in Europe, and may therefore be tainted as well. Among the companies affected were several international enterprises such as Heinz, Nestlé, Cadbury, Mars and Kraft. The outbreak was a serious setback for China's efforts to assure both its population and foreign buyers about the safety of its products, many of which are made for export. The revelation that complaints about the infant formula had begun in 2007 further undermined the country's attempts at reassuring its citizens and its clients. To complete the cover-up: Chinese journalists knew about the tainted formula for months but were kept from publicizing it until the Olympic games were over. The desire to protect China's image as a gracious host thus trumped the protection of the public's health.

The economic volatility of the different markets and the \$700 million bailout of the credit industry in early fall seemingly eclipsed most health issues. But the final rescue package was “sweetened” with several additions, including one granting coverage of mental services parity with physical health care. This was intended to switch the votes of several representatives who would have otherwise voted against the proposed bill. Traditionally, insurers have set higher co-payments and deductibles and provided more restrictive coverage (fewer visits, fewer hospital days) for mental health services than they do for physical health services. These differences will not be permitted when the parity legislation goes into effect on January 1, 2010. Many insurers will therefore having

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Calculating Your Risk of Death from Disease and Accidents

The *Journal of the National Cancer Institute* has done us all a great favor in publishing an article that provides a rational way to evaluate the multiple health warnings that bombard us almost daily. The article provides simple tables that allow the reader to view their 10-year risk of dying from 10 causes (for men) or 12 causes (for women), with nine overlapping. The researchers chose to analyze both the most common causes of death as well as those diseases that have received particular attention in the media. The list includes heart disease, stroke, cancer (lung, colon, breast, cervical, ovarian and prostate), pneumonia, influenza, AIDS, chronic obstructive pulmonary disease and accidents, as well as death from all causes.

The need for risk information derives from the cacophony of scary warnings emanating from television, magazines, newspapers and the internet. Advocacy groups add their voices to those of pharmaceutical companies. Neither the public nor health professionals have a way

of knowing how to evaluate these multiple messages which can lead to confusion, cynicism, unwise choices or unnecessary use of treatments.

These authors used the National Center for Health Statistics for 2004 and data from the 2004 U.S. Census to calculate age- and sex-specific death rates. The effect of smoking on relative risks of death from various causes came from the American Cancer Society. The calculated risks were put into four tables (two for males and two for females as a function of smoking status, see pages 6 and 7). The tables provide the 10-year risk of dying from a specific disease (see list above), accident, or all causes based on one's sex, age (35 to 75 in five year increments) and smoking status (never, current or former). Risks are presented as the number who will die out of 1000 people of that age within the next 10 years. Thus, the reader can use the tables to answer two important questions: "How big is my risk and how does this risk compare with other risks?"

In men, accidents are the single

largest cause of death until age 50 when heart disease becomes the largest cause. Smoking produces a dramatic increase in risk; only at age 75 do death rates for men who never smoked and current smokers become equal. This apparent disconnect occurs because fewer current smokers are alive at that age who might die from non-smoking-related causes. For smokers, lung cancer becomes a greater risk than heart disease from age 60 on. The harm from smoking led the authors to conclude that, "The effect of smoking on the chance of dying is similar to the effect of adding 5 to 10 years of age [to your current age]."

For a 60 a year-old man who never smoked and who wants to know his risk of dying from colon cancer, the table shows that over the next 10 years, five men out of 1000 will die; the risk of dying from prostate cancer is even lower: 2 men out of 1000 will die over that period. For men who never smoked, heart disease is the greatest cause of death with the chance of dying from heart disease

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to adjust their coverage so that mental health services are treated the same as the rest of the services covered. It is anticipated that the change will affect 113 million people.

November marked the publication of findings from a major research project called the JUPITER study. The study found that the statin Crestor (generic name rosuvastatin) can cut the risk of heart attack, stroke, and death among patients who do not have high cholesterol level but test positive for C-reactive protein, which indicates inflammation in the body. The five-year study, which included

18,000 patients, was cut short after two years because of the statin's apparent benefits. Nevertheless, the Public Citizen Health Research Group questioned some of the results of the study, which was sponsored by the drug company that manufactures Crestor. In the study, people using Crestor had a significantly increased occurrence of newly-acquired diabetes. In addition, Crestor has been associated with muscle deterioration and kidney problems.

