

Health Letter

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Cheap Trick: Bush's health-savings accounts are a bargain — provided you never get injured or sick

The following article was written by Barbara T. Dreyfuss, a freelance writer who was a Wall Street health-policy analyst for many years. It is reproduced with the permission of the American Prospect, in which it appeared in September of this year as part of a series of articles entitled Axis of Drivel.

In 1996, Terry Johnson, the human-resources director for Ada County, Idaho, was excited about his new health-care coverage. He had just helped the county become the first in the United States to offer employees a medical savings account (MSA) as an alternative to traditional indemnity health insurance, and he was eager to try it. The accounts would be exempt from state taxes up to \$2,000.

Under the program, Johnson would contribute \$900 to this account and his employer, the county, would contribute the remaining \$1,100. Johnson could use that money for medical expenses, and if he remained healthy and didn't use it up that year, it would carry over to the next year. He could even withdraw the money for any other use, although he would pay taxes on it (and if he was not yet 59, he would also pay a 10-percent penalty). Along with this he would have an insurance plan. The one catch: He would be responsible for the first \$2,000 in costs should he become sick. But the

idea was that the MSA would be there to cover this high deductible.

"So I was thinking it's going to be great for me because at least I would have something to show for my good health at the end of the year," says Johnson. As a generally healthy person, he says, he felt that traditional insurance was a waste. "I just never got anything out of that benefit."

But Johnson made a bad gamble. That year, he decided to go hang gliding. "I broke my ankle," he notes ruefully. "And that pretty much ate up the funds because I had to have two operations." Because the county paid into the savings account in installments, and had only put in \$400 when Johnson sought medical care, not only did he have to pay the \$900 deductible employees were responsible for, he also had to front the full \$2,000 deductible "right off the bat." If he had stayed in his traditional insurance plan, he would have had a \$100 deductible and 20-percent co-

payments for doctor services, up to an \$800 limit. While both plans may have cost him about the same amount in the end (it is unclear what the co-payments would have amounted to under the traditional plan), the MSA was definitely not the boon he had hoped for.

Things did not go much better for the county. It did save \$39,000 in insurance premiums for its employees, but that was only about half what it had expected, as fewer people than anticipated enrolled in the catastrophic insurance. Worse, Ada officials were shocked that, as a result of the MSA, premiums for the employees who remained in the traditional insurance plan were going to skyrocket. "There was cherry-picking," Johnson told me, "because the MSAs drew all the healthy folks that would otherwise subsidize those that stayed in the rich traditional plan." With the traditional plan serving only the sick-

continued on page 2

CONTENTS

You Have Reached the Medicare Program

Where inaccurate information is the order of the day.....5

Product Recalls

August 18 to September 14, 2004

Contact lenses, laser printers, and kids' bike helmets to watch out for6

Outrage of the Month

Whistleblowers calling the shots.....12

CHEAP TRICK, *from page 1*

er employees, its costs mounted. In fact, the insurance company Regence Blue Shield of Idaho told the county that if it continued with the MSAs, it could expect premiums to jump an astronomical 15 percent — at a time when health-insurance-premium increases were the lowest in 30 years. (Nationally, employer premiums increased 2.1 percent in 1997 and 0.5 percent in 1996, according to a KPMG Peat Marwick survey.) At the end of 1997, the county dropped the MSA option.

Despite skepticism of MSAs by many employers, unions, and workers, promotion of such tax-free savings accounts and high-deductible insurance plans has lived on thanks to a band of ideologically minded conservative Republicans who have pressed for legislation and regulations to make them more attractive. With the arrival of George W. Bush in the White House, their efforts succeeded. Now, with health-care costs rising at double-digit rates and the latest data available showing more than 43 million Americans uninsured in 2002, health care is again a major campaign issue. And at the core of Bush's health-care campaign platform is expansion of these schemes.

Bush called for that in his State of the Union address and lauds them at virtually every campaign stop. In March, at a discussion sponsored by the Chamber of Commerce, he declared, "I've made my stand. I believe that the best health-care policy is one that trusts and empowers consumers, and one that understands the market."

Tax-free MSAs, along with high-deductible plans, are simply a way to make individuals pay a larger share of their health-care costs. Conservatives put a pretty face on the system, calling it "consumer-directed health care," a term designed to play off the public backlash against the tight restrictions that were imposed in the past by HMOs. They argue that consumers, not insurers, should determine what care they need. And they should pay for it themselves, with money that employers and

employees put aside in various tax-free accounts. People will become wise shoppers, they argue, look for bargains, and purchase only the care they need. Conservatives predict that this will drive down costs. And for major medical problems, they argue, people will have catastrophic insurance.

Nixon administration economist Jesse Hixson is often credited with developing the concept of health banks to fund health care. But it was Patrick Rooney, former head of Golden Rule Insurance Company, who spearheaded the political organizing that ultimately got state and then federal action. Rooney has poured more than a million dollars into Republican coffers since 1989. Golden Rule, now part of UnitedHealthcare and run by Rooney's daughter, was a pioneer in health savings account (HSA) schemes. Rooney's zeal for MSAs dates to a 1990 meeting with John Goodman, founder of the National Center for Policy Analysis (NCPA), who in turn had been converted to the cause by Hixson. Rooney joined the center's board and helped fund it. The NCPA, along with a bevy of conservative think tanks — including the Galen Institute, the American Enterprise Institute, the Cato Institute, and The Heritage Foundation — are the champions of consumer-directed care. Rooney also pulled together a group of small insurers, which founded the Council for Affordable Health Insurance in 1992, to promote it.

