

**MED BRIEFS**

**No Flu Shot Shortage**

Health and Human Services Secretary Michael Leavitt says the U.S. will have enough vaccine for the coming flu season. Federal health officials had limited vaccine to those most at risk, but have now released it for anyone. The vaccine is for common flu types.

**Roche Suspends Tamiflu Sales**

Roche Holding said it temporarily suspended shipments of Tamiflu to nongovernment recipients in the U.S. to ensure that enough of the antiviral drug will be available for the flu season. U.S. companies and organizations apparently have been hoarding the drug, which is most effective in treating bird flu.



**Bristol-Myers Profit Falls Short**

Shares of Bristol-Myers Squibb fell after it missed Wall Street estimates on Friday, a day after the company warned it may abandon an experimental diabetes drug. Bristol-Myers reported third-quarter earnings of 31 cents a share, down from 44 cents the prior year and 2 cents below First Call views.

**Crawford Resignation A Mystery**

Health and Human Services officials will look into the resignation of Food and Drug Administration Commissioner Lester Crawford less than three months after his confirmation. Crawford had been embroiled in a flap over Barr Pharmaceuticals' bid for a non-prescription morning-after pill.



Crawford resigned on Sept. 23.

# HEALTH & MEDICINE

## Merck Seeks Cure For Financial, Operational Woes

**Bad News Keeps Piling Up**

Fosamax takes latest hit, though analysts see reason for hope under new CEO

BY PETER BENESH  
INVESTOR'S BUSINESS DAILY

Another month, and more bad news for Merck.

Yes, profit rose 8% in the third quarter. But sales dipped 2%. And the company continues to face more lawsuits over possible side effects from its Vioxx painkiller.

Merck also took a blow in October when the Supreme Court denied the company's appeal to extend its patent on osteoporosis drug Fosamax for another 10 years.

Fosamax, which accounts for 8% of Merck revenue, will go generic in 2008. The same is expected in the European Union, where Fosamax's patent expires in 2007.

Merck also reported that sales of Zocor, its statin blockbuster, fell 14% in the third quarter. The main reason: Zocor patents have been expiring in Europe, and patients are switching to generics. Zocor's U.S. patent expires in June.

Meanwhile, the Vioxx mess continues. In September, a Texas jury hit Merck with an award of more than \$250 million to the widow of a man who'd taken the drug.

In a mid-October report, Bear Stearns analyst John Boris speculated that Merck's Vioxx liability could hit \$10 billion.

To round out October, Merck learned that a hoped-for blockbuster is likely a dead duck. The drug is Pargluva, for diabetes. It's developed through a joint venture with Bristol-Myers Squibb.

The Cleveland Clinic Foundation analyzed clinical trial data and found twice as many deaths and heart problems in adults who took Pargluva over those on placebos or

established drugs.

While that was bad news for Merck, it would have been even worse news had the drug actually gone to market like Vioxx.

"The days when you can be receiving signals of adverse events and ignore those signals have to end," said Joel Hay, professor of pharmaceutical economics and policy at the University of Southern California. "And if you are the last to know about troubles with your drug, you have a serious problem."

Merck's serious problem is plain to see. The company has reported sales declines in four of the past five quarters. Its third-quarter profit gain ended a run of seven straight quarters of declines. The stock trades near 27 — down from a high of 45.24 on Oct. 1, 2004, the day after it pulled Vioxx.

It's been a long fall for a company that only a few years ago could seem to do no wrong.