Public Citizen petitioned the FDA to immediately ban the diabetes drug Avandia (rosiglitazone) because of the drug's serious risks, including liver failure and an increased risk of heart

attacks, heart failure, bone fractures, anemaia and macular (retinal) edema with vision loss. Lack of evidence that benefits outweigh these risks led the American Diabetes Association and the European Association for the Study of Diabetes to advise against using rosiglitazone, given other treatment options available.

As the *Health Letter* goes to press, the appointment of Tom Daschle as Secretary of the Department of Health and Human Services is all but assured. Daschle is on the record as an advocate for educating the population on the "emptiness of antireform rhetoric" and making the moral argument for change. ♦

Current Screening Recommendations from the U.S. Preventive Services Task Force*

DISEASE	MEN	WOMEN
CANCER		
Lung	Insufficient evidence to recommend screening with either X-ray or low dose CT scanning.	Insufficient evidence to recommend screening with either X-ray or low dose CT scanning.
Colon	Every 10 years starting at ≥ 50 years for those at average risk.	Every 10 years starting at ≥ 50 years for those at average risk.
Prostate	Inadequate evidence to determine if PSA screening improves outcome (< 75 yr); no benefit in men ≥ 75 yrs.	
Breast		Mammography for women > 40 yrs. Screening every other year; [other groups recommend over 50] no data for over 74 yrs. Use accredited screening center with quality assurance standards.
Ovarian		None recommended.
Cervical		Sexually active women 21-65 with a cervix.
COPD (Chronic Obstructive Pulmonary Disease)	Lung function test for those with chronic cough, increased sputum production, wheezing, or dyspnea. Smoking cessation counseling and pharmacologic therapies for smokers.	Lung function test for those with chronic cough, increased sputum production, wheezing, or dyspnea. Smoking cessation counseling and pharmacologic therapies for smokers.
INFECTION		
Pneumonia	Pneumococcal vaccine for those ≥ 65	Pneumococcal vaccine for those ≥ 65 .
Flu	Flu vaccine for those ≥ 50	Flu vaccine for those ≥ 50 .
AIDS	Testing for those ≥ 13 years who are at increased risk for HIV infection.	Testing for those ≥ 13 years who are at increased risk for HIV infection and all pregnant women.
HEART DISEASE	No benefit of ECG*, ETT, or EBCT in adults at low risk of coronary artery stenosis or coronary heart disease; insufficient information in adults at high risk. Recommend screening for high blood pressure ≥ 18 .	No benefit of ECG*, ETT, or EBCT in adults at low risk of coronary artery stenosis or coronary heart disease; insufficient information in adults at high risk. Recommend screening for high blood pressure ≥ 18 .

* Source: U.S. Preventive Services Task Force, <http://www.ahrq.gov/clinic/uspstfix.htm#Recommendations>.

exceeding the chances of dying from lung, colon, and prostate cancers combined at every age.

For a 60 year-old woman who never smoked, the risk of dying from breast cancer over the next 10 years is seven out of 1000. Her risk of

dying from heart disease is twice as high: 14 out of 1000 over ten years, while for a smoker, the risk is 31 out of 1000 and for a former smoker, the risk decreases to 18 out of 1000. Heart disease is the single largest cause of death in women from age 60 on (see

tables on pages 6 and 7).

Whether you smoke or not, to keep your odds of an early death as low as possible, the U.S. Preventive Services task Force (www.ahrq.gov) publishes recommendations for screening. ♦



PASS THE TORCH

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

To participate, visit www.citizen.org/passthetorch

Risk Chart for Men (Current and Never Smokers)†

Find the line closest to your age and smoking status.† The numbers tell you how many of 1,000 men will die in the next 10 years from....