Despite those efforts, the brave new world of consumer health care didn't really begin on the national level until 1996. (A number of states like Idaho had already allowed accounts exempt from state taxes to be used for health expenses.) After a fierce partisan battle, Republicans enacted legislation to allow tax-free accounts, called MSAs, but only for small businesses and self-insured people. Consumers were also required to buy high deductible insurance, which also required consumer co-payments. Democratic opposition, led by Senator Ted Kennedy, limited the number of people in such plans to 750,000. The

Government Accounting Office reported that after two years, only 50,172 people were enrolled.

Then Bush, pressured by conservative Republicans on Capitol Hill and pro-tax-cut and small-business groups, came into office, determined to dramatically speed up the adoption of these tax breaks and insurance schemes. First the Treasury Department, in 2002, approved Health Reimbursement Accounts, another form of tax-free fund. Paid by employers, employees can use them to pay health-care costs. But these were limited in appeal because they were not portable from job to job and workers could not contribute to them.

Then, last November, with strong help from the White House, Republican congressional leaders succeeded in attaching to the Medicare prescription-drug bill a tax-free account that corrects these problems and threatens to dramatically alter health insurance as we know it. Former House Speaker Newt Gingrich, a strong opponent of a government-run Medicare program and of comprehensive employer insurance programs, was instrumental in persuading reluctant Republicans to vote for the Medicare bill because it allows these tax-free funds, dubbed HSAs. Gingrich lauds them as "the single most important change in health-care policy in 60 years." The new law now allows funds to be contributed by both employers and employees, rolled over if not used, and taken from job to job. It's also available to everyone. But it requires people with the savings accounts to have only a catastrophic insurance plan with a high deductible.

Experts believe that, thanks to the new law, consumer-directed health care is about to take off. Strapped with 14-percent premium increases in 2003, employers are desperate for a strategy to cut costs, and HSAs are a more subtle way to shift costs on to workers than merely raising premiums. Many employers appear ready to offer the HSA-catastrophic plans as an option alongside traditional insurance, but others will offer employees various savings-account-high-deductible insurance options only.

President Bush and administration officials are on a crusade to get the

word out to employers. Almost immediately after Bush signed the Medicare law in December, the Treasury Department issued guidelines to jumpstart the plans and, in all, eight have been issued in the eight months since the law passed. On May 19, Treasury Secretary John Snow told a Senate Aging Committee hearing that HSAs are "one of the single best ideas" to deal with rising health-care costs.

Republicans also see HSAs as a way to slash budgets for federal and state employees, both by shifting health costs on to workers and by reducing overall utilization. They would like to use them in Medicaid and Medicare, too. In April, the Office of Personnel Management asked insurance carriers for proposals to offer HSAs to federal employees next year. Gingrich, now at his own think tank, has launched a project to promote these accounts to states. It's aimed at having all state-employee health plans and Medicaid programs offer HSAs within three years. Gingrich is also lobbying Congress to open Medicare to HSAs. And Lumenos Inc., which administers consumer-directed plans for employers who directly pay employee health expenses, has already been talking with top officials in three states about setting up such a plan for disabled Medicaid enrollees.

On a state level, no one has been a more ardent supporter of HSAs than the president's brother, Florida Governor Jeb Bush. After signing legislation June 14 requiring all insurers in Florida to offer HSAs to small businesses, he started a two-month road show, hosting town-hall meetings throughout the state to promote them. Press reports indicate that Bush wants to provide HSA-type accounts for Florida's Medicaid recipients as well.

The problem is, these accounts may be "one of the single best ideas," as Snow put it, to deal with rising health-care costs for employers, but they are one of the worst for individual employees. While Terry Johnson was lucky to have an insurance package that limited his liability to \$900, most employers will not be so gener-

ous, leaving anyone foolish enough to sign up for an HSA with the possibility of enormous health-care debts. First, the new Medicare law calls on families to pay at least the first \$2,000 in costs; individuals must pay, at a minimum, the first \$1,000, but the deductible is up to the employer, and many plans will likely require much higher ones. The current average deductible in insurance plans is \$300 for an individual and \$600 for families.

Supporters argue that employers can offset these costs by contributing to the savings account. But the whole premise of this approach is that people must feel some pain in paying for health care or they won't be wise consumers, so no employer is going to totally cover the deductible. In fact, a survey of almost 1,000 companies, most with more than 500 employees, conducted by Mercer Human Resource Consulting and released in April, found that 39 percent did not anticipate putting any money into savings accounts.

Besides the huge deductibles, consumers will have co-payments as well. While the law does set limits for total out-of-pocket spending, deductibles, and co-payments for in-network care, these are set at a high \$5,000 for individuals and a whopping \$10,000 for families. In fact, consumers can get stuck with even higher medical bills. First, the liability limits only apply if people use doctors and hospitals in the insurer's approved network. If a person decides, for whatever reason, to go to a provider outside the network, there is no ceiling on what he or she pays out of his or her own pocket. What's more, the insurance and spending caps only apply to "covered" care. Republicans are already trying to reduce the scope of care that insurers are required to cover. In that regard, House Speaker Dennis Hastert has endorsed legislation to allow people to buy insurance in other states if their own imposes too many mandates on insurers.