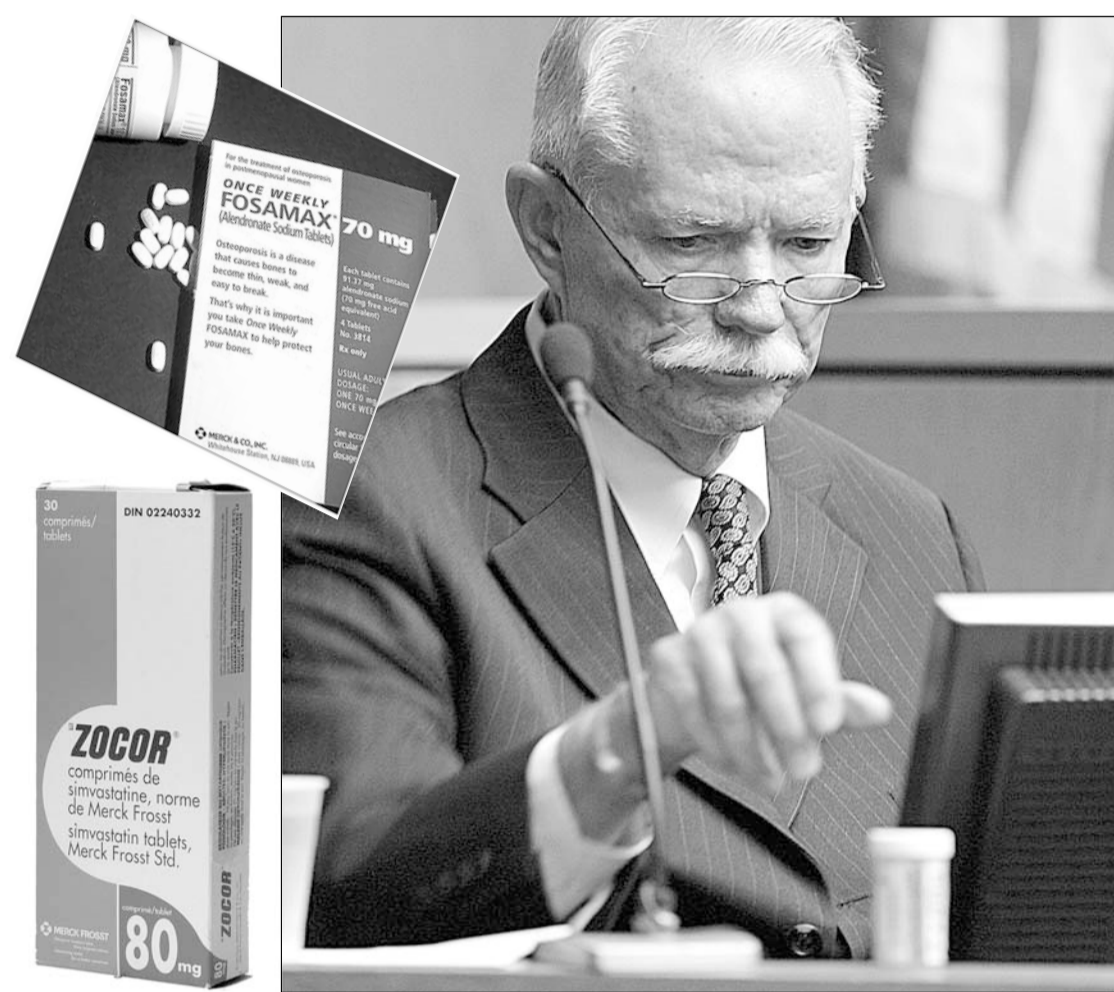
In the 2003 book "The Chief Executive," author Fran Hawthorne wrote that Merck "pioneered groundbreaking drugs for cholesterol and hypertension, topped all rivals in sales and was named America's most admired company by Fortune seven years in a row — a record still unmatched."

She blames Merck's slide mostly on Raymond Gilmartin, who took over as chief executive in 1994 and served in the post until this past May. "Gilmartin wasn't a scientist; he wasn't even from the pharmaceutical industry," Hawthorne wrote. "He was a Harvard MBA."

One problem, says analyst Albert Rauch of A.G. Edwards, is that Merck adopted "an ivory-towerish corporate culture."

That's changing under new CEO Richard Clark, Rauch says.

He cites a shift in executive attitude — starting with a quarterly conference call on Oct. 24. The CEO now participates and answers questions. "For the first time manage-



Shortly after Frederick Humeston, upper right, testified against Vioxx maker Merck in Atlanta, the star-crossed pharma learned that it lost its patent on Fosamax, top left, while sales of its statin blockbuster Zocor plunged. AP

ment made themselves available," Rauch said.

Judging from his comments at the recent conference call, Clark clearly wants Merck to get back in the good graces of its shareholders.

"The investor community is important to us and I believe the senior leadership of the company should communicate regularly with you," he said.

Investors aren't the only ones drug firms should communicate with, says Meg Columbia-Walsh, head of the health care practice of trend forecaster Faith Popcorn's BrainRe-

serve.

She says the whole industry must rebuild credibility by getting close to the lives of people, Oprah-style. Drug makers also would do well not to underestimate the knowledge of the average consumer.

"We're a nation of first-year medical students," Walsh said. "If we're diagnosed, we'll go online and find out what we need to know. We'll call people and network, we'll go to chat rooms. We'll reach out to each other for information."

USC's Hay has another recommendation: Drug firms should do more

"outcomes research." Data to see how patients react to drugs are abundant, he says.

"It's available from health care organizations, Medicare and Medicaid... (Veterans Affairs) — it's real-world usage data," Hay said.

He says the Vioxx problem could have been avoided if Merck had been more vigilant about data and had evaluated it more rapidly and accurately.