Age	Smoking	Vascular Disease		Cancer			Infection			Lung Disease	Accidents	All Causes Combined*
		Heart Disease	Stroke	Lung	Colon	Prostate	Pneumonia	Flu	AIDS	COPD		
35	Never smoker	1	1						2		5	15
	Smoker	7	1	1	Fewer than 1 death				2		5	42
40	Never smoker	3	1	1	1				2		6	24
	Smoker	14	2	4	1				2	1	6	62
45	Never smoker	6	1	1	1				2		6	35
	Smoker	21	3	8	1		1		2	2	6	91
50	Never smoker	11	1	1	2	1	1		1		5	49
	Smoker	29	5	18	2	1	1		1	3	5	128
55	Never smoker	19	3	1	3	2	1		1	1	5	74
	Smoker	41	7	34	3	1	2		1	7	4	178
60	Never smoker	32	5	2	5	3	2		1	1	5	115
	Smoker	56	11	59	5	3	3		1	16	4	256
65	Never smoker	52	9	4	8	6	3			3	6	176
	Smoker	74	16	89	7	6	5			26	5	365
70	Never smoker	87	18	6	10	12	6			5	7	291
	Smoker	100	26	113	9	10	9			45	6	511
75	Never smoker	137	32	8	13	19	12			6	11	449
	Smoker	140	39	109	11	15	16			60	9	667

† A never smoker has smoked less than 100 cigarettes in his life and a current smoker has smoked at least 100 cigarettes or more in his life and smokes (any amount) now.

* The numbers in each row do not add up the chance of dying from everything combined, because there are many other causes of death besides the ones listed here.

Risk chart for men who currently or have never smoked. The chart indicates the number of men — current smokers (bold type) and never smokers — per 1000 who will die from various diseases and from all causes combined during the next 10 years, beginning at the indicated age. Shaded area indicates age group and disease combinations with less than 1 death per 1000. COPD = chronic obstructive pulmonary disease.

Risk Chart for Men (Former Smokers)*

Find the line closest to your age. The numbers tell you how many of 1,000 men will die in the next 10 years from...

Age	Vascular Disease		Cancer			Infection			Lung Disease	Accidents	All Causes Combined
	Heart Disease	Stroke	Lung	Colon	Prostate	Pneumonia	Flu	AIDS	COPD		
35	2	1	1	Less than 1 death				2		5	23
40	4	1	1	1	1			2		6	34
45	10	1	4	1	1	1		2	1	6	49
50	17	2	7	2	1	1		1	2	5	72
55	27	3	13	3	2	1		1	7	4	107
60	41	6	22	5	3	2		1	12	5	166
65	60	11	32	7	6	4			20	5	247
70	90	18	44	10	11	7			34	7	362
75	135	31	53	12	18	14			50	11	519

* A former smoker has smoked at least 100 cigarettes in his life but no longer smokes. The numbers in each row do not add up the chance of dying from everything combined, because there are many other causes of death besides the ones listed here.

Risk chart for men who used to smoke. The chart indicates the number of male former smokers per 1000 who will die from various diseases and from all causes combined during the next 10 years, beginning at the indicated age. Shaded area indicates age group and disease combinations with less than 1 death per 1000. COPD = chronic obstructive pulmonary disease.

Risk Chart for Women (Current and Never Smokers)†

Find the line closest to your age and smoking status†. The numbers tell you how many of 1,000 women will die in the next 10 years from...