While some supporters argue that employees will have lower premiums to pay, even if their deductibles and co-pays rise, that is not necessarily so. How much employees pay in premi-

ums will be up to the employer. More generally, "Employers will use it as a reason to shift costs on to employees or get out of the business altogether," says JoAnn Volk, legislative representative for the AFL-CIO. "And they will say, 'I'll make a contribution to your account, [then] you're on your own.'" Neil Trautwein, the National Association of Manufacturers' assistant vice president for human-resources policy, agrees. "We see the wheels coming off employer-based health care," he says. "Costs have risen to such an extent, and Americans are aging. We really see increasing problems with maintaining the employer-based model into the future." He worries that unless Americans can be persuaded to buy into the idea of consumer-directed care, "increasingly calls will come for a government-run system."

Chris Jennings, deputy assistant to President Clinton on health policy and now an informal adviser to the John Kerry campaign, says that concern about workers losing employer insurance coverage is one of Kerry's problems with HSAs. Jennings points to a recent study by MIT economist Jonathan Gruber, which warned that HSAs could increase the number of uninsured as employers use HSAs as an excuse not to provide coverage.

Some smaller employers have started to use HSAs in the six months the law has been in effect, although the law passed too late in the benefit enrollment cycle for most large employers to make the shift. But it looks like they'll catch up next year. The Mercer survey found that nearly 75 percent are "very or somewhat likely" to offer an HSA by 2006. Another survey, by the National Business Group on Health, of 159 of the nation's largest companies found one-third expecting to offer a consumer-directed plan next year. The Mercer study also found that nearly half of large employers surveyed hope that HSAs will let them back away from retiree benefits, as workers will now be able to accumulate tax-free cash to pay for retirement health costs.

continued on page 4

CHEAP TRICK, from page 3

Forcing workers to shoulder a much larger part of their medical expenses to cut health-care costs for employers is likely to harm consumers in other ways, too. To begin with, Jennings warns that these plans, to the extent that they reduce overall costs, do so by “reduc[ing] the use of desirable as well as undesirable care.” In other words, people will stop getting the care they need in addition to the care they don’t need.

Initial results at firms with tax-free accounts show that these accounts cut use of services. People go to the doctor less often, have fewer surgeries, make fewer hospital visits, and use fewer medicines. Textron Inc., which manufactures aircraft and other products, has shifted all its employees into consumer-directed plans. The company started in 2002 with the 1,500 employees in its corporate office center and at Textron Financial. An analysis of two years of claims data for the pilot program enrollees, compared with when they had traditional PPO insurance, found overall medical usage down 7 percent, inpatient hospital admissions down 22 percent, outpatient hospital visits down 6 percent, emergency-room visits for less severe conditions down 9 percent, total surgeries down 11 percent, physician office visits up 3 percent, diagnostic tests down 5 percent, and total prescriptions down 1 percent. Aetna found a similar pattern for 13,500 people who enrolled since January

2003 in its health reimbursement arrangement.

Conservative Republicans would applaud these numbers. But what happens if the upshot is many more people not getting the treatment they

...what happens if the upshot is many more people not getting the treatment they need?

need? “It leads to a reduction in care, period, including care that’s needed,” warns Karen Davis, president of the Commonwealth Fund, a foundation that sponsors health-policy research. Not only will more people end up waiting until illnesses are urgent before they go for care, she says, but public health could be affected as people avoid going to the doctor for what they think are coughs and colds but turn out to be more serious infectious diseases.

Another long-term drawback of MSAs and high-deductible plans will be rising premiums for those with traditional insurance. Congressional Budget Office analysts, citing Ada County’s experience, warned that other such experiences and

“economic theory” indicate those who would choose such plans would be the “relatively young and healthy.” Despite denials by HSA advocates, preliminary data confirms this. Humana Chief Actuary John Bertko stated at a Joint Economic Committee hearing in February that at his own company, early evidence showed that those who went into these types of plans “are clearly healthier.”

That leaves the less healthy covered by traditional comprehensive insurance, which drives premiums up. A “death spiral for comprehensive coverage is definitely a risk,” warns Edwin Park of the Center on Budget and Policy Priorities. This breaks down the “basic function of insurance,” warns Davis. “The purpose of insurance is to collect premiums from everyone, healthy and sick, and you use the money to help the sick pay their medical expenses.” Concerned about this, many insurers offer employers — and employers offer employees — only these products as a total replacement for traditional insurance. Bertko told the Joint Economic Commission that Humana, for example, would do this in order to “maintain the integrity of this risk pool.”

Even conservative champions of consumer-directed health plans may find them unsatisfactory in the long term, says Liz Fowler, a Democrat staffer on the Senate Finance Committee. Fowler stood up at a Hill forum on consumer-directed health

continued on page 5

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THE 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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You Have Reached the Medicare Program. Please Hold for the Next Available Source of Inaccurate Information.

The Medicare program sprawls like almost no other in the federal government: each year, 41 million elderly and disabled beneficiaries generate 930 million claims at a cost to the taxpayer of \$271 billion. You'd think that at least they'd get the phones to work. You'd be wrong.

A program this complex is bound

to generate a cascade of questions both from beneficiaries and from providers (mostly doctors and hospitals). To function efficiently, the program must be able to quickly and accurately answer those questions; a Medicare web site serves this function in part. Other inquiries are handled by interactive voice

response (IVR), the often cloying system in which the caller has to navigate a tangled telephone tree to get his or her question answered.