"The drug industry often tells us that outcomes research is too expensive," Hay said. "But look at the potential liability of not doing it."

**Q&A**

## New Reporting Rule May Drive Health Savings Accounts

**Retirees Eat Up Funds**

Private accounts will cut costs, offer choice, says economic adviser

BY GLORIA LAU  
INVESTOR'S BUSINESS DAILY

Until recently, investors didn't have to worry about companies' health care obligations to workers and retirees. And before disclosure rules changed a decade ago, it was hard for analysts and investors to even know how much they cost.

The legal change cut the number of retirees with company-sponsored medical coverage. A decade ago 44% of them had it; less than 20% do today. And most of that 20% gets insurance only because of their old union-type contracts.

In December 2006, a similar law will make municipal governments tell the public and their bond investors what they're providing for retiree health care. This may lead more employers to seek ways to cut costs.

Paul Zane Pilzer, an economist and former Presidential adviser, predicts that consumer-directed health plans linked to health savings accounts (HSAs) will be the solution. He sees them taking over the health care system in 10 years.

HSAs are high-deductible plans that let employers pay a fixed amount to an employee's medical care; the worker chooses how to spend that amount. What the worker doesn't spend, he keeps.

Critics say these plans will abandon workers who have little expertise to choose the care providers. And they will force workers to pay more of their medical costs.

Pilzer disagrees. He co-founded Salt Lake City's Extend Benefits LLC, which works with clients like Continental Airlines and AutoNa-

tion to provide individual insurance plans for their workers. In mid-October, former America Online chief Steve Case's venture, Revolution Health Group, bought two-thirds of Extend.

Pilzer spoke to IBD. **IBD:** Why should consumers opt to take more control of their medical care?

**Pilzer:** Because unlike pensions, health benefits can be terminated at any time — (except) union contracts. Companies are prohibited from eliminating pensions, even if they go through bankruptcy. Not the case with health benefits.

**IBD:** Why should investors care and what can they do?

**Pilzer:** Most companies with union employee contracts like General Motors have retiree health benefits to pay, but I can't stress enough that these are open-ended obligations.

Who knows what new devices will be invented tomorrow and that you, the investor, will become obligated to pay for? Our medical industry is constantly defining new diseases that weren't (considered) diseases a few years ago and coming up with new treatments.

Yesterday's cause of death is today's cause of disability. People used to die of strokes, but today strokes only disable them. This trend is good if you're the person who doesn't want to die, but it's bankrupting many of our largest and oldest corporations.

I'd encourage every analyst worth his salt to state the retiree health obligation of every company he follows. Investors need to be as well-versed about a company's health care obligations as he is about the company's business.

I'll take my chances when I invest that a company will make a good widget, but I'd rather not take my chances that a company's retiree

**Paul Zane Pilzer**



■ Economist and former adviser to Presidents Reagan and George H.W. Bush

■ Co-founder of Salt Lake City's Extend Benefits LLC, which helps clients, such as

Continental Airlines and AutoNation, provide insurance plans for workers

■ Sold two-thirds ownership of Extend to former America Online chief Steve Case's company, Revolution Health Group, in mid-October

gets cancer. The auto industry companies with their unionized health benefits are only the tip of the iceberg. Municipal governments will

face a major crisis in December 2006 when the new GAAP (generally accepted accounting principles) rules come.

Today Buffalo, N.Y., spends more on retiree health care than employee health care.

**IBD:** What makes you think that health savings accounts are inevitable? Most U.S. workers today happily buy low-deductible plans through their employers.

**Pilzer:** Your older readers will remember that 30 years ago we faced a crisis in life insurance and pensions. Back then, most corporations had defined-benefit retirement plans. When you retire we'll pay you X dollars for as long as you live, adjusted for cost of living.

Most U.S. companies realized that they would go bankrupt with such a plan. So they switched from defined-benefit to defined-contribution pensions. They had no choice.

A similar change is about to take

place in health care. To put it in perspective, growth in health care costs now exceeds profit for any of the Fortune 500 companies.

Today 2 million Americans have health savings accounts. The law (permitting HSAs) passed in December 2003, but because of the (annual insurance enrollment cycles), HSAs are effectively brand new this year.

**IBD:** How would health savings accounts impact the medical system?

**Pilzer:** When consumers spend their own money, their decisions will be more cost conscious. In 1997, Lasik eye surgery was introduced for \$3,000 an eye and was done only in hospitals. Insurers refused to pay for it.