Age	Smoking	Vascular Disease		Cancer					Infection			Lung Disease	Accidents	All Causes Combined #
		Heart Disease	Stroke	Lung Cancer	Breast Cancer	Colon Cancer	Ovarian Cancer	Cervical Cancer	Pneumonia	Flu	AIDS	COPD		
35	Never smoker	1			1						1		2	14
	Smoker	1	1	1	1						1		2	14
40	Never smoker	1			2	1			Fewer than 1 death			1	2	19
	Smoker	4	2	4	2						1	1	2	27
45	Never smoker	2	1	1	3	1	1				1		2	25
	Smoker	9	3	7	3	1	1		1		1	2	2	45
50	Never smoker	4	1	1	4	1	1						2	37
	Smoker	13	5	14	4	1	1		1			4	2	69
55	Never smoker	8	2	2	6	2	2	1	1			1	2	55
	Smoker	20	6	26	5	2	2	1	1			9	2	110
60	Never smoker	14	4	3	7	3	3	1	1			2	2	84
	Smoker	31	8	41	6	3	3	1	2			18	2	167
65	Never smoker	25	7	5	8	5	4	1	2			3	3	131
	Smoker	45	15	55	7	5	3	1	4			31	3	241
70	Never smoker	46	14	7	9	7	4	1	4			5	4	207
	Smoker	66	25	61	8	6	4	1	7			44	4	335
75	Never smoker	86	30	7	10	10	5	1	8			6	7	335
	Smoker	99	34	58	10	9	4		14			61	7	463

† A never smoker has smoked less than 100 cigarettes in her life and a current smoker has smoked at least 100 cigarettes or more in her life and smokes (any amount) now.

* The numbers in each row do not add up the chance of dying from everything combined, because there are many other causes of death besides the ones listed here.

Risk chart for women who currently or have never smoked. The chart indicates the number of women — current smokers (bold type) and never smokers — per 1000 who will die from various diseases and from all causes combined during the next 10 years, beginning at the indicated age. Shaded area indicates age group and disease combinations with less than 1 death per 1000. COPD = chronic obstructive pulmonary disease.

Risk Chart for Women (Former Smokers)*

Find the line closest to your age. The numbers tell you how many of 1,000 women will die in the next 10 years from...

Age	Vascular Disease		Cancer					Infection			Lung Disease	Accidents	All Causes Combined
	Heart Disease	Stroke	Lung Cancer	Breast Cancer	Colon Cancer	Ovarian Cancer	Cervical Cancer	Pneumonia	Flu	AIDS	COPD		
35	2	1	1	1						1		2	15
40	2	1	2	2						1	1	2	26
45	5	1	3	3	1	1				1	1	2	37
50	7	1	5	4	1	1		1			3	2	52
55	10	3	11	6	2	2	1	1			7	2	80
60	18	5	17	6	3	3	1	1			14	2	125
65	34	9	23	8	5	3	1	3			26	3	191
70	59	18	32	9	7	4	1	5			42	4	302
75	101	34	35	10	9	4	1	10			52	7	452

*A former smoker has smoked at least 100 cigarettes in her life but no longer smokes. The numbers in each row do not add up the chance of dying from everything combined, because there are many other causes of death besides the ones listed here.

Risk chart for women who used to smoke. The chart indicates the number of female former smokers per 1000 who will die from various diseases and from all causes combined during the next 10 years, beginning at the indicated age. **Shaded area** indicates age group and disease combinations with less than 1 death per 1000. COPD = chronic obstructive pulmonary disease.

Product Recalls

October 21, 2008 - November 15, 2008

This chart includes recalls from the Food and Drug Administration (FDA) Enforcement Report for drugs and dietary supplements, and Consumer Product Safety Commission (CPSC) recalls of consumer products.

DRUGS AND DIETARY SUPPLEMENTS

The recalls noted here reflect actions taken by a firm to remove a product from the market. Recalls may be conducted on a firm's own initiative, by FDA request or by FDA order under statutory authority. If you have any of the drugs noted here, label them "Do Not Use" and put them in a secure place until you can return them to the place of purchase for a full refund. You can also contact the manufacturer. If you want to report an adverse drug reaction to the FDA, call (800) FDA-1088. The FDA Web site is www.fda.gov. Visit www.recalls.gov for information about FDA recalls and recalls issued by other government agencies.