The program has to cope with a barrage of 21 million calls from providers annually, 52% of which are handled by the IVR system. The

continued on page 6

CHEAP TRICK, from page 4

care, sponsored by the bipartisan Alliance for Health Reform, to tell the panelists who back the concept to try it before they tout it. Fowler said she is enrolled in a health reimbursement account that includes a \$1,000 savings account contributed by her employer, the government. She is responsible for another \$600 before insurance — which includes a 20 percent co-payment for in-network care (40 percent for out of network) — kicks in. How well has it worked?

"Let me tell you," she said at the gathering, "my experience has been awful. I don't consider it consumer-directed, and it certainly is not consumer-friendly. I have a Ph.D. in health policy and also a law degree, and if that's not an informed consumer It's impossible to tell what's covered. I had allergies ... [and] a bum knee and needed physical therapy. They still can't tell me exactly how much I owe. Some things are paid for under the \$1,000 at first, but not covered if you don't use it in the \$1,000 and have to seek care for it later on. Some things make your doughnut grow bigger; for example, if you use out-of-network services. ... I found out my allergy shots were \$700 and my colleague ... who has [the] same doctor, his allergy shots were \$400. So I wouldn't say it's an open box, I would say it's a black box."

Conservatives, however, are

hoping that most consumers won't oppose these changes, especially if employers gradually transition to consumer-directed plans and much greater employee costs. "If you put a frog in hot water, it will jump out," says Dr. David Himmelstein, a founder of Physicians for a National Health Program. "But if you put it in cold water and slowly boil it, you can cook it." Hopefully consumers will tell employers exactly what they think of these plans before the entire health-care system has been cooked.

Editor's Note: The idea of medical savings accounts goes in a completely opposite direction from what is desperately needed in this country: A single-payer health care system, eliminating the role of those for-profit entities who are either providing health services or selling insurance. Recent criticism of medical (sometimes called health) savings accounts includes a poignant essay by Stanford University health care system expert, Dr. Victor Fuchs who wrote in the *New England Journal of Medicine* in 2002:

"Finally, there is the question of values. Should health insurance be organized on the same principles as automobile or homeowner's insurance? When drivers with good safety records or homeowners who install smoke detectors are charged less for their automobile or homeowner's insurance, most people see the system as fair and conducive to

socially desirable behavior. But the actuarial model applied to health care conflicts with a sense of justice and collective responsibility: it attacks a core element of what it means to be a society. In the long run, the extreme actuarial approach will probably be rejected by the people of the United States as an unsatisfactory way of providing basic health care for all."

"The timing of such a change [towards a social insurance model], however, will depend largely on factors external to health care. Major changes in health policy are political acts undertaken for political purposes. The political nature of such changes was apparent when Bismarck introduced national health insurance to the new German state in the 19th century. It was apparent when England adopted national health insurance after World War II; and it will be apparent in the United States as well. National health insurance will probably come to the United States after a major change in the political climate — the kind of change that often accompanies a war, a depression, or large-scale civil unrest. Until then, the chief effect of the new [medical savings] plans will be to make young and healthy workers better off at the expense of their older, sicker colleagues." ■

Product Recalls

August 18 — September 14, 2004

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

DRUGS AND DIETARY SUPPLEMENTS

The recalls noted here reflect actions taken by a firm to remove a product from the market. Recalls may be conducted on a firm's own initiative, by FDA request or by FDA order under statutory authority. A Class I recall is a situation in which there is a probability that the use of or exposure to the product will cause serious adverse health consequences or death. Class II recalls may cause temporary or medically reversible adverse health consequences. A Class III situation is not likely to cause adverse health effects. If you have any of the drugs noted here, label them "Do Not Use" and put them in a secure place until you can return them to the place of purchase for a full refund. You can also contact the manufacturer. If you want to report an adverse drug reaction to the FDA, call (800) FDA-1088. The FDA web site is www.fda.gov.

Name of Drug or Supplement; Class of Recall; Problem

Abilify Tablets (aripiprazole), 5 mg, 30 count bottles, Rx only; Class II. Dissolution Failure (9 month stability).

Amitriptyline HCL, 10mg, 100 and 1000 count bottles, Rx only; Class III. Impurities: impurity level exceeded at the 9 month stability point.

Lot #: Quantity and Distribution; Manufacturer

Lot Nos. T018H03 and T019H03, Exp. 08/05; 301,965 bottles distributed nationwide; Bristol-Myers Squibb Company; New Brunswick, NJ

Lot Nos. T018H03 and T019H03, Exp. 08/05; 4,697 bottles of 1000 and 45,435 bottles of 100 distributed nationwide; Vintage Pharmaceuticals LLC

continued on page 7

MEDICARE PROGRAM, from page 5
remainder is forwarded to customer service representatives (CSRs). The vast majority of inquiries seek to establish the status of a particular claim, but 500,000 calls a year involve potentially complex policy-related inquiries. These provider inquiries formed the focus of a recent investigation by the Government Accountability Office (GAO), a research branch of Congress. The full report is available on the Internet at <http://www.gao.gov/new.items/d04669.pdf>.

In its study, the GAO made a series of 300 phone calls to inquiry lines, seeking the answers to four common policy-related questions. One question asked about Medicare policy on billing for multiple procedures on a single patient if they took place on the same day. Another inquired about reimbursement policies for services delivered by physical therapy students.

Actually, it didn't much matter what the question was: the CSRs couldn't

answer them properly in nearly all cases. Overall, the GAO judged a pathetic 4% of responses to be "correct and complete," 42% to be only "partially correct or incomplete" and a full 54% to be simply "incorrect." Obviously, there is a major systemic problem.

