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Today's Top Stories

1. Genentech: Second Raptiva patient has PML

By Tracy Staton Comment | Forward

Suddenly, PML is cropping up all over the place. Genentech announced another case of progressive multifocal leukoencaphalopathy, the potentially deadly brain infection, in a 73-year-old women who used its Raptiva psoriasis treatment. It's the second PML case reported among Raptiva users, both in patients in their 70s. Both patients died.

According to a Dear Doctor letter issued by the company, Genentech believes that Raptiva "likely increases the risk of PML." In addition, both patients used the drug for several years, raising the possibility that prolonged Raptiva exposure, combined with older age, may further increase that PML risk.

Genentech says it's working with the FDA on any "appropriate next steps." As you know, Raptiva's label was updated last month with a "black box" warning of serious infections, including PML. Meanwhile, Merck KGaA, which markets Raptiva in Europe, said it's working with European regulators on a label update and that it's also "seeking to determine if further action is needed."

So far this year, PML has been reported not only in these two Raptiva patients, but in several patients taking the Biogen Idec multiple sclerosis treatment Tysabri; in patients on the Novartis immunosuppressant drugs--used in transplant patients but also off-label for some lupus sufferers--CellCept and Myfortic; and in one patient using Genentech's arthritis treatment Rituxan.

- read the Genentech release
- check out the *PharmaTimes* article

- get the Merck news from *Healthcare Digital*

Related Articles:
Genentech's Raptiva gets 'black box' warning
Genentech: Raptiva patient has PML

Read more about: PML, drug safety, Raptiva, Genentech

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2. Byetta uptick, Icahn news boost Amylin

By Tracy Staton Comment | Forward

Maybe Amylin Pharmaceuticals isn't so bad off after all. With Carl Icahn boosting his stake in the company and Byetta sales reversing their downward slide, industry observers are taking another look at the embattled company.

Byetta's fourth quarter sales are still down 9 percent year-over-year, but the diabetes med boosted scrips by 3.9 percent during the first week of this month, IMS Health data shows. As you know, Byetta has been beset by doubts since August, when the FDA flagged cases of pancreatitis in patients who used the drug, including six deaths. There's no proof that Byetta caused the problem, but scrips numbers deteriorated anyway. Until now.

And as Byetta sales are ticking upward, Carl Icahn has been snapping up Amylin stock. At less than $7 a share these days, it's a lot cheaper than it was just three months ago, when it was trading at almost $30. Just since June 30, Icahn has added some 4 million shares to his Amylin stake, bringing it to a total of 10.7 million.

Other investors are apparently following along: Amylin was up 8 percent Monday to $6.91.

- get the *Associated Press* news
- check out Mike Huckman's take at *Seeking Alpha*
- read *The Street*'s coverage

Related Articles:
Are investors overreacting to Amylin news?
Amylin lays off 340 as Byetta flags
Lilly, Amylin suffer on Byetta deaths
Amylin: Byetta outperforms Januvia
FDA seeks tougher labeling for Byetta after deaths

Read more about: Pharma Stocks, Amylin, Byetta, Carl Icahn

3. Is pharma liable for knockoff meds, too?

By Tracy Staton Comment | Forward

While we were watching *Wyeth v. Levine* have its day in the U.S. Supreme Court, another Wyeth case hit the California appeals courts--and what happened there stunned drug-law types. That's because three justices ruled Wyeth could be held liable for harm caused not by one of its own drugs, but by a generic version of a medication that went off patent more than 25 years ago.

In the case of *Conte v. Wyeth*, a woman alleged that she developed a neurological disorder because of her long-term use of metoclopramide, the copycat form of Wyeth's acid-reflux med Reglan. Conte argued that Wyeth should have warned doctors that Reglan and its generic forms shouldn't be used for more than 12 weeks at a time. The trial judge ruled for Wyeth.

But in a unanimous ruling, the appeals court reversed that decision. "As the foreseeable risk of physical harm runs to users of both name-brand and generic drugs," Justice Peter Siggins wrote in the court's opinion on the case, "so too runs the duty of care."

