Message

From: Williams, Jane L [Jane.WILLIAMS@mallinckrodt.com]
Sent: 7/1/2013 4:40:29 PM
To: Cardetti, Lisa M [Lisa.Cardetti@mallinckrodt.com]
Subject: RE: Mallinckrodt Daily News Report 01 July 2013

I think they are just sending to the managers. I may need to forward unless we can add. Will find out and let you know.

From: Cardetti, Lisa M
Sent: Monday, July 01, 2013 12:17 PM
To: Williams, Jane L
Subject: RE: Mallinckrodt Daily News Report 01 July 2013

I am not receiving this. How can I get signed up?

Thanks,
Lisa

Lisa Cardetti I Regional Account Manager
Mallinckrodt Pharmaceuticals
675 McDonnell Blvd. I Hazelwood, MO 63042
T: 816.214.5286 I M: 314.452.2845
lisa.cardetti@mallinckrodt.com I www.mallinckrodt.com

From: Williams, Jane L
Sent: Monday, July 01, 2013 8:51 AM
To: Becker, Steven A; Cardetti, Lisa M; Kazemi, Kian L; McKendrick, Rich; New, Bonnie I; Romer, Peter M; Alexander, Dan; Colvin, Darren A; Ottosen, Danny J; Ryan, Edward R; Sigel, Tom J
Subject: FW: Mallinckrodt Daily News Report 01 July 2013

Team,

Are you receiving this daily news feed?

Jane

From: Mallinckrodt Daily News Report [mailto:Mallinckrodt@dimoso.com]
Sent: Monday, July 01, 2013 7:36 AM
To: Mallinckrodt Daily News Report
Subject: Mallinckrodt Daily News Report 01 July 2013

Mallinckrodt Daily News Report 1 July 2013

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Fears over the use of Ritalin leads to major inquiry, The Telegraph - 28 June 2013

Govt to finalise FDI policy in pharma before FIPB meet, Hindustan Times - 30 June 2013

Pangea VI swoop nets $41m-worth of fake medicines, Securing Industry - 28 June 2013

'Biosimilar' drug ruling to hit Big Pharma, The Financial Times - 28 June 2013

DEA: Walgreens was pushing oxycodone sales amid Rx-drug epidemic, Orlando Sentinel - 29 June 2013

Osceola deputies arrest seven for Walgreens pharmacy burglaries, WFTV - 29 June 2013

MALLINCKRODT CORPORATE NEWS

Mallinckrodt Goes Solo, Touting Abuse-Resistant Drugs
Investor's Business Daily
29 June 2013

Shares of Mallinckrodt are set to start trading Monday on the company's first day apart from parent Covidien, bringing investors a big new player in medical products.

Mallinckrodt (MNK) might be the newest stock on the market, but the company is 145 years old, evolving from a chemical firm into a diverse medical company. It was acquired by Avon Products (AVP) in 1982 and by Tyco International (TYC) in 2000.

In 2007, Tyco spun out its medical businesses as Covidien (COV). As the medical industry has caught spinoff fever lately in the drive to please shareholders, the company decided to further divide itself.

The Mallinckrodt now trading on the market is a somewhat pared-down version of its former self. The old chemical business is gone, along with the veterinary unit and a few other product lines. What remains are two equally sized but disparate parts: a growing specialty pharma business, and a shrinking medical-imaging business.

In an interview with IBD, Mallinckrodt CEO Mark Trudeau admitted there aren't many operating synergies between the two halves of the company, though there is "financial synergy."

"The good news about the imaging business is that we've been doing it for so long, and are so well established, that there's very low competitive intensity," he said. "We're able to drive a lot of cash out of that, which we can use to fund our research and development and our commercialization efforts on the spec pharma side."

The drug business, though, faces far more competition, especially since many of the company's medicines are generic. Trudeau says the firm's key advantage is its experience with controlled substances, which are subject to stringent FDA regulations due to their potential for abuse. For instance, the FDA has been encouraging the manufacture of opioid painkillers such as OxyContin and Opana in tablets that can't readily be crushed, and therefore snorted or injected by addicts.

Mallinckrodt recently became the first company to file for approval for a generic version of Concerta, the popular attention deficit/hyperactivity drug first marketed by Novartis (NVS).

"The active ingredient is methylphenidate — a controlled substance we know extremely well," Trudeau said. "But the formulation for Concerta itself is very challenging. A number of other companies have tried to do that formulation. We were first to file in three of the four marketed strengths."

Mallinckrodt's small pipeline — it includes three potential branded drugs and five generics — is similarly focused on tamper-resistant forms of familiar compounds, mostly painkillers. MNK-795, which was submitted to the FDA in May, is a combination opioid painkiller that uses extended-release technology licensed from Depomed (DEPO). Trudeau says such products could generate

hundreds of millions in annual sales.

Not everyone is convinced Mallinckrodt is sufficiently buffered from the competition. Morningstar analyst David Krempa recently pointed out that the firm's main branded product, Exalgo, will lose patent protection next year, "so Mallinckrodt will essentially be attempting to build a branded pain business from scratch." It will be doing so with a smaller salesforce and infrastructure than its big-pharma rivals, Krempa added.

Nonetheless, the company is expecting growth this year. In guidance issued on May 3, the company said sales in fiscal 2013 ending Sept. 27 will rise 7% to 11% over the 2012 figure of $2.1 billion. Pharma sales were projected to grow 21% to 25%, with at least $125 million from generic Concerta and $100 million from Exalgo. It did not issue EPS guidance but said its EBITDA (earnings before interest, taxes, depreciation and amortization) margin will be 17% to 21%.

http://news.investors.com/technology/062913-661855-covidient-spins-off-mallinckrodt.htm

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BMO Capital Markets Cuts Price Target on Covidien (COV)
The Dividend Daily
28 June 2013

BMO Capital Markets reported on Friday that it has lowered its price target on healthcare product company, Covidien plc (COV).

The firm has maintained an “Outperform” rating on COV, but has cut the company’s price target from $72 to $64. This price target suggests a 2% upside from the stock’s current price of $62.86.

An analyst from the firm noted, “Covidien management has provided a tremendous amount of detail to aid investors with their evaluations of ‘RemainCo’ and Mallinckrodt as standalone businesses, and we believe the transaction is well understood. Now the focus will shift to execution, against FY2Q13 results which raised some questions, and FY2013 guidance, which we view as reasonable, if not somewhat conservative. This said, our investment thesis on COV remains: the company’s diversified portfolio and global footprint should allow it to manage through changes in healthcare, drive operating margin expansion, and deliver revenue above the market growth rate, looking for mid-single-digits that could be leveraged to high-single-digits/low-double-digits over time.”