Part of the reason, according to the GAO, is the failure of the inquiry lines to send policy-related questions, which can require labyrinthine answers, to specially trained CSRs. Instead, these more-challenging questions crop up only sporadically among the 1,700 calls the CSRs field monthly, so they never develop the necessary expertise. The policy-related information provided to the CSRs is often fragmented and the CSRs are forced to improvise their responses based on newer information on the Internet and older paper documents. Moreover, the available information is often confusing and written in complex language.

Medicare is particularly hamstrung

by very high rates of CSR turnover. Although the turnover rate at call centers for beneficiaries is 10% per year, approximating the industry standard, the turnover rate for the provider lines runs at 23%.

To add fuel to the fire, the call centers exercise little meaningful quality control over the CSRs. The call centers typically monitor only one call per CSR per month, compared to the eight or more recommended in the call center industry. During these calls, there is a heavy emphasis on the niceties of vocal tone, volume and politeness, with little specificity on what constitutes accuracy. (In a previous report, the GAO recommended that Medicare revamp its definition of accuracy to be more specific, but two years later this has not come to pass.)

The GAO issued a number of common-sense recommendations to improve this sorry state of affairs. If the past is any predictor of the future, don't expect the agency to jump on them. Until then, let the provider beware! ■

DRUGS AND DIETARY SUPPLEMENTS *cont.*

<i>Name of Drug or Supplement; Class of Recall; Problem</i>	<i>Lot #: Quantity and Distribution; Manufacturer</i>
<p>5% Benzoyl Peroxide Gel packaged in 1-oz. tubes, 12 per case, OTC, under the following private labels: 1) Schnucks; 2) Harris Teeter; and 3) Finast.</p> <p>Invisible Acne Cream (Benzoyl Peroxide 10%), 1-oz. tubes, 12 per case, OTC, under the following private labels: 1) Western Family Maximum Strength Invisible Acne Cream; 2) Meijer Invisible Acne Cream Maximum Strength; 3) Stop & Shop Maximum Strength Invisible Acne Cream; 4) Best Yet Absolute Elements Maximum Strength Invisible Acne Cream; 5) Premier Value Maximum Strength Invisible Acne Cream; 6) Finast Maximum Strength Invisible Acne Cream; 7) Personal Expressions Vanishing Acne Cream; 8) HyVee Maximum Strength Invisible Acne Cream. Class II. Bacterial contamination.</p>	<p>Numerous lots; 48,588 tubes distributed nationwide; Quailis, Inc.; Des Moines, IA</p>
<p>Cenestin (synthetic conjugated estrogens, A) Tablets, 0.625 mg., Rx only, 1000 count bottles, Class III. Stability Failure: 36 month stability failure due to excessive moisture.</p>	<p>Lot No. 98387, Exp. 06/05; 861 bottles distributed nationwide; Barr Pharmaceuticals, Inc.; Cincinnati, OH</p>
<p>Children's Motrin Tablets (Ibuprofen), 50 mg, 24 Grape-Flavored Chewable Tablets, Pain Reliever/Fever Reducer, over-the-counter; Class II. Mislabeling, printing defect on carton label dosing chart for ages 4-5 may incorrectly indicate 8 tablets instead of 3 tablets. Note: bottle label correctly indicates 3 tablets.</p>	<p>Lot No. JBM074, Exp. 02/06; Lot No. HSM192, Exp. 01/06; Lot No. JBM006, Exp. 02/06; 172,080 bottles of 24 tablets distributed nationwide; McNeil Consumer & Specialty Pharmaceuticals, Division of McNeil-PPC, Inc.; Fort Washington, PA</p>
<p>Diprivan (propofol) 1% Injectable Emulsion, 10mg/ml, 100 ml Vial, For IV administration, Sterile, Nonpyrogenic; Class II. Presence of particulate matter.</p>	<p>Lot No. 4429J, Exp. 07/05; 11,234 vials distributed nationwide; AstraZeneca Pharmaceuticals Lp, Newark, NJ</p>
<p>Embrex 600, Prenatal vitamin plus chewable calcium tablets, Rx only, Class III. Labeling. There is no warning for Phenylketonurics, and no list of inactive ingredients; the chewable Calcium tablets contain aspartame. Labeling declares 600 mg of Calcium carbonate; product contains 600 mg of calcium as calcium carbonate. Labeling declares thiamine mononitrate; product contains thiamine hydrochloride. Labeling declares zinc sulfate but product contains zinc oxide.</p>	<p>Numerous lots; 90,475 boxes of 91 sets of two tablets distributed nationwide; Andrx Pharmaceuticals, Inc.; Davie, FL</p>
<p>ESTRACE Tablets, (estradiol tablets, USP), 1mg, 100 tablets, Rx only; Class II. Mislabeling: Outer carton incorrectly states contains 0.5mg estradiol whereas the bottle label correctly states contains 1.0mg estradiol.</p>	<p>Lot No. 4A79546, Exp. 01/07; 2,348 bottles distributed nationwide; Warner Chilcott Labs; Rockaway, NJ</p>
<p>Member's Mark(r), Pain Reliever, Fever Reducer, Acetaminophen 500 mg, Non Aspirin Extra Strength, 500 Caplets; Class II. Presence of foreign substance.</p>	<p>Lot No. 3KB0745A, No expiration date given; 29,760 bottles, 500 count bottles distributed nationwide; Leiner Health Products; Carson, CA</p>
<p>Niaspan Tablets (niacin extended release tablets), 1000 mg, 100 count bottles, Rx only, Class III. Dissolution Failure.</p>	<p>Lot No. 0208000003, Exp. 03/05; 4,152 bottles distributed nationwide; KOS Pharmaceuticals, Inc.; Miami Lakes, FL</p>
<p>Premarin Tablets (conjugated estrogens tablets, USP), 100 tablet bottles, Rx only; Class III. Dissolution Failure by manufacturer (Wyeth)</p>	<p>Lot Nos. A49547A, A49547B and A49547C; Exp. 05/05; 16,081 100-tablet bottles distributed nationwide; Cardinal Health; Zanesville, OH</p>