Will that verdict stand when it inevitably reaches the California Supreme Court? Liability lawyers want to say "No." Two attorneys who blog about drug and device law wrote that the ruling "stands product liability law on its head." And one of them, Mark Herrmann, a Jones Day partner, told *Law.com*, "Virtually all the precedents went the other way." And over at *In the Pipeline*, Derek Lowe pronounces himself incredulous. "How Wyeth can be held liable for the use of a product that it did not manufacture, did not label and did not sell is a mystery to me." Stay tuned.

- read the article at *Law.com*
- check out the *In the Pipeline* post
- see the story at *AmLawDaily*

Read more about: lawsuits, Reglan, Conte v. Wyeth, Wyeth

4. Cephalon hikes prices to fight generic

By Tracy Staton Comment | Forward

Today's *Wall Street Journal* dissects a familiar drug-pricing strategy: pre-patent-expiration sticker shock. On the table is the Cephalon narcolepsy treatment (and sometime cognitive booster) Provigil. That drug faces generic competition in 2012. Naturally, Cephalon doesn't want to say goodbye to all that brand-name revenue; the drug brought in $707 million during the first nine months of this year, or about half of the company's year-to-date sales of $1.43 billion.

So Cephalon is developing a longer-acting version of Provigil, to be dubbed Nuvigil. The new formulation is set to launch next year. In preparation for that launch, Cephalon has been ratcheting up the price of Provigil, to give users reason to switch to the less-expensive new version. "You should expect that we will likely raise Provigil prices to try to create an incentive for the reimbursers to preferentially move to Nuvigil," the *WSJ* quotes a Cephalon VP as saying.

And here's how those numbers are shaking out so far: Provigil is now 28 percent more expensive than is was in March and 74 percent costlier than it was four years ago, according to DestinationRx. And Cephalon plans to continue raising that price, the *WSJ* says.

The idea is that, by the time 2012 rolls around, most Provigil users will have switched to the cheaper Nuvigil, which will be under patent through 2023. Firmly entrenched as Nuvigil users, they'll have less reason to adopt the cheaper generic. Or so Cephalon hopes.

- read the *WSJ* story
- check out the post at the *WSJ Health Blog*

Related Articles:
Pros use pills to boost brainpower
Cephalon pays CEO more than hefty rivals
FTC sues Cephalon for blocking generics
Provigil - Top 10 Warnings and Recalls

Read more about: drug prices, generic competition, Cephalon, Nuvigil

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5. J&J yanks mom-offending Motrin ad

By Tracy Staton Comment | Forward

A Johnson & Johnson online ad has captured headlines all over the place. Too bad it's the wrong kind of headline. The online commercial looked to promote the Motrin painkiller to new moms. But its flip approach got them all riled up instead.

The ads promise Motrin can treat backs, necks, and shoulders that ache from Mom's toting baby in one of those slings or packs that keep infants close and their mothers' hands free. Baby-wearing women were not amused. Offended moms spewed complaints via Twitter, YouTube, and various motherhood blogs. Some even called for a boycott of the medicine, which is one of the standard treatments for childhood fevers.

By the end of the day yesterday, J&J had posted an apology on the Motrin.com website and pulled the online commercial. Magazine ads are also set for the axe, though they'll take longer to get out of circulation. The ad was "meant to engender sympathy and appreciation for all that parents do for their kids, a VP of marketing wrote on JNJ BTW, the company's blog, "but did so through an attempt at humor that missed the mark."

As the *Wall Street Journal* noted, both the outcry and the swift response shows how quickly Internet-savvy consumers can influence corporate behavior.