Recalls and Field Corrections: Drugs – CLASS I

Name of Drug or Supplement; Problem; Recall Information

Rize 2, The Occasion Capsules Sexual Performance Enhancer for Men, 469mg proprietary herbal blend, packaged in 1 capsule blister cards and 3, 12 and 30 capsule bottles; Unapproved New Drug; product tested positive for thio-methisosildenafil an analog of sildenafil. Sildenafil is the active ingredient of a FDA-approved drug used for Erectile Dysfunction (ED). Lot #s: CG-84 exp. date 11/2010; GD-98 exp. date 08/2010; CC-06 exp. date 06/2010; 709 exp. date 09/2010; CG-79 exp. date 11/2010; Updated to all lots, July 28, 2008. Updated to all lots on July 28, 2008; Devine Dist. DBA Jack Dist.

Rose 4 Her Capsules Sexual Enhancer for Women, 427mg proprietary herbal blend, packaged in 1 capsule blister cards and 3 capsule bottles; Unapproved New Drug; product tested positive for thio-methisosildenafil an analog of sildenafil. Sildenafil is the active ingredient of a FDA-approved drug used for Erectile Dysfunction (ED). Lot #s: CG-78 exp. date 11/2010. Updated to all lots on July, 28 2008; Devine Dist. DBA Jack Dist.

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

Bacitracin ointment, USP, net wt. 1 oz (28.4 g), Bacitracin Zinc, USP 500 units, made in USA; 16,559 units; Product exceeds microbial specifications. Lot #: L033B06A exp. date 02/2009; Vintage Pharmaceuticals LLC.

Daytrana (methylphenidate transdermal system), 3.3mg/hr patches, 30 patches per box, Rx only; 343,830 patches; Product does not meet peel force specification for removing patch liner. Lot #: 2750211, exp. date 10/31/2009; Shire PLC.

Bellamine-S Tablets, Rx only, 100 Tablets; cGMP Deviations; lack of stability indicating methods. All lots within expiry; The Harvard Drug Group.

Fenoglide (Fenofibrate) Tablets, 120 mg, 7 Count Bottles, Rx only, Physician Samples; 56,268 bottles; Failed Dissolution Specifications; 3-month stability. Lot #: 0704784; Sciele Pharma, Inc.

Chewable Tri-a-vite w/FL Tablets, 1 mg, Rx only, 100 Tablets; cGMP Deviations; lack of stability indicating methods. All lots within expiry; The Harvard Drug Group.

Formula B Tablets (Vitaplex), Rx only, 100 Tablets; cGMP Deviations; lack of stability indicating methods. All lots within expiry; The Harvard Drug Group.

Daytrana (methylphenidate transdermal system), 1.6mg/hr patches, 30 patches per box, Rx only; 469,110 patches; Product does not meet peel force specification for removing patch liner. Lot #s: 2819811, exp. date 12/2009; 2764211, exp. date 10/2009; Shire-US Inc.

Guanfacine Tablets, USP, 1 mg, 100 Tablets, Rx only; cGMP Deviations; lack of stability indicating methods. All lots within expiry; The Harvard Drug Group.

Hemorrhoidal HC 25 mg suppositories, hydrocortisone acetate, 12 and 24 count, Rx only; 62,088 units; Product exceeded microbial limit for Total Aerobic Count, Total Yeast and Mold Count. Lot #s: L038A07A, exp. date 07/2011; L038A07B exp. date 07/2011; Vintage Pharmaceuticals LLC.

Hyoscyamine Sulfate Tablets SL, 0.125 mg, Sublingual/Oral/Chewable, Rx only, 100 Tablets; cGMP Deviations; lack of stability indicating methods. All lots within expiry; The Harvard Drug Group.

Hyoscyamine Sulfate Tablets, 0.125 mg, Rx only, 100 tablets; cGMP Deviations; lack of stability indicating methods. All lots within expiry; The Harvard Drug Group.

Levothroid (levothyroxine sodium tablets, USP), 50 mcg, packaged in 100- and 1,000-tablet bottles; 49,103/100-tablet bottles & 1,932/1,000-tablet bottles; Product may not maintain potency over shelf life. Lot#s: 070743, exp. date 07/2008; 070744, exp. date 07/2008; 070745, exp. date 07/2008; exp. date 07/2008; 080709, exp. date 07/2008; 080710, exp. date 07/2008; 080711, exp. date 07/2008; 080735, exp. date 08/2008; 080740, exp. date 08/2008; Lloyd Inc.