continued on page 8

DRUGS AND DIETARY SUPPLEMENTS *cont.*

Name of Drug or Supplement; Class of Recall; Problem

Prempro (conjugated estrogens/medroxyprogesterone acetate tablets) 0.45 mg/1.5 mg tablets, Rx only, 1 EZ-DIAL Dispenser of 28 tablets; Class III; Dissolution Failure.

Promotional Antibacterial Soap labeled as "Diovan (valsartan tablets), 40mg, 80mg, 160mg, 320mg", 8 fl. Oz. (235mL) bottles, Compliments of Novartis; Class III. Misbranded.

Risperdal (Risperidone) Tablets, 3 mg, 60 count bottles, Rx only; Class II. Adulterated; Presence of Foreign Tablets.

Zovia 1/50E-28 Tablets (Ethinodiol Diacetate and Ethinyl Estradiol, USP), 1.0 mg/0.050 mg, Each pink tablet (21) contains ethinodiol diacetate 1mg and ethinyl estradiol 50 mcg, Each white tablet (7) contains inert ingredients, 6 tablet dispensers, 28 tablets each, Rx only; Class III

Zovia 1/35E-28 (Ethinodiol Diacetate and Ethinyl Estradiol, USP) 1.0 mg/0.035 mg, Each light pink tablet (21) contains ethinodiol diacetate 1mg and ethinyl estradiol 35 mcg, Each white tablet (7) contains inert ingredients, 3 tablet dispensers, 28 tablets each, Rx only, Class III. There is potential for film/foil separation in the blister packaging of the product.

Lot #: Quantity and Distribution; Manufacturer

Lot No. A46796; Exp. 03/05; 24,871 units distributed nationwide; Richmond Division of Wyeth; Richmond, VA

No Lot No. provided; 100,000 bottles distributed nationwide; Novartis Pharmaceuticals Corp.; East Hanover, NJ

Lot No. 3NG583, Exp. 11/05; Lot No. 4AG756, Exp. 12/05; 10 bottles distributed nationwide; Top Rx, Bartlett, TN

Numerous lots; 566,951 cartons distributed nationwide; Watson Laboratories, Inc.; Corona, CA

MEDICAL DEVICES

Device recalls are classified in a manner similar to drugs: Class I, II or III, depending on the seriousness of the risk presented by leaving the device on the market. Contact the company for more information. You can also call the FDA's Device Recall and Notification Office at (301) 443-4190. To report a problem with a medical device, call (800) FDA-1088. The FDA web site is www.fda.gov.

Name of Device; Class of Recall; Problem

Private Eyes, Diam 14.0 BC 8.6, Contents: one sterile daily wear soft contact lenses, 38% water, 62% polylacon, immersed in 0.9% buffered saline solution USP, Cosmetic Use Daily Wear Decorative Theatrical Contact Lenses, packed in vials labeled sterile; Class II. The contact lenses were repacked in vials that were not sterile as indicated on the vial labeling.

Lot #: Quantity and Distribution; Manufacturer

The majority of the vials in stock at the firm have Lot No. BB43; Exp. 08/06; 618 vials distributed in MA, TX, WA; The Contact Lens Store, Inc.; Marietta, GA

CONSUMER PRODUCTS

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

Name of Product; Problem

Candles. The dried apples and cinnamon in the candle can ignite causing a flare up and breaking the glass, posing a fire hazard.

Lot #: Quantity and Distribution; Manufacturer

Kitchen Krumblers Apple Cinnamon Candle; 1,200 sold at The Country Door Catalog and Web site from February 2004 through May 2004; Mostly Memories Inc.; Ozark, MO; (800) 659-6473

Name of Product; Problem

Children's Athletic Shoes. The 1.5-inch to 1.75-inch rubber tab at the top of the heel can detach from the shoe, posing a choking hazard to young children.

Children's Furniture Sets. The red paint on the chair contains excessive lead levels, posing a lead poisoning hazard to young children.

Dinette Chairs. The stretch bar which connects to the chair's legs can detach during normal use, causing the user to fall and suffer injuries.

Electric Scooters. Improper wiring can cause a short circuit, posing a fire hazard. In addition, inadequate insulation may expose electrical wiring, which poses a shock hazard.

Four Wheel Drive Eiger ATVs. Mislocated welds securing the upper front suspension arm mounting brackets to the frame. The mounting bracket could break off during riding, reducing rider control and resulting in loss of control of the ATV. Loss of control could result in a crash and severe personal injury or death.

Laser Printers. These printers can short-circuit, posing an electrical shock hazard to consumers.

Maternity and Nursing Pillows. If infants are placed on these pillows and left unattended, there is a risk of suffocation. Infant pillows and cushions are banned under the Federal law. Infant pillows have a flexible fabric covering, are loosely filled with plastic beads, easily flattened, intended for use by infants under 1 year old, and capable of conforming to the body or face of an infant.