- here's the video
- read the story at *Scientific American*
- check out the *WSJ*'s article

Related Article:
Johnson & Johnson - Top 13 Ad Budgets

Read more about: Motrin, Johnson & Johnson, Drug advertising

Also Noted

TODAY'S SPOTLIGHT... More cancer meds hitting the market

Thanks to smart research and a better understanding of cancer, more anti-cancer meds are hitting the market than ever before, according to a study by Cancer Research UK. In a study of 974 cancer drugs, the organization found that, if current trends continue, about 18 percent of those would make it through clinical development to become standard treatments; that's up from previous estimates of 5 percent, according to *Pharmacy Europe*. Report

> U.S. Attorneys in New Jersey filed a lawsuit seeking a shutdown of three Actavis plants until they are brought into compliance with testing, manufacturing laws and FDA regulations. Report

> Two Johnson & Johnson subsidiaries that make and distribute a painkilling skin patch must pay nearly $16.6 million to the family of a suburban woman who died from a drug overdose while using the product, a jury ruled Monday. Report

> The European Medicines Agency said Sanofi-Aventis has decided to withdraw its application for an extension of indication for the breast cancer treatments Taxotere and Docetaxel Winthrop. Report

> Teva Pharmaceutical Industries is challenging two patents on the AIDS drug Truvada, which are owned by Emory University and licensed exclusively to Gilead Sciences. Report

> Johnson & Johnson is axing its global sponsorship with the International Olympic Committee after less than three years. The move leaves the 2010 Vancouver Winter Olympics and London 2012 without key funding. Report

> Merck KGaA is interested in acquisitions, especially in the US, but the German group is not going to charge into the market despite the credit crunch wiping millions of dollars off the value of possible targets. Report

> Medical device maker Medtronic says its fiscal 2009 second-quarter profit fell, mainly on legal charges for a patent dispute with Johnson & Johnson. Report

> Targeted cancer drugs like Herceptin and Glivec have greatly improved pharma's oncology pipeline success rates, according to a new study. Report

> Scottish pharmaceutical company ProStrakan Group said yesterday it was on course to break even late next year. Report

> Standard & Poor's said Monday drug developer Wyeth will replace Anheuser-Busch Cos. on the S&P 100 index. Report

> Data analyzing Zyrtec's crossover found many patients didn't follow the drug over the counter, according to a Nielsen-Wolters Kluwer Health report. Report

> Researchers found that the leukemia drug Gleevec shows promise at treating or even reversing Type I diabetes. Report

> PDI, a provider of sales and marketing services to the biopharmaceutical industry, on Monday named Nancy Lurker as chief executive. Report

> Merck said it would voluntarily delist its common shares from the NASDAQ OMX-PHLX, formerly the Philadelphia Stock Exchange (PHLX), following a decision by the exchange to discontinue the PHLX XLE equity trading platform. Release

> German regulators cleared Eli Lilly's acquisition of all ImClone's common stock at $70 per share. Release

> Hey, it's not all bad news out there. Despite the drumbeat of reports on the fallout from the credit crisis, Pacira and ZafGen report lining up new rounds. Report

> With virtually no new money flowing for construction projects, Alexandria Real Estate Equities has had to postpone the second phase of the East River Science Park. Report

> Reviewers for the FDA say that Theravance's experimental antibiotic telavancin was "possibly" related to some of the deaths reported among volunteers taking the drug. Report

> The *Philadelphia Business Journal* is outlining the drop in investment cash for biotech companies in New Jersey and Pennsylvania. Last year, developers in both states were able to haul in over a billion dollars for their work. In the first three quarters of this year, the figure slumped to $550 million. Report

> Renowned Australian scientist Ian Frazier says he's preparing to start clinical trials on a new skin cancer vaccine. The work is related to his groundbreaking research that helped create Merck's Gardasil, a vaccine for cervical cancer. The new vaccine also targets papillomavirus, an infection that helps spur the transformation of abnormal cells into cancer cells. Report

And Finally... A large long-term trial has found that vitamin C and E supplements prevent heart disease no better than placebos. Report

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INDUSTRY VOICES

NICE tries to expand healthcare coverage

Comment | Forward

by Bob Goldberg

This week Senator Max Baucus released a blueprint to create a national health plan. A central feature of his proposal is something called the The Health Care Comparative Effectiveness Research. The Institute is modeled on Britain's National Institute for Health and Clinical Excellence (NICE) which was established to compare the relative value of

medical technology. The Institute has enthusiastic support from advocates of government-run healthcare and the health insurance industry's lobby, America's Health Insurance Plans (AHIP). Both groups argue that the institute should compare treatments for the same disease, find which works best, chuck the one's that are less effective and use the savings to pay for expanded insurance coverage.