Major Pharmaceuticals Lisinopril Tablets, USP; 10 mg; packaged in 45-ct. bottles and 90-ct. bottles; Rx only; 36,922/45-ct. and 2,273/90-ct. bottles; Some of the tablets may contain metal. Lot #s: L-1406 (45-ct. bottles), exp. date 06/2010; L-1406A (90-ct. bottles), exp. date 06/2010. Legacy Pharmaceutical Packaging LLC.

Micardis® HCT (telmisartan and hydrochlorothiazide) Tablets, 40mg/12.5mg, 7-tablet blister strip in folding carton, professional sample, Rx-only; 103,284 units; Professional sample folding cartons labeled Micardis® HCT 40mg/12.5mg may contain blister strip for Micardis® HCT 80mg/12.5mg tablets which could result in double intended dose of telmisartan. Lot #: 605396A, exp. date 05/2009; Boehringer Ingelheim Pharmaceuticals, Inc.

Thyro-Tab (levothyroxine sodium tablets), 0.050 mg, packaged in bulk drums intended for repackaging, Rx only; 19,296,674 tablets; Product may not maintain potency over shelf life. Lot #s: HA17607, exp. date 07/2008; HB17607, exp. date 07/2008; HC17607, exp. date 07/2008; HA21107, exp. date 08/2008; HB21107, exp. date 08/2008; Lloyd Inc.

Multi Vita-Bets with Fluoride Chewable Tablets, Multivitamin and Fluoride Supplement, 0.25 mg, Rx only, 100 and 1000 Tablets; cGMP Deviations; lack of stability indicating methods. All lots within expiry; The Harvard Drug Group.

Multi Vita-Bets with Fluoride Chewable Tablets, Multivitamin and Fluoride Supplement, 0.5 mg, Rx only, 100 and 1000 Tablets; cGMP Deviations; lack of stability indicating methods. All lots within expiry; The Harvard Drug Group.

Nystatin USP, non-sterile powder for Rx Compounding; 3,988 bottles; Product is absorbing water over shelf life due to inadequate tightening of cap at time of manufacture. Lot #s: (200)8011850; (200)8152717; Paddock Laboratories, Inc.

Perphenazine tablets, USP, 2 mg, 4 mg, 8 mg, 16 mg, Rx only, 100 and 500 tablets; 436,184 bottles; Cracking and splitting of tablets. Many lots. Vintage Pharmaceuticals LLC.

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THE PUBLIC CITIZEN HEALTH RESEARCH GROUP

Health Letter

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CONSUMER PRODUCTS

Contact the Consumer Product Safety Commission (CPSC) for specific instructions or return the item to the place of purchase for a refund. For additional information from the Consumer Product Safety Commission, call their hotline at (800) 638-2772. The CPSC web site is www.cpsc.gov. Visit www.recalls.gov for information about FDA recalls and recalls issued by other government agencies.

Name of Product, Problem, Recall Information

5 Tier Lighted Showcases. The lighted showcase's plug adaptor can overheat and melt the adaptor's plastic housing, posing a fire hazard. Seventh Avenue, (800) 991-4442 or www.seventhavenue.com.

Best Friends Yin Yang Necklaces Sets. The recalled necklaces contain high levels of lead. Lead is toxic if ingested by young children and can cause adverse health effects. (866) 859-9281 or www.claire.com.

Blue Ember Gas Grills. The gas grills can be assembled improperly exposing the gas burner hoses to excessive heat, posing fire and burn hazards to consumers. Keesung Manufacturing Co. Ltd. and Unisplendor Corp., (866) 740-7849 or www.fiestagasgrills.com.

Casper the Friendly Ghost® Halloween Mini-Figurines. The recalled Halloween figurines contain high levels of lead in the paint. Coyne's & Company Inc., (800) 336-8666 or www.coyne.com.