Monster Rockets. The cap on the water tank can unexpectedly and forcibly project off when it is quickly unscrewed from the tank, posing a risk of impact injuries to users or bystanders. In addition, the rocket's tail can strike a user or bystander on descent, if the rocket is not fully launched, posing a risk of injury.

Nursing Pillows. If infants are placed on these pillows and left unattended, there is a risk of suffocation. Infant pillows and cushions are banned under the Federal law. Infant pillows have a flexible fabric covering, are loosely filled with plastic beads, easily flattened, intended for use by infants under 1 year old, and capable of conforming to the body or face of an infant.

Lot #: Quantity and Distribution; Manufacturer

Nike(tm) Get-Go and Little Get-Go Children's Athletic Shoes ; about 9,000 sold nationwide from June 2004 through August 2004; Nike USA, Inc.; Beaverton, OR; (800) 344-6453; www.nikebiz.com

Kid's Essentials Five-Piece Folding Furniture Set; about 3,800 sold nationwide from July 2003 through June 2004; Meco Corp.; Greeneville, TN; (800) 251-7558; www.meco.net

"Windsor" style dinette arm chairs. About 380 sold at American Signature Home and Value City Furniture stores in the Midwest and South during the month of April 2004; American Signature Inc.; Columbus, OH; contact store where chairs were purchased

Leoch Electric Scooters (also known as "Red Dragon" and "E-Scooter"); 58,950 sold at Target stores nationwide from February 2003 through June 2004; Target Corp.; Minneapolis, MN; (800) 440-0680; www.target.com

Eiger "QuadRunner" ATVs by Suzuki, model year 2004; about 240 sold nationwide from May 28 through August 16; Suzuki Motor Corporation; Brea, CA; (800)444-5077 to find the nearest Suzuki dealer

Lexmark, Dell and IBM Laser Printers; recall includes the following model numbers: Lexmark E232, E232t, E330, E332n, E332tn; IBM Infoprint 1412, 1412n; Dell 1700 and 1700n; 39,431 sold nationwide from May 2004 through August 2004; Lexmark International Inc.; Lexington, KY; <http://recall.lexmark.com> or (877) 877-6218; www.1700printer.com or (888) 245-3959; www.printers.ibm.com or (800) 426-7378

Big V Maternity and Nursing Pillows; about 1,000 sold nationwide from June 2003 through May 2004; Theraline Inc.; Wendell, MA; (866) 843-7254

Super Soaker Monster Rockets; about 230,000 sold nationwide from January 2004 through August 2004; Hasbro Inc.; Pawtucket, RI; www.supersoaker.com

Boston Billows Nursing Pillows; about 8,000 sold nationwide from February 2000 through December 2003; Boston Billows Inc.; Nashua, NH; (877) 274-4606

continued on page 10

<i>Name of Product; Problem</i>	<i>Lot #: Quantity and Distribution; Manufacturer</i>
PowerBook Computer Batteries. An internal short can cause the battery cells to overheat, posing a fire hazard to consumers.	Rechargeable batteries used in 15-inch PowerBook G4 computers; about 28,000 sold nationwide from January 2004 through August 2004; Apple Computer Inc.; Cupertino, CA; (800) 275-2273; www.apple.com/support/powerbook/batteryexchange
Ranges and Wall Ovens. The ranges and wall ovens have faulty wiring, which can melt and cause the oven to short circuit. The appliance can then stop working and pose a shock hazard to consumers.	General Electric, Hotpoint, Kenmore, and Americana brand freestanding electric ranges and double wall ovens; 28,300 ranges sold from June 2004 through July 2004; General Electric Appliances Co., Louisville, KY; (800) 326-1076
Ranges, Double ovens, and Oven-Microwave Combinations. All of the appliances use faulty wiring, which can overheat, melt through the insulation and cause a short circuit. They may pose a shock hazard to consumers if the appliance is not properly grounded.	Whirlpool and KitchenAid brand freestanding ranges, double ovens, and oven-microwave combination products; 24,500 sold from April 2004 through July 2004; Whirlpool Corp.; Benton Harbor, MI; (866) 770-6751
Scooters. The front column of the scooter does not meet impact resistance standards. The handlebar column can break if the scooter hits an object, which can cause the rider to fall and suffer injuries.	SlideCarver Scooters; 161 sold nationwide from December 2003 through July 2004; BMW of North America, LLC, of Woodcliff Lake, NJ; (800) 831-1117
Scuba BC Inflators. The Power Inflator Buttons can stick, which can cause uncontrolled inflation of the BC. This could cause divers to ascend too fast, resulting in decompression sickness as well as the danger of an embolism.	Oceanic-brand Reliant Buoyancy Compensator (BC) Inflators and AERIS-brand AW3 BC Inflators; about 11,600 sold nationwide from February 2004 through June 2004; Pelagic Pressure Systems; San Leandro, CA; (888) 854-4960
Scuba BC Inflators. The SCUBA BC bladder can have a slow leak because of imperfections within the machining of the stainless air barrel of their inflators. This can cause unexpected buoyancy problems with divers, possibly resulting in decompression sickness.	Halcyon SCUBA Buoyancy Compensator (BC) Inflators; about 4,000 sold nationwide from October 2003 through May 2004; Halcyon Manufacturing; High Springs, FL; (800) 425-2966; www.halcyon.net
Stroller Attachments. The Buggy Board's red connecting pins can break, causing the board to partially detach from the stroller or carriage, posing a fall hazard to the user.	Lascal "Buggy Board" stroller attachments; about 11,500 sold nationwide from January 2003 through July 2004; Regal Lager Inc.; Kennesaw, GA; (877) 242-5676; www.regallager.com
Toddler Bicycle Helmets. The helmets do not comply with impact testing requirements in the Consumer Product Safety Act.	Schwinn-brand Toddler Bicycle Helmets; about 9,000 sold nationwide from January 2004 through July 2004; PTI Sports Inc.; Rancho Cucamonga, CA; (800) 515-0074
Water Slides. These water slides have an excessive length of rope attached to the safety mat that presents a risk of entanglement in the water. This poses a drowning hazard to users.	Astroslide Inflatable Water Slides; about 7,500 sold nationwide from January 2004 through May 2004; Aviva Sports; Osage Beach, MO; (573) 346-1402