Baucus claims the Institute's decisions would not be binding. The problem is that voluntary decisions don't stay voluntary for long. NICE decisions were immediately adopted by Britain's National Health Service to determine what it would pay for and to further tighten the government's control over healthcare.

Comparative effectiveness advocates like the fact that NICE focuses on the value of care. Recently the group ruled that four drugs used to extend the life of people with stomach cancer "aren't effective enough to warrant their high cost and shouldn't be prescribed to new patients." NICE decided that the $39,000 the drugs would cost to keep people alive wasn't worth the money.

NICE determines what's valuable by assuming that anything that costs too much isn't worth the money, even if it helps people live longer or better for a year. That so-called 'quality-adjusted life year' is the upper limit NHS uses to determine what it will pay for. To NICE, breast enhancements and Viagra are a bargain, but new drugs for stomach cancer are a waste of money.

Many comparative effectiveness advocates claim that in America, which spends more per person on health than Britain, the appraisals would only eliminate "wasteful" care. Tell that to Barbara Wagner. She's enrolled in Oregon's Health Plan which used comparative effective analysis from Oregon's Drug Effectiveness Review Project to tell her it wouldn't pay for Tarceva, a drug proven to extend life in people with her particular type of lung cancer.

DERP receives funding from the federal government's Agency for Health Care Quality and Research, which already produces comparative effectiveness research. AHRQ also funds the comparative effectiveness institutes of HMOs who, along with DERP, crank out reports used by Medicaid and insurance plans to ration drugs for cancer, mental illness, arthritis and other serious disease in over 25 states.

AHRQ and these organizations would essentially run the new Institute with a budget of about $300 million a year. The legislation says they should do large studies that compare one drug or device to another. Such research take years to complete. All the better if you want to dodge paying for some new cancer drug or medical device. And such studies ignore racial, gender or genetic differences that allow doctors to match the right treatment to the right patient. That makes it easier to conclude that there is no difference between any treatments, and to recommend using the cheapest available.

Comparative effectiveness fans point to the ALLHAT trial (Antihypertensive and Lipid-Lowering Treatment to Prevent Heart Attack Trial) as another "gold standard" for what they want. That five-year, 42,000 patients trial compared older blood pressure drugs (diuretics) against newer medicines in reducing heart attacks.

The study concluded cheaper diuretics were just as effective at reducing death from all forms of heart failure. Michael Weber, professor of medicine at Downstate Medical Center and a study adviser, points out diuretics only seemed better overall because the study produced a 40 percent excess stroke rate in African American patients who were given a

type of blood pressure drug called ACE inhibitors. It's known that blood pressure in African Americans responds poorly to ACE inhibitors. The one-size-fits-all approach to treating hypertension taken in ALLHAT exposed black patients to certain danger and even death.

Comparative effectiveness is marketed as a tool for promoting better health and universal coverage. In fact, it's used mainly to deny people care when they need it most by the folks holding the purse strings. Both NICE and the new Institute will ration care by deciding some lives are worth saving and others are not. The difference is, in America, the insurance companies have found a way to have us pay them to do it. - *Bob Goldberg*

Read more about: Robert Goldberg, NICE, Industry Voices

Webinars

> Stop Data Bleeding - Enterprise IT Security and Management Strategies - Dec. 11, 1 pm ET / 10 am PT

Join **FierceHealthIT Editor**, Anne Zieger; Jesse Kozikowski, **Server Analyst at Aspirus Wausau Hospital**; and Axel Wirth, **National Healthcare Solutions Architect at Symantec** to learn best practices on how to maintain a secure and healthy infrastructure on remote devices without compromising clinical needs. **Register Today!**

Events

> World Vaccine Congress China 2008 -December 1-5 2008

The Congress will be the largest meeting devoted exclusively to the research on vaccines and asociated technologies for disease prevention and treatment. There are 78 sessions and 5 workshops will be included in the event. Register today.