Children's Two-Way Radios. The rechargeable batteries in the radios can leak electrolyte, posing a chemical burn hazard to consumers. Cobra Electronics, (888) 252-9889 or www.cobra.com.

CORAL Swim 'N Score Pool Stix. Children can fall or land on these dive sticks in shallow water and suffer impalement injuries. Eye and other facial injuries are also possible. In April 2001, CPSC banned certain types of dive sticks. Modell's Sporting Goods, (800) 275-6633 or www.modells.com/recall.

Cybox Treadmills. The treadmills can speed up unexpectedly while in use due to a malfunction with the lower control board, posing a fall hazard to consumers. Cybox International Inc., (866) 897-9199 or www.Cyboxintl.com.

Duracell 130W Combo Power Adapters used with notebook computers. The adapters can fail and overheat. This can pose a burn hazard to consumers. Battery-Biz Inc., (800) 780-6552 or www.battery-biz.com.

DYMO® LabelWriter® Power Adapters used with printers. The power adapters can fail, causing the printer to overheat. This can pose a burn hazard to consumers. DYMO, (888) 658-3904 or www.dymo.com.

Fit & Fresh™ Smooth Blend Mixers. While placing the cup on or off the base of the mixer, the mixer can be unexpectedly turned on, activating the blade. This can pose a serious laceration hazard to consumers. MEDport LLC, (800) 858-8840 or www.medportllc.com.

Gas Match and Ready, Aim: Fire Multi-Purpose Lighters. The multi-purpose lighters fail to meet federal safety standards because they might not contain a child-resistant mechanism, posing a potential fire and burn hazard to young children. YMCA Trading Inc., (866) 950-9622 or tradingymca@hotmail.com.

Ghost Tealight Holders. The recalled tealight holder can ignite posing a fire and burn hazard to consumers. Crate & Barrel, (800) 451-8217.

Homelite Chain Saws. The chain brake can fail to stop the chain on its first application, posing a risk of laceration to consumers. Homelite Consumer Products Inc., (800) 242-4672 or www.homelite.com.

Honda Off-Road Competition Motorcycles. The weld on the right side of the swing arm can fail, causing the rider to lose control and crash. This could pose a risk of injury or death to riders. American Honda Motor Co. Inc., (866) 784-1870 or www.powersports.honda.com.

Krylon Outdoor Spaces UV Fabric Protector. Overexposure to fumes, vapor or spray mist from the product can pose a serious respiratory hazard to consumers. The Sherwin-Williams Co., (888) 304-3769 or www.krylon.com.

Lithium-Ion Batteries used in Hewlett-Packard, Toshiba and Dell Notebook Computers. These lithium-ion batteries can over-

heat, posing a fire and burn hazard to consumers. Sony Energy Devices Corporation, Hewlett-Packard Co.: (800) 889-2031 or www.hp.com/support/BatteryReplacement; Toshiba: (800) 457-7777 or <http://www.bxinfo.toshiba.com>; Dell: (866) 342-0011 or www.dellbatteryprogram.com.

Mini-Telesvisor Toys. Surface coating on the toy television could contain excessive levels of lead, violating the federal lead paint standard. OKK Trading, (877) 655-8697 or www.okktoys.com.

Murray Front Engine Riding Lawn Mowers. The two-piece fuel tanks on the riding mowers can separate at the seam, causing fuel to leak. This can pose fire and burn hazards to consumers. Briggs & Stratton Power Products Group LLC, (800) 227-3798 or www.briggsandstratton.com.

My Little Train Classics Toy Trains. The recalled toy contain small parts which can detach, posing a choking hazard to young children. JA-RU Inc., (800) 231-3470.

Rage Wireless Guitars. A circuit board defect can cause AA batteries used in the guitar to leak if the batteries are installed incorrectly, posing a risk of chemical burns to consumers. Performance Designed Products LLC, (800) 331-3844 or www.pdp.com.