Now, eight years later, Lasik costs \$500 an eye and the procedure is done in strip malls or shopping centers nationwide. This competition and drop in price also will happen to many other medical products.

**Market-Leading Medical Stocks**

The top stocks in the medical sector, ranked by the total of their Earnings Per Share and Relative Price Strength Ratings.

Rank	Company	Medical Subgroup	Ticker	Price	% Off High	EPS Rating	Rel Str Rating	SMR Rating	A- A+ Last Qtr Next Qtr Last Qtr	Funds In Stock	EPS Change	EPS Change	Sales Change
1	Quality Systems	Computer Sftwr	QSII	63.61	-14.24	98	97	A	16	46	42.9	36	36
2	Cutera Inc	Systems/Equip	CUTR	25.36	-6.9	98	97	B	9	300	100	43	43
3	Hi Tech Pharmacal	Generic Drugs	HITK	33.02	-6.91	98	96	B	8	60	11.1	27	27
4	Birner Dental Mgmt	Medical/Dental-Srvcs	BDMS	20.1	-4.29	97	97	C	0	47	..	15	15
5	Psychiatric Solutions	Outpt/Hm Care	PSYS	52.03	-8.32	97	94	B	24	41	35.5	23	23
6	Alcon Inc	Products	ACL	132.5	-2.11	96	94	A	0	53	36.7	12	12
7	Express Scripts Inc	Medical/Dental-Srvcs	ESRX	72.42	10.43	94	95	C	11	34	16.7	2	2
8	Genentech Inc	Genetics	DNA	87.09	-8.32	96	93	A	22	46	57.1	46	46
9	Adv Neuromodulation	Products	ANSI	60.91	-0.77	91	97	B	18	13	4.3	26	26
10	Meridian Bioscience	Products	VIVO	20.69	-10.08	90	98	A	9	67	0	39	39

**UNDER THE MICROSCOPE**

## Drug Firm Aims High, Hits Mark

**Celgene Corp.**

Summit, N.J.  
celgene.com

Sometimes it takes a small company to turn adversity into opportunity. So says Robert Hugin, chief financial officer of Celgene.

When Celgene saw there might be new uses for a drug that once caused birth defects, it had 30 employees. Now it has more than 900. The drug is Thalidomide, used in the 1950s as a sleeping aid and for morning sickness. The consequences were horrific for parents and their cruelly deformed children.

Today, a dozen years after a Rockefeller University researcher came to Celgene with the idea of safe possibilities for Thalidomide, the company is on a roll.

It found that Thalidomide derivatives can help treat myeloma and myelodysplastic syndrome (MDS). Its latest drug is Revlamid, close to approval by the Food and Drug Administration.

Multiple myeloma is an incurable but treatable cancer of the blood. It hits five or six people out of every 100,000. This year, 16,000 new U.S. cases are likely to arise.

MDS, which strikes people mostly over 60, is not a cancer. It's a failure of the bone marrow to produce enough blood cells. More than 15,000 cases are diagnosed in the U.S. each year.

Celgene expects Revlamid to be a blockbuster, Hugin says. It's the successor to an earlier drug, Thalomid. Celgene has found in trials that some patients respond better to one or the other.

Myeloma and MDS are diseases that get little attention from drug makers, says Christopher Raymond, analyst with Robert W. Baird, which anticipates business from Celgene.

A big plus is that Revlamid is an oral drug, not an injection, Raymond says.

"Physicians may use it almost immediately as standard care," he said.

Still, he's "measured" in his expectations for the drugs.

**THE FINANCIALS**

Celgene has delivered rising profit since the start of 2003. First Call's consensus is for 2005 earnings of 54 cents a share, up 59% from last year. They see 2006 profit reaching \$1.01 a share.

**THE COMPANY**

Founded in 1986, Celgene had its IPO in 1987. Analyst Raymond says management has done wonders. "They took Thalidomide and turned the company into a formidable biotech story."

The firm has its U.S. sales force ready to go, Hugin says. The next big decision is how to sell Revlamid in Europe — whether to partner with a bigger drug firm or launch its own sales force in the EU.

Tricky decision, says Raymond. "Investors look at a partnership as validation for Revlamid."

It may prove wiser to go solo, Hugin says. "We want to fully leverage around the world the products in our pipeline."

**LOOKING AHEAD**

That pipeline is full of other possible uses for Revlamid. Hugin says that some 50 trials of Revlamid are under way in other cancers.

Once the FDA gives the green light, Celgene will be ready for a U.S. launch, Hugin says. It already has supplies stockpiled, made by contract manufacturers.

The firm is building its own plant in Switzerland to supply Revlamid to the whole world.

Peter Benesh