> Webinar: Clinical Trial Management - Nov 19, 2008 at 1pm EST/10am PT

StudyManager's next informative webinar, Clinical Trial Management, examines the creation of **an effective strategic plan that leverages technology to avoid common pitfalls that plague clinical trials.** Space is limited, so sign-up today!

> Webinar: Efficiency Management in Quality Operation, COQ & KPI for QC and QA

3 Webinars you do not want to miss: (I) QC Resource Planning, Scheduling and Cost of Quality (COQ); (II) Key Performance Indicators (KPI) in Quality Operation; (III) Batch Record Documentation Errors Reduction Methodology & QA Efficiency Management. **To Register Click here.**

> Drug Discovery and Clinical Development in India: December 7-10, Mumbai

This conference will continue to serve as an international and neutral forum to address

current solid scientific research in India pertaining to global development of drugs and biologics. Read more.

> Contemporary Pharmacovigilance and Risk Management Strategies Jan 11, DC

This comprehensive four-day program will address the current complexities and controversies in pharmacovigilance and risk management throughout all phases of development and marketed use via discussion of the latest safety-related regulatory initiatives and more. Click here to read more.

> ePharma Summit 2009 - February 9-11, 2009 - Philadelphia, PA

Pharmaceutical Marketing Professionals: Learn how to leverage digital marketing to drive sales and help consumers and physicians make better, more informed healthcare decisions at the most innovative pharmaceutical marketing event. Register or learn more at www.epharmasummit.com.

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> How Pharmaceutical CFOs are Turning a Top-line Problem into a Bottom-line Success

In this white paper, learn how CFOs today are increasingly taking center stage in value creation.

> Successful Pharmabiotech Alliance Strategies: Driving synergies, avoiding failure and managing relationships

This report examines 9 case studies that profile varying approaches to deal structuring and relationship management, and charts the current and future alliance activities of the top ten pharmaceutical companies. Recent major joint ventures, acquistions and licensing deals are evaluated and the latest trends and developments affecting alliance management are assessed.

> Trends in Pharmaceutical Portfolio Management - Strategies to maintain profitability despite adversity

With growing competition, Pharma companies are under increased pressure to deliver additional value for key stakeholders through their portfolios. Use this report to understand the recent trends in portfolio development strategies and learn from best practices. Read more.

> In-depth Strategic Insight from Global KOLs in 30+ Therapeutic Areas

MedPredict's therapeutic area reports are designed to dig deep into pipelines and unmet needs. Primary interviews with our panel of over 1,000 global thought leaders include analysis of clinical trials, emerging trends, and predictions on what will and won't make it, and why. Browse Latest Reports.

> Sales Force Effectiveness

The traditional sales force model is no longer effective as doctors are no longer the key prescribing decision makers. Governments and payers are implementing cost cutting initiatives and promoting generic use in an attempt to control escalating healthcare costs. This has made it increasingly difficult for sales representatives to promote expensive branded drugs to doctors. **Read more.**

> Whitepaper: Gifts to Physicians: Just a Simple Thank-You or a Corporate Risk?

Reports from the industry associations and various journals state that approximately 94% of physicians had received food, drug samples, or other reimbursements and payments from industry. The question becomes, "so what"? **This paper** provides guidance and insights on collecting and reporting gifts and payments to healthcare professionals.

Jobs

> Vice President of Sales and Marketing - Harvard Group International

The Vice President of Sales and Marketing will be responsible for the marketing strategy, market development, and product forecasting, market research and implementation, sales forecast and budget plus opinion leader development. The Vice President of Sales and Marketing will cross multiple customer channels in strategy development which will include pharmaceutical, diagnostic, biotechnology, academic, and OEM environments.

> Sponsorship Sales - Technology Vision Group

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