Rechargeable Batteries and Recharging Station for Didj Custom Gaming System. The rechargeable batteries included with the Recharging Station can overheat if the gaming system is placed into the recharging base upside down, posing a burn hazard to consumers. LeapFrog Enterprises Inc., (800) 701-5327 or www.leapfrog.com/recall.

Serta Zipper-Covered Foam Core Mattresses. The mattresses fail to meet the mandatory federal open flame standard for mattresses, posing a fire hazard to consumers. Serta International Mattress Co., (866) 675-3853 or www.serta.com.

Shimano Dura Ace Carbon Clincher Wheels for Bicycles. Rim surface and spoke hole plugs on the wheel can cause a puncture to the inner tube, resulting in a flat tire. This can cause the rider to lose control and fall. Shimano American Corp., (800) 353-4719 or bike.shimano.com.

Toy Xylophones. Surface paint on the toy xylophone contains excessive levels of lead, violating the federal lead paint standard. King Import Warehouse, (972) 241-5464.

Wooden Toys. Small parts can detach and break from the toy, posing a choking hazard to young children. In addition, the size of the rattle handle violates voluntary rattle standards. Earth Friendly LLC, (888) 360-6292 or www.earthfriendlyllc.com/recall.

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National Women's Law Center titled *Nowhere to Turn: How the Individual Health Insurance Market Fails Women* points out the discrimination to which women may be subjected to in the individual market.

The most egregious barrier facing women is having some insurers deny them coverage altogether. Women who have had a c-section may be rejected for coverage unless they have been sterilized. And survivors of domestic violence may be rejected in nine states and DC.

Furthermore, most individual health insurance policies exclude maternity care. Instead, such care can be purchased through a supplemental policy which is often expensive and restricted in scope. Benefits may be capped, and often include a waiting period. Women may therefore be left with high out-of-pocket expenses.

Gender rating allows insurance companies in most states to charge men and women different premiums for the same coverage. Most charge women more than men until age 55, after which some charge men more. The differences fluctuate widely within and between states, and can be quite high: in Columbus, Ohio, for example, a 30-year-old woman pays 49 percent more than her male counterpart for Anthem's Blue Access Economy Plan. Companies base their premiums on "experience," meaning claims experience, and justify the differential as reflecting women's greater utilization of health services, particularly during the childbearing years. As a result, women are penalized for their gender in most states, the exceptions being Minnesota, Montana, New Hampshire and North Dakota, which explicitly prohibit insurers from considering gender when setting health insurance rates.

State-by-state reform addresses a pressing issue, but does not ensure equity for women in general. Assigning a different price tag to health care on the basis of gender contradicts the values held by most Americans. Those who believe in the social insurance will see this as violating the principle of solidarity. And those who purport to protect family values should be offended by the fact that the health of women and their offspring is treated as a commodity, both purchasable and expendable.

Discrimination against people seeking insurance based on age, gender, health status, occupation and location is clearly another strong argument in favor of junking our current multi-payer health insurance system in favor of a single payer system. Equitably socializing the costs of life-important health care onto the whole population is a must. ♦

Is the Uterus a Pre-Existing Condition?

Group health insurance is based on the principle of pooling the health care risks of a group of people to make the individual costs predictable and manageable. The larger the numbers, the more likely that high risks and low risks will offset each other, thereby leveling costs. One of the many attractive features of a single-payer health care system is that with everyone in the group, the costs are indeed level and, for example, Medicare premiums are the same for everyone. Further, the average health risk for those in the pool will not vary markedly over time. But under our current, increasingly unworkable multiple-payer system, the largely for-profit health coverage providers need to maintain the attractiveness of the

risk pool to different segments of the population with different expected costs. They therefore set premiums based on factors associated with differences in health expenditures. These include age, gender, health status, occupation and location. This is especially toxic for those who must purchase their own insurance.

For those who are not covered by an employer or other group, who are not covered under Medicare, or who earn too much to qualify for Medicaid or other public programs, there is no recourse other than to buy insurance in the individual market. This market is very unevenly regulated. As a result, buyers lack many of the protections that employer-based health plans are required to have. A recent report by the



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