Covidien shares were mostly flat during Friday morning trading. The stock is up 9% YTD.

The Bottom Line Shares of Covidien plc (COV) have a 1.66% yield, based on Friday morning’s price of $62.63.

Covidien plc (COV) is not recommended at this time, holding a Dividend.com DARS™ Rating of 3.4 out of 5 stars.

http://www.dividend.com/news/2013/bmo-capital-markets-cuts-price-target-on-covidien-cov/

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MALLINCKRODT PRODUCT NEWS

MALLINCKRODT COMPETITOR NEWS

Chutes & Ladders
Fierce Biotech
28 June 2013

Mylan ($MYL) has appointed Roger Graham as president of Mylan Specialty. Graham joins Mylan from Advandx, where he was the company's chief commercial officer and developed its growth strategy for the U.S. and European markets.

http://www.fiercebiotech.com/story/douglas-ingram-named-president-allergan/2013-06-28

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Teva Pharmaceuticals a Dodgy Dividend Choice
Investor Place
29 June 2013

Competition dampens profits and future potential

Teva Pharmaceutical (TVA) develops, manufactures, markets, and distributes pharmaceutical products worldwide. This dividend achiever has paid dividends since 1984, and has increased them for 13 years in a row.

The company's last dividend increase was in February 2013 when the Board of Directors approved a 25% increase in the quarterly distribution to 32 cents per share. The company's peer group includes Actavis (ACT), Taro Pharmaceutical (TARO) and Revlon (REV).

Over the past decade this dividend growth stock has delivered an annualized total return of 8.10% to its shareholders.

The company has managed to deliver a 7.30% average increase in annual EPS since 2003. Analysts expect Teva to earn $5.07 per share in 2013 and $5.54 per share in 2014. In comparison, the company earned $2.25 per share in 2012. Over the next five years, analysts expect EPS to rise by 6.81% per annum.

Earnings per share have been following a general uptrend, which has been quite volatile however. The company's U.S. operations have benefited from the recent launches of new generic products such as Lexapro and Actos. The patent cliff experienced by big pharma is beneficial for generics manufacturers such as Teva. Generics account for over half of the company's sales. The company is under intense competition in the generic pharmaceuticals market, where being first to file might offer a slight competitive advantage to the filer.

However, Teva is not immune to the patent cliff itself. Its multiple-sclerosis drug Copaxone, accounting for 17% of sales in 2012, will face competition from Mylan Laboratories as early as 2015.

Future growth could also be realized from strategic acquisitions. The firm is expecting to benefit from the 2011 acquisition of Cephalon in terms of synergies, as well as adding its portfolio of products through its distributions pipeline.

The return on equity for Teva has been on the decline from a high of 27% in 2003. Currently, it is below 10%, but if earnings projections materialize, it could go up to 15%. I generally want to see at least a stable return on equity over time. I use this indicator to assess whether management is able to put extra capital to work at sufficient returns.

The annual dividend payment in U.S. dollars has increased by 27.60% per year over the past decade, which is higher than the growth in EPS.

A 27% growth in distributions translates into the dividend payment doubling almost every two and a half years on average. If we look at historical data, going as far back as 1990, one would notice that the company has managed to double distributions every three years on average.

The dividend payout ratio has increased from 12% in 2003 to 46% in 2012. A lower payout is always a plus, since it leaves room for consistent dividend growth minimizing the impact of short-term fluctuations in earnings.

Currently Teva is attractively valued at 17.20 times earnings, yields 2.80% and has a sustainable distribution. Unfortunately, I am not certain if it has the durable competitive advantages that would help it differentiate itself from competitors. It looks like in the generic drugs industry, companies do not have any competitive advantages related to branding, that would allow them to charge

premium prices.

In the long-run, commodity producers cannot realize excessive profits, that would translate into fat future dividends. As a result, I do not plan on initiating a position in the stock.

http://investorplace.com/2013/06/teva-pharmaceutical-teva-dividend-stock-analysis-act-rev-taro-teva/

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Pfizer To Receive $2.15 Billion In Patent Lawsuit Settlement
University Chronicle
28 June 2013

Teva Pharmaceuticals Industries Ltd and Sun Pharmaceutical Industries Ltd will pay $2.15 billion to settle a patent lawsuit brought by pharmaceutical giant Pfizer Inc. The lawsuit was related to Pfizer's patented acid-reflux drug, Protonix. This is the first instance of generic drugmakers paying damages for marketing a copy of an existing drug for which patents have yet to expire, known as an "at-risk" launch.

Protonix recorded peak annual revenue of almost $2 billion in 2007. However, sales of the drug plunged following the launch of generic versions by Teva in 2007 and Sun Pharma in 2008. The patent covering pantoprazole, the active ingredient in Protonix, didn't expire until January 2011.

In April 2010, after a protracted legal battle, a New Jersey jury ruled that Teva had infringed the Protonix patent. The patent was held by Nycomed, now a Takeda subsidiary, and the drug was licensed to Wyeth, now owned by Pfizer. Takeda will receive 36 percent from the settlement, totaling about $774 million, with the rest going to Pfizer.

Damien Conover, an analyst at Morningstar, said that the Pfizer case was unique among these types of lawsuits as it involved a "composition of matter patent," which is one of the stronger patent protections available. Conover said, "We see more at-risk launches but probably of less powerful patents." Aaron Gal, an analyst with Bernstein Research, said, "It is an important milestone, setting a 'book-end' case for the industry. It will serve to encourage patent settlements."

Israel-based Teva, the world's largest generic drugmaker, will pay $1.6 billion and India's Sun Pharma will pay $550 million. Teva announced that it would record a charge of nearly $930 million in the second quarter, in addition to the $670 million provision recorded in 2012. In February, Teva said that it might face legal losses of up to $2.07 billion resolving the case.

http://www.ssuchronicle.com/2013/06/28/pfizer-to-receive-2-15-billion-in-patent-lawsuit-settlement-nysepfe/

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Ranbaxy still bullish on overseas plans
Hindustan Times
30 June 2013

Pharmaceutical major Ranbaxy Laboratories is chalking out plans for overseas acquisitions to grow its business, despite its recent setbacks in the United States where it agreed to pay hefty fine linked to regulatory violations.

"Our focus is now to develop business via local, global acquisitions and forming alliances," said Arun Sawhney, CEO and MD, Ranbaxy. "Future growth will be driven by the bunch of new markets we are looking at."

The company is exploring Canada, Mexico, Brazil, Poland, Romania, Nigeria, Morocco, Egypt and New Zealand among others for expansion. "We are looking for right partners and we will be bold, irrespective of size of deal or money involved," Sawhney said.

Each country will have a different focus area, and Ranbaxy is developing a slew of products

towards this.

To tap the new markets, he said, “We may shift the proportion of business with slightly higher share of drugs under chronic therapeutic segment. This will include cardiovascular, urology and dermatology drugs.” For India, acute therapeutics including anti-infection drugs are the focus.

Ranbaxy is looking to move on after recent issues in the US, where it has pleaded guilty to felony charges for manufacturing norms violation and is to pay $500 million in fines.

http://www.hindustantimes.com/business-news/CorporateNews/Ranbaxy-still-bullish-on-overseas-plans/Article1-1084906.aspx

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UK drug regulator reviewing Ranbaxy's regulatory issues
The Economic Times
29 June 2013

NEW DELHI: The UK drug regulator is reviewing the Ranbaxy Labs regulatory issues in the light of recent revelations to see whether the situation warrants any future action.

Taking a cue from the US Department of Justice, UK drug regulator Medicines and Healthcare products Regulatory Agency (MHRA) has said it is reviewing the Ranbaxy Labs regulatory issues in the light of recent revelation to see whether the situation warrants any future action. The drug regulator is currently in discussion with the US Food and Drug Administration, other EU and global regulators for the same.

"In light of the recent declaration made by Ranbaxy, we are consulting with other EU and international regulators including the FDA to review whether any further action is deemed appropriate," an MHRA spokesperson said in a recent statement. Last month, Ranbaxy pleaded guilty in the US to criminal and civil charges of falsification of data and marketing 'adulterated drugs' there and agreed to pay a penalty of $500 million to settle the charges with the Department of Justice.

In the same statement, the British regulator acknowledged that despite several focused inspections in collaboration with multiple drug regulators since 2006, it has found that the company complied in general with EU good manufacturing practice (GMP). It also added that 'no evidence that any of the products on the UK market manufactured by Ranbaxy are or have been of unacceptable quality'.

A mail sent to a Ranbaxy remained unanswered till going to the press.

MHRA said that a Good Clinical Practice (GCP) inspection of one of the Ranbaxy sites in India was conducted in February 2009. "This concentrated on bioequivalence activities. Some non-compliances with GCP were observed but these did not indicate a significant risk to patients", the UK drug regulator said.

The site will be scheduled for a re-inspection within the next 12 months, the drug regulator said.

Since 2005, the World Health Organization, in conjunction with other international drug regulators from Australia, South Africa, and the UK has conducted nine inspections at Ranbaxy's company's Paonta Sahib facility alone.

Commenting on its inspections after the 2008 US FDA warning letter was issued, WHO says: "Some non-compliance was observed and Ranbaxy thereafter submitted documentation describing corrective and preventive actions, which were assessed by the inspection team and found acceptable."

In the case of data manipulation, the intent is to supply false information but situations also occur in which submissions are not accurate because the systems for ensuring that dossiers are kept up-to-date and/or manage change management are inadequate, WHO adds. As ET had reported, the Indian drug regulator is also currently conducting inspections at the company's Paonta Sahib

and Dewas facility. The drug regulator is also testing company's drugs for quality.

http://articles.economictimes.indiatimes.com/2013-06-29/news/40271900_1_drug-regulator-ranbaxy-labs-british-regulator

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After Ranbaxy, Wockhardt episodes must for drug cos to disclose global regulators' action
The Economic Times
1 July 2013

NEW DELHI: Pharma companies would now have to immediately disclose to the government, if overseas drug regulators impose restrictions on their facilities located in India, according to a new order issued by the Drug Controller General of India.

This mandate of more stringent disclosures on safety alerts of international drug regulators comes after the country's two top drugmakers Ranbaxy Labs and Wockhardt Ltd [BSE 6.45 %] fell foul of the US Food & Drug Administration.

In a circular issued last week, the central drug regulator has asked all state drug controllers "to direct manufacturers (in their states)...as and when such issues are raised and actions like restriction/alert are issued by any drug regulatory authorities abroad in respect of drugs manufactured and exported from India, the details of the same should be immediately brought to the notice of the office of DCGI as well as the state drug control authority." ET had reported last week that the central drug regulator was planning to ask pharma companies to make immediate disclosures if international drug regulators took adverse actions against their India based facilities. The report said that the DCGI was putting in place this early warning technique to follow up promptly and monitor if the redmarked plants are following current good manufacturing practices under the domestic drug law.

The central drug regulator has told the state drug controllers that such a move is warranted "so that its impact in Indian scenario can be assessed and necessary action is taken to ascertain the quality, safety and efficacy of the drugs in the country". Currently, pharma firms are not required to make any such disclosures in India. The drug regulator says India is exporting drugs to more than 200 countries. DCGI says the same drugmakers are manufacturing and marketing similar drugs in the domestic market as well.

http://economictimes.indiatimes.com/news/news-by-industry/healthcare

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Actavis, Inc. to Host Second Quarter 2013 Earnings Conference Call and Webcast
PRNewswire
28 June 2013

PARSIPPANY, N.J., June 28, 2013 /PRNewswire via COMTEX/ -- Actavis, Inc. ACT +0.29% , announced today that it intends to release second quarter 2013 financial results on Thursday, July 25, 2013, prior to the open of the U.S. financial markets. The Company will host a conference call and webcast at 8:30 a.m. Eastern Time on Thursday, July 25, 2013 to discuss its financial results. The dial-in number to access the call is US/Canada (877) 251-7980, International (706) 643-1573, and the Conference ID is 12382077.

A taped replay of the conference call will also be available beginning approximately two hours after the call's conclusion and will remain available through 12:00 midnight Eastern Time on August 8, 2013. The replay may be accessed by dialing (855) 859-2056 and entering pass code 12382077. From international locations, the replay may be accessed by dialing (404) 537-3406 and entering the same pass code. To access the webcast, go to Actavis' Investor Relations Web site at http://ir.actavis.com. A replay of the webcast will also be available.

About Actavis, Inc.Actavis, Inc. ACT +0.29% is a global, integrated specialty pharmaceutical company focused on developing, manufacturing and distributing generic, brand and biosimilar products. Actavis has global headquarters in Parsippany, New Jersey, USA.

Operating as Actavis Pharma, Actavis develops, manufactures and markets generic, branded generic, legacy brands and Over-the-Counter (OTC) products in more than 60 countries. Actavis Specialty Brands is Actavis' global branded specialty pharmaceutical business focused in the Urology and Women's Health therapeutic categories. Actavis Specialty Brands also has a portfolio of five biosimilar products in development in Women's Health and Oncology. Actavis Global Operations has more than 30 manufacturing and distribution facilities around the world, and includes Anda, Inc., a U.S. pharmaceutical product distributor.

For press release and other company information, visit Actavis' Web site at http://www.actavis.com.

http://www.marketwatch.com/story/actavis-inc-to-host-second-quarter-2013-earnings-conference-call-and-webcast-2013-06-28

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Takeda Nycomed signs agreement with Shire for the Calcichew portfolio
The Pharma Letter
28 June 2013

Japan's leading drugmaker Takeda Pharma's (TYO: 4502) Takeda Nycomed subsidiary (renamed as such after the acquisition of the Swiss Nycomed business acquired in a 9.6 billion-euro [$12.6 billion at current exchange rate] deal [The Pharma Letter May 19, 2011]) has signed an agreement with Ireland-headquartered Shire Pharmaceuticals Ireland (LSE: SHP) to transfer the UK and Irish marketing authorizations for the Calcichew portfolio from Shire to Takeda in January 2014. Financial terms of the deal were not disclosed.

Takeda announced yesterday (June 27) that it has signed a short term extension to the supply and distribution agreement with Shire relating to the ownership and promotion of the Calcichew portfolio. The companies will collaborate on marketing activities in 2013, with Shire responsible for sales and distribution until December 31 and Takeda taking on the promotion and marketing from July 1.

The Calcichew D3 portfolio is indicated for the prevention and treatment of vitamin D/calcium deficiency and for the supplementation of vitamin D and calcium as an adjunct to specific therapy for osteoporosis, in pregnancy, in established vitamin D dependent osteomalacia and in other situations requiring therapeutic supplementation of malnutrition.

Will add 'significant' UK/Ireland revenues

Yasuhiro Fukutomi, managing director of Takeda UK and cluster lead for UK and Ireland, said the agreement is an 'exciting' development, noting that: "The Calcichew portfolio will add significant financial revenues to Takeda in the UK and Ireland and there is significant potential for growth in both countries. We have successfully repatriated other products to Takeda UK over the last three years and we will work to repeat this success with the Calcihew portfolio."

In January 2014, the marketing authorizations for the portfolio will transfer to Takeda in both countries (exact timing subject to regulatory approval).

http://www.thepharmaletter.com/file/123210/takeda-nycomed-signs-agreement-with-shire-for-the-calcichew-portfolio.html

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Forest Labs reports positive phase III trail results evaluating FDC of nebivolol and valsartan for hypertension
PharmaBiz
29 June 2013

Forest Laboratories, Inc., a company identifies, develops, and delivers pharmaceutical products that make a difference in people's lives, has reported positive topline results from an eight-week pivotal phase III clinical trial evaluating the efficacy and safety of investigational fixed dose

combination (FDC) of nebivolol and valsartan for the treatment of hypertension.

The combination of nebivolol and valsartan demonstrated statistically significant reductions in diastolic blood pressure (DBP) vs. both nebivolol alone and valsartan alone at eight weeks, which was the primary endpoint. The FDC also met the key secondary endpoint of change from baseline in systolic blood pressure (SBP) at eight weeks.

The single pivotal nebivolol/valsartan FDC trial was designed to meet the required regulatory "Combination Rule," comparing a FDC against the highest approved dose of each component drug.

"These phase III results in patients with Stage 1 or Stage 2 hypertension are exciting and demonstrate the potential benefits of this novel FDC -- a first-in-class beta blocker/ARB combination," said Marco Taglietti, MD, senior vice president of Research and Development and President, Forest Research Institute. "We are very pleased with these results which demonstrate the efficacy and safety profile of this combination and support the potential use of the nebivolol/valsartan FDC as a new treatment option for patients with hypertension who need dual therapy to reach their blood pressure goals."

Based on these positive results, Forest plans to submit a regulatory filing with the Food and Drug Administration (FDA) in the first quarter of calendar year 2014.

This pivotal eight-week randomized, double-blind, placebo-controlled clinical trial in 4,161 hypertension patients studied nebivolol 5, 10, 20, and 40mg and valsartan 80, 160, and 320mg alone and in fixed dose combinations.

The study consisted of a one-week screening period, followed by six weeks of placebo wash-out, an eight-week double-blind treatment period, and a one-week down-titration period. During the double-blind treatment period, patients were initially randomized to one of eight treatment groups: FDC nebivolol/valsartan 5/80, 5/160, or 10/160mg; nebivolol 5 or 20mg; valsartan 80 or 160mg or placebo. After four weeks, all dosages were doubled.

The primary endpoint was change from baseline in mean sitting trough DBP at eight weeks for FDC dose 20/320mg versus nebivolol 40mg (the highest approved nebivolol dose) and versus valsartan 320mg (the highest approved valsartan dose), and FDC doses 10/320mg and 10/160mg versus corresponding monotherapies. Across these doses, the incremental reduction in DBP for the combination vs. nebivolol was -1.2 to -2.4 mm Hg; (p value 0.03 to <0.0001) and versus valsartan was -3.7 to -4.4 mm Hg (p value <0.0001).

The key secondary endpoint was change from baseline in sitting trough SBP at eight weeks for the FDC doses 20/320mg, 10/320mg and 10/160mg vs. the same monotherapy components evaluated for DBP. Across these doses, the incremental reduction in SBP for the combination vs. nebivolol was -2.9 to -3.6 mm Hg; (p value 0.0013 to <0.0001) and versus valsartan was -3.0 to -3.9 mm Hg (p value 0.0011 to <0.0001).

Treatment with nebivolol/valsartan FDC was well-tolerated in the study. Across all FDC doses the most common adverse events (incidence = 2% and greater than placebo) were fatigue (0.9% to 2.3% vs. 1.1% in placebo) and dizziness (1.6% to 2.3% vs. 0.4% in placebo).

Nebivolol/ valsartan (5/80mg, 5/160mg, 10/160mg, 10/320mg, and 20/320mg) is an investigational fixed dose combination. Nebivolol/valsartan FDC combines two US FDA approved, once daily, blood pressure lowering agents with different mechanisms of action. It is being evaluated as a potential treatment for hypertension in patients who need combination therapy.

Nebivolol (marketed in the US as Bystolic) is cardioselective up to and including the 10mg dose and in extensive metabolizers. While nebivolol's mechanism of action has not been definitively established, possible factors include vasodilation and decreased peripheral vascular resistance (PVR). Other possible factors include reduced heart rate and myocardial contractility, suppression of renin, and reduced sympathetic activity. Nebivolol is indicated for the treatment of hypertension and is effective at lowering blood pressure when taken alone or in combination with other anti-

hypertensive agents.

Valsartan is an angiotensin II receptor blocker (ARB) that blocks the binding of angiotensin II to the AT1 receptor in many tissues, such as vascular smooth muscle and the adrenal gland, thereby preventing its vasoconstrictor and aldosterone-secreting effects. Valsartan has been well studied in many different patient populations and is an effective antihypertensive agent.

Hypertension has been described as a “neglected disease” because of the lack of attention given to it and the serious cardiovascular (CV) consequences of having high BP, such as strokes and MI. The prevalence of hypertension is on the rise. According to the National Institute of Health Statistics, 28.6% of adults in the United States (~88 million) have hypertension. Inadequate treatment of hypertension is a significant public health problem. Numerous antihypertensive drugs, from a variety of pharmacologic classes and with different mechanisms of action, have been shown in randomized controlled trials to reduce CV morbidity and mortality, and it can be concluded that it is BP reduction that is largely responsible for those benefits. Elevated systolic or diastolic pressure causes increased CV risk, and the absolute risk increase per mm Hg is greater at higher blood pressures, so even modest reductions of severe hypertension can provide substantial benefit.

Two-thirds of patients will require more than one drug to achieve BP goals. The Seventh Report of the Joint National Committee on Prevention, Detection, Evaluation, and Treatment of High Blood Pressure (JNC 7) recommends initial combination therapy for most patients with stage II hypertension, and add-on therapy for treated patients in all stages whose BP remains uncontrolled.

Forest Laboratories' longstanding global partnerships and track record developing and marketing pharmaceutical products in the United States have yielded its well-established central nervous system and cardiovascular franchises and innovations in anti-infective, respiratory, gastrointestinal and pain management medicine.

http://www.pharmabiz.com/NewsDetails.aspx?aid=76208&sid=2

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Abbott Hosts Conference Call for Second-Quarter Earnings
PR Newswire
28 June 2013

ABBOTT PARK, Ill., June 28, 2013 /PRNewswire/ -- Abbott (NYSE: ABT) will announce its second-quarter 2013 financial results on Wednesday, July 17, 2013, before the market opens.

The announcement will be followed by a live webcast of the earnings conference call at 8 a.m. Central time (9 a.m. Eastern), and will be accessible through Abbott's Investor Relations Web site at www.abbottinvestor.com. An archived edition of the call will be available after 11 a.m. Central time.

http://www.marketwatch.com/story/abbott-hosts-conference-call-for-second-quarter-earnings-2013-06-28

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Shipping up to Boston: Johnson & Johnson debuts new Innovation Center
Mass Device
28 June 2013

Johnson & Johnson celebrates the grand opening of its latest Innovation Center in Massachusetts, where the healthcare giant aims to tap into Boston's biotech start-up culture.

Johnson & Johnson (NYSE:JNJ) threw open the doors and cracked champagne at last night's grand opening of its new Innovation Center, a modest 9,000-sqaure-foot space in Cambridge, Mass., it calls a "hotbed for life science innovation."

The grand opening, which featured caricature artists, performers and life-sized statues of famous

scientists, sent a message about the kind of collaborative, open-door policy the Innovation Center hopes to foster between business, academia and early-stage product developers.

J&J pulled in the new Innovation Center's leader, Robert Urban, from nearby MIT's Koch Institute for Integrative Cancer Research. The company and Urban emphasized that the new space is not only a heat-seeking missile for pipeline technologies, but also a fostering home for early-stage biotech companies looking to get their products off the ground.

"We hope to make it simply much easier for innovators anywhere to begin to understand there is a mechanism by which [they] can collaborate with J&J," Urban told Xconomy.

J&J said it's already inked deals with 2 local private biotechs in the Bay State, Rodin Therapeutics and Vedanta Biosciences, as well as with the LabCentral non-profit and a research center at Mount Sinai in New York.

The Kendall Square Innovation Center is 1 of 4 incubators J&J is opening in Shanghai, San Francisco and London.

http://www.massdevice.com/news/shipping-boston-johnson-johnson-debuts-new-innovation-center

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MALLINCKRODT INDUSTRY NEWS

Fears over the use of Ritalin leads to major inquiry
The Telegraph
28 June 2013

Children as young as three are being prescribed Ritalin, the British Psychological Society has warned as they launch a major inquiry into the use of the drug.

Pressure on councils and medical budgets is leading to overprescription of psychotropic drugs to treat conditions such as attention deficit disorder (ADHD), it is said.

Over the past decade there has been a boom in the use of Ritalin, and experts are calling for tougher controls and a reduction in the number of prescriptions handed out.

The British Psychological Society (BPS) has launched the investigation amid fears that cuts in funding for recommended ADHD treatments such as counselling have led to over reliance on medication.

National guidelines for England and Wales state ADHD should be treated "comprehensively" with psychological, behavioural and educational help.

However, Vivian Hill, chair of the BPS's medicalisation of childhood working group, said that this is not always the case and the inquiry is a response to a "high level of concern".

"Budgets have been cut and psychiatrists feel they can't follow the official guidelines, which recommended therapy before drugs are prescribed. In the UK, often the first response now is to issue drugs, not offer therapeutic help," she told the Times Educational Supplement.

Despite official guidance that the psychotropic drugs, which include Ritalin, are unsuitable for those under six "hundreds" in this age group are being given the medication, including those as young as three, Ms Hill said.

Her group - which will talk to parents, children, teachers and experts about young people with mental health needs – will also examine why children from poorer backgrounds appear more likely to be prescribed with medication.

NHS figures show that the numbers of prescriptions for Ritalin quadrupled from 158,000 in 1999 to 661,463 in 2010.

But without support which addresses the cause of the problem, drugs may have little impact, warned Ms Hill who is Director of Professional Educational Psychology Training at the University of London's Institute of Education.

Professor Tim Kendall, director of the National Collaboration Centre for Mental Health, added that there had been a move toward parent training programmes, but these were disappearing with the "squeeze" on local authority and NHS budgets and social care

"There has been a rise in the use of methylphenidate (Ritalin) on the basis that there hasn't been much else available," he said.

The BPS is not the first body to raise concern about the use of Ritalin, and in the past experts have warned against the number of young children being prescribed and the strength of the medication which is used.

Although the long term effects on young children have not been established, it can cause nausea, fatigue and mood swings and has in the past been linked to suicide.

There are fears from the US that drugs companies are exacerbating the excessive use of the psychotropic drugs.

Professor Allen Frances, emeritus professor at Duke University in North Carolina and an expert in mental health diagnosis, has claimed that the use is "out of hand", and although some of the medication is necessary its use is "stimulated by aggressive and misleading marketing by drugs companies".

http://www.telegraph.co.uk/health/children_shealth/10149490/Fears-over-the-use-of-Ritalin-leads-to-major-inquiry.html

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Govt to finalise FDI policy in pharma before FIPB meet
Hindustan Times
30 June 2013

The government is likely to finalise FDI policy with regard to existing drug companies ahead of the FIPB meeting on July 5, which is scheduled to take up as many as 10 foreign investment proposals.

The Department of Industrial Policy and Promotion (DIPP) has raised concerns over spate of acquisitions of domestic pharma firms by multinationals. The DIPP has sought the intervention of the Prime Minister's Office on this matter.

Government sources said that on an average about 25% of the FIPB agenda is related with pharma sector.

The continuing acquisitions of Indian pharma firms by foreign companies would pose serious problems in availability of life-saving drugs to consumers in near future, they added.

Earlier, the department had asked the Foreign Investment Promotion Board (FIPB) not to take decision on any related proposal.

FDI policy in the sector has already been discussed at the PM level in December last year. Accordingly, all foreign investments in existing domestic pharma firms was allowed only after clearance by the FIPB.

With no let up in multinationals seeking nod to acquire stake in Indian pharma firms despite government putting norms to check it, the DIPP has raised concerns stating the FDI policy in the sector needs a relook again at the PMO level.

Currently, India permits 100% FDI in pharma sector through automatic approval route in the new

projects but the foreign investment in the existing pharma companies were allowed only through FIPB's approval.

In 2008, Japanese firm Daiichi Sankyo had bought out the country's largest drug maker Ranbaxy for $4.6 billion. US-based Abbot Laboratories had acquired Piramal Health Care's domestic business for $3.7 billion.

Since April 2000, $10.3 billion FDI has come into the pharmaceutical sector, nearly 5% of the total foreign inflows the country has received.

The current policy says that "the government may incorporate appropriate conditions for FDI in brownfield cases, at the time of granting approval".

The 10 applications for FDI in drug firms include the proposals of US-based Mylan Laboratories, Mauritius-based Castleton Investment, Mumbai-based Ferring Therapeutics and Hyderabad-based Verdant Life Sciences.

http://www.hindustantimes.com/India-news/newdelhi/Govt-to-finalise-FDI-policy-in-pharma-before-FIPB-meet/Article1-1084691.aspx

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Pangea VI swoop nets $41m-worth of fake medicines
Securing Industry
28 June 2013

The latest Interpol-backed operation against online sales of illicit medicines has resulted in the seizure of almost 10 million drugs worth an estimated $41m.

Operation Pangea VI also resulted in 58 arrests, somewhat fewer than the 79 arrests made during last year's operation which seized 3.75m drugs with a value of around $10.5m.

The week-long clampdown focused on Internet Service Providers (ISPs), electronic payment systems and delivery services and resulted in more than 9,000 websites linked to the trade in illicit medicines being taken down.

That is around half the number of websites shut during Pangea V in 2012, suggesting that the enforcement activity is starting to have durable impact on the scale of illicit trade in medicines carried out online.

As well as raids at addresses linked to the illicit pharmaceutical websites, some 522,000 packages were inspected by customs and regulatory authorities, of which 58,000 were seized.

The enforcement agencies were also able to suspend the payment facilities of illegitimate pharmacies and disrupt "a substantial number" of spam messages peddling fake medicines, according to Interpol, which said that 175 investigations have now been launched into a range of offenses including the illegal manufacturing, selling and supplying counterfeit or unlicensed medicines.

Among the fake medicines seized during Pangea VI were antibiotics, cancer medications, antidepressants, medicines to treat narcolepsy, asthma, arthritis, diabetes and epilepsy, and the usual haul of erectile dysfunction (ED) drugs.

Specific counterfeits uncovered during the operation included copies of GlaxoSmithKline's diabetes drug Avandaryl (glimepiride and rosiglitazone), generic versions of Pfizer's Celebrex (celecoxib) for arthritis, Teva/Cephalon's narcolepsy drug Provigil (modafinil) and clozapine, a tightly-controlled and potentially hazardous medicine used to treat severe cases of schizophrenia.

The US Food and Drug Administration (FDA) highlighted some of the rogue pharmacy websites taken down during the action, which included examples that would be hard to spot by consumers such as www.walgreens-store.com and www.c-v-s-pharmacy.com.

Pangea VI was coordinated by Interpol and carried out with the involvement of the World Customs Organization, the Permanent Forum of International Pharmaceutical Crime, the Heads of Medicines Agencies Working Group of Enforcement Officers, the Pharmaceutical Security Institute and Europol.

"Transnational criminal networks are taking advantage of the Internet to deceive consumers into buying fake and often dangerous medicines with a wanton disregard for the health risks this poses to the unsuspecting buyers," said Interpol secretary general Ronald Noble.

"These are significant steps forward in safeguarding the health and safety of the public, and in dealing a major blow to the criminal groups behind the counterfeiting of medical products," he added.

http://www.securingindustry.com/pharmaceuticals/pangea-vi-swoop-nets-41m-worth-of-fake-medicines/s40/a1766/

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'Biosimilar' drug ruling to hit Big Pharma
The Financial Times
28 June 2013

European regulators have approved the first generic versions of a complex biological medicine, paving the way for competition that will sharply dent revenues for several of the world's biggest pharmaceutical companies.

The European Medicines Agency said on Friday it had authorised two "biosimilar" versions of Johnson & Johnson and Merck's rheumatoid arthritis drug Remicade.

The decision is the first time in the industrialised world that the multibillion-dollar annual market for monoclonal antibodies has been opened to generic producers, after a long period during which investors assumed such complex "large molecule" biological medicines would be protected from the cut-price competition of "small molecules" once patents expire.

It also signals the growth of biosimilar drug producers from Asia, with the newly approved versions developed by Celltrion of South Korea, which in turn has licensed them to Hospira for use in Europe, North America, Australia and New Zealand. The company has to date filed for European regulatory approval of eight different monoclonal antibodies.

Ronny Gal, an analyst with Bernstein, said in a research note: "This is a watershed moment for the field of biosimilars."

Drug companies producing monoclonal antibodies have long argued that biosimilars are not identical and carried higher risks for patients. They have so far delayed similar regulatory approvals in the US.

Andrew Baum, an analyst with Citigroup, wrote that the decision "[probably] increases the biosimilar risk premium for multinationals", with Roche, AbbVie and Johnson & Johnson particularly exposed on drugs including Herceptin for cancer. He said it could also dampen demand for UCB's monoclonal antibody Cimzia.

European regulators studied clinical trials conducted by the generic producers using their biosimilar versions of Remicade called Remsima and Inflectra, and concluded they were of equal quality, safety and efficacy to the original medicine.

They authorised the generic versions for the full range of uses for treating autoimmune diseases granted to Remicade, including rheumatoid arthritis and Crohn's disease.

Without any equivalent ruling by the US Food and Drug Administration, the Remicade rivals will not yet be sold in the US and in some European countries competition will be prevented by patents which remain in place until 2015.

However, Hospira said it would launch Inflectra this year in eastern and central European countries where there are no patents in force, in a move set to swiftly start eroding Remicade's $2bn in annual European sales.

Bernstein estimated generic monoclinals would claim 40 per cent of the European market by 2018, while cautioning that despite regulatory approval, producers would still need to persuade individual doctors familiar with Remicade to switch and prescribe the new, cheaper alternatives.

http://www.ft.com/cms/s/0/b25b49de-e00a-11e2-bf9d-00144feab7de.html#axzz2XmUOE5eD

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DEA: Walgreens was pushing oxycodone sales amid Rx-drug epidemic
Orlando Sentinel
29 June 2013

While the prescription drug problem was reaching epidemic proportions in Florida, the U.S. Drug Enforcement Administration said, corporate officials at Walgreens implemented bonus programs that incentivized pharmacists to sell oxycodone and ignore "red flags" that customers were abusing the popular painkiller.

Despite warnings from Oviedo's police chief to Walgreens' CEO that the pharmacy's parking lots in his city had "become a bastion of illegal drug sales and drug use," sales for the popular painkiller oxycodone skyrocketed more than 2,000 percent at the Lockwood Boulevard store.

A manager at Walgreens' distribution center in Jupiter raised concerns about enormous volumes of oxycodone ordered from its Florida pharmacies — questioning how they could even store so many bottles — but corporate supervisors, according to the DEA, apparently did nothing.

When the DEA issued a suspension order on the distribution center in September, banning it from dispensing controlled substances to its stores in Florida and the East Coast, the federal drug agency was armed with a bevy of internal information about Walgreens' practices.

DEA documents obtained by the Orlando Sentinel through a Freedom of Information request said that, at a time when seven people a day were dying in Florida because of prescription drugs, Walgreens was pushing its employees to sell even more oxycodone.

According to the documents, signed by DEA Administrator Michele Leonhart, Walgreens distributed large amounts of controlled substances in Florida that it knew or should have known were improper.

Earlier this month, Walgreens agreed to pay a record $80 million penalty to resolve the DEA's investigation into its dispensing practices in Florida.

As part of the agreement, the distribution center and the top six Florida pharmacies — including the one Oviedo pharmacy — are banned from dispensing certain drugs — including the popular painkillers OxyContin and Vicodin, and the sedative Xanax — until 2014.

"These administrative actions were inevitable based on how the Walgreens distribution center and its top six retail pharmacies in Florida were abusing their DEA registration," agency spokeswoman Mia Ro said Friday.

Walgreens spokesman Jim Graham told the Sentinel that as part of the agreement with DEA, the company has "identified specific compliance measures — many of which Walgreens has already taken — ... to provide our team members with the tools, training and support they need to ensure the appropriate dispensing of controlled substances ...."

Graham also said the company has placed "order quantity limits" on all controlled substances.
Bonuses for scripts filled

According to the DEA investigation, Walgreens had compensation programs for pharmacy employees in which bonuses were based on the number of prescriptions filled at the pharmacy.

In July 2010, Walgreens' corporate headquarters in Illinois analyzed oxycodone dispensing for its Florida stores, ranking each pharmacy by the number of such prescriptions dispensed in June of that year.

That spreadsheet was sent to Walgreens' supervisors with the admonition: "look at the stores on the bottom end .... We need to make sure we aren't turning legitimate scripts away. Please reinforce."

The Walgreens store on Lockwood Boulevard in Oviedo was ranked 444th on that list, filling on average only four oxycodone prescriptions per day in June 2010.

But soon, the store's oxycodone sales rose drastically.

The Oviedo store bought 6,600 pills in June 2010, but in June 2011, purchased 169,700 pills — an increase of 2,471 percent.

Oviedo police began arresting customers in the parking lot for selling or trading their pills with other people. Officers were concerned customers were getting high in the parking lot and getting on the roads, endangering the public, said Chief Jeffrey Chudnow.

He wrote letters to the two stores in his jurisdiction after each arrest stemming from the prescriptions they filled, telling the pharmacists the pills were not used for legitimate treatment.

"I wrote letters to the CEO and president of Walgreens Corporation, telling them what was going on at the parking lot and at the store ... and asking for their cooperation," Chudnow told the Orlando Sentinel.

The police chief hoped he could cut the drug supply off at its source.

"I got no response," he said. "I received nothing back from the corporate office."

Despite the chief's pleas, the DEA found pharmacists at the Lockwood Boulevard store and another Walgreens in Oviedo dispensed prescriptions of commonly abused drugs to people they knew were arrested for drug offenses at their pharmacies.

"I find this to be a staggering disregard of Walgreens' obligations under the Controlled Substance Act," DEA Administrator Leonhart wrote.

While the average U.S. retail pharmacy in 2011 purchased 73,000 pills of all formulations of oxycodone for the entire year, Walgreens' distribution center shipped 145,300 oxycodone pills to the Oviedo pharmacy in July 2011 alone.

At the same time Oviedo's police chief was pleading with Walgreens' CEO for help, corporate officials initiated a Florida pharmacy store review initially titled, "Focus on Profit." That was later changed to "Focus on Compliance."

Leonhart said her concerns were not limited to the top six Walgreens stores, which also include pharmacies in Hudson, Fort Myers, Port Richey, and two in Fort Pierce.

The distribution center in Jupiter ships oxycodone to more than 800 pharmacies in Florida, many of which sell the painkiller in amounts that far exceed the state and national average, the documents said.

In addition to the $80 million penalty Walgreens agreed to pay the federal government, the DEA agreement requires the top six Florida pharmacies to stop selling drugs like oxycodone until May 2014, and the distribution center cannot dispense that and similar drugs until September 2014.

Meanwhile, Oviedo's police chief said officers have seen a major difference at the Walgreens pharmacy in his jurisdiction.

"Once they were suspended from filling the scripts," Chudnow said, "all that traffic stopped."

http://articles.orlandosentinel.com/2013-06-29/health/os-walgreens-oxycodone-investigation-dea-20130629_1_walgreens-mia-ro-oxycodone-sales

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Osceola deputies arrest seven for Walgreens pharmacy burglaries
WFTV
29 June 2013

OSCEOLA COUNTY, Fla. — Deputies said they recovered more than 21,000 prescription pills after arresting seven men in connection with a string of burglaries at Walgreens pharmacies in Osceola County.

Osceola County detectives said they have been investigating the string of burglaries since the beginning of June. There's been a total of seven break-ins at Walgreens locations in Osceola County, in addition to similar incidents in surrounding counties, officials said.

In each case, the suspects broke into a window at the pharmacy using a sledge hammer or ax and stole prescription drugs, according to officials.

After identifying 23-year-old Christopher Collins, 19-year-old Deveon Gibbs and 28-year-old Byron Clark as possible suspects, several units of the Osceola County Sheriff's Office conducted an undercover investigation.

Sheriff's office officials said that on June 27, undercover deputies followed Collins, Gibbs and Clark and witnessed them break into a Walgreens on Edgewater Drive in Orlando. All three men were subsequently taken into custody. Deputies said prescription pills and a sledge hammer were found in the suspects' vehicle.

Further investigation led deputies to identify four more suspects involved in the crimes, officials said. Those suspects, 21-year-old Marcus Hargrove, 21-year-old Kirkston Smith, 22-year-old Cederick Brooks and 21-year-old Daron Livingston, were arrested at a Super 8 motel on W. Irlo Bronson Memorial Highway in Kissimmee, where they were staying.

Investigators said in a search of two hotels room and two vehicles, they found more than 21,000 prescription pills with a total street value of about $1 million.

All seven suspects were arrested and charged with trafficking oxycodone, trafficking hydrocodone, trafficking hydromophone and trafficking morphine. Collins, Gibbs and Clark are also facing burglary and grand theft charges.

According to officials, all of the men are from Texas. Collins, Gibbs and Clark are documented gang members and have been suspected in pharmacy burglaries in other states, deputies said.

http://www.wftv.com/news/news/osceola-deputies-arrest-seven-walgreens-pharmacy-b/nYZJS/

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Common Painkiller Linked To Heart Attack And Stroke, UK Warning
Medical News Today
1 July 2013

Common painkiller, diclofenac, raises the risk of heart attack and stroke among patients with serious underlying heart conditions, the UK's Medicines and Healthcare Products Regulatory Agency (MHRA) has warned.

MHRA specifies that patients with circulatory problems, heart disease, heart failure, or a previous stroke or heart attack should stop using diclofenac.

Diclofenac is known under several trade names, including Diclomax, Defenac, Diclofex, Dyloject, Econac, Enstar, Flamrase, Flamatak, Motifene, Rheumatac, Rhumalgan, Volsaid, and Voltarol.

Diclofenac is an NSAID (non-steroidal anti-inflammatory drug), and is used for the treatment of painful conditions, including dental pain, migraine, gout, sprains and strains, arthritis, and pain after surgical procedures. Diclofenac alleviates pain and lowers inflammation.

Diclofenac, naproxen and ibuprofen are the most commonly used anti-inflammatory medications in the United Kingdom.

MHRA says its warning follows a European review of Diclofenac which identified a slight increase in the risk of stroke and heart attack.

Deputy Director of the MHRA's Vigilance and Risk Management of Medicines Division, Dr. Sarah Branch, said:

"Whilst this is a known risk and warnings have been included in patient and healthcare information for some time, this advice is now being updated. For many patients diclofenac will continue to provide safe and effective pain relief but is no longer suitable for certain at risk groups.

"Those with underlying heart conditions currently taking diclofenac should speak to their GP or pharmacist at their next routine visit to consider an alternative pain relief treatment. Patients with certain cardiovascular risk factors such as high blood pressure, raised cholesterol, diabetes and smoking should only use diclofenac after careful consideration with their GP or pharmacist."

The MHRA added that the new treatment advice applies to systemic formulations, including capsules, tablets, suppositories, and injection. It does not apply to topical formulations of Diclofenac (gels or creams).

MHRA's new advice to doctors regarding diclofenac

Diclofenac is now contraindicated for patients diagnosed with:

- cerebrovascular disease

- congestive heart failure (New York Heart Association [NYHA] classification II-IV)

- ischaemic heart disease

- peripheral arterial disease

At their next routine appointment, patients with these conditions should be offered alternative treatment.

"Diclofenac treatment should only be initiated after careful consideration for patients with significant risk factors for cardiovascular events", including high blood pressure (hypertension), diabetes mellitus, smoking, hyperlipidemia.

MHRA's new advice to pharmacists regarding diclofenac

Diclofenac can be purchased as an OTC (over-the-counter) medication at the pharmacy without a prescription at low doses (≤75 mg/day) for short-term use (up to 3 days).

When supplying OTC diclofenac, pharmacists should:

Check whether the customer has established cardiovascular disease or significant risk factors for cardiovascular events. If they do, exclude the supply (do not give it to them).

Tell customers that OTC diclofenac is to be used for up to three consecutive days only - they should check with their doctors for longer periods.

Tell customers that NSAIDs must be taken only one at a time.

Diclofenac is commonly used worldwide

A study published in PLoS (February 2013 issue) found that diclofenac is the most commonly used NSAID in the 15 countries studied. The authors added that Diclofenac was listed in the essential medicines list of 74 nations, while naproxen (which is much safer) in just 27 countries.

An article published in the journal Circulation (May 2011 issue) revealed that diclofenac users were three times more likely to die or have a repeat heart attack within one week of use

http://www.medicalnewstoday.com/articles/262677.php

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Walgreen Company (WAG), Cardinal Health Inc (CAH), AmerisourceBergen Corp. (ABC): A 6% Drop in the Largest National Drugstore Is a Buying Opportunity
Motley Fool
28 June 2013

Walgreen Company (