OUTRAGE, from page 12
industry, where almost every doctor, hospital and pharmaceutical company has some dealing with federal health programs."

It continues by stating that "the drug-maker Schering-Plough Corp. agreed in July to pay \$346 million to settle charges that it paid a kickback to a health insurer in an attempt to evade a law requiring it to give its

lowest prices to Medicaid, the government health program for the poor. The U.S. Attorney in Philadelphia began investigating the case after three disgruntled employees of a Schering-Plough subsidiary filed a civil lawsuit on the government's behalf, claiming their employers were committing a fraud. Their reward for risking their careers will be rich — the trio will split \$31.7 million as part of

the settlement.

That case came on the heels of a government suit against drug giant Pfizer Inc., which agreed in May to plead guilty to criminal charges and pay \$430 million in fines to settle charges that a company it owns illegally promoted non-approved uses for a drug by flying doctors to lavish resorts. The man who blew the whistle, a scientist, was awarded \$26.6

OUTRAGE, from page 10
million.

Federal prosecutors in Philadelphia are pursuing a claim against Medco Health Solutions Inc., a pharmacy benefits company that three whistleblowers claim engaged in a variety of improper practices, including sending patients fewer pills than they paid for and improperly accepting payments from drug companies in exchange for promoting their medications."

The statute largely fell out of use until 1986, when it was strengthened with the intent that it would be used against defense contractors. Since then, its use has been on the rise.

Lawsuits filed by private-sector whistleblowers paved the way for a government investigation that ultimately recovered \$1.7 billion in fines and damages from HCA Inc., the nation's largest for-profit hospital company. Prosecutors said the company had paid kickbacks to physicians and overbilled government health programs.

TAP Pharmaceutical Products Inc. agreed to pay \$875 million in 2001 to resolve criminal and civil charges in connection with its pricing and marketing of the cancer drug Lupron. The number of whistleblower cases has surged, from 82 in 1990, to more than 300 a year.

In fiscal 2003, the Department of Justice said it recovered a record \$2.1 billion under the False Claims Act. About \$1.48 billion of that total came directly from suits initiated by private citizens, who in return reaped \$319 million in rewards.

Marilyn May, an assistant U.S. attorney who was involved in the case against Schering-Plough, said corporate canaries are worth the money.

"In the absence of direction from an insider, whether that person has filed a complaint, or come to us with information, it is difficult to find information about fraud being committed by companies," she said. "We'll still do it, but it is certainly easier when you are pointed in the right direction."

Companies that decide to fight, rather than settle, can face triple damages, plus a ban from doing busi-

ness with the government.

This whole concept is reminiscent of the more traditional vigilantes. In this case, the object of vigilance is the corporation, the vigilante a former or present employee. The penalties are occurring more often and are becoming an increasingly larger part of the costs of our \$1.7 trillion per year health care system. ■

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Discovering Health Care Fraud and "Telling": Whistleblowers

A recent Associated Press story by David Caruso discussed health whistleblowers. The article started out by saying "The mob calls them rats, or stool pigeons, or canaries. Corporate America has a gentler term — whistleblowers — but maybe just as much to fear from insiders who threaten to tell all about company scandals involving government contracts."

"Thanks to a Civil War era law that offers potentially huge rewards to people who expose fraud against the government, federal prosecutors have won a series of multimillion dollar settlements with the help of insiders willing to turn the tables on their bosses in exchange for a big payout."

The Civil War era law Caruso was

referring to is the False Claims Act which, he points out was "enacted during the Civil War to prevent fraud by profiteering military supply companies. The False Claims Act allows people who file the suits on behalf of the government to keep as much as 25 percent of the total recovered."

The part of that law encouraging such whistleblowing is the Qui Tam provision. Qui Tam is the Latin abbreviation for "Who sues on behalf of the King as well as for himself." It is an action under a statute that establishes penalties for certain acts or omissions that can be brought by an informer and in which a portion of the penalties, fines, or awards can be awarded to the whistleblower.

An early court case involving this

law pointed out that Qui Tam actions are based on the theory "that one of the least expensive and most effective means of preventing frauds on the Treasury is to make the perpetrators of them liable to actions by private persons acting, if you please, under the strong stimulus of personal ill will or the hope of gain."

When a statute imposes a penalty, and gives that penalty in part to the person who sued, and the other part to the commonwealth, or some charitable, literary, or other institution, such actions are called Qui Tam actions.

The Associated Press story points out that "the biggest recent impact of this law has come in the health care

continued on page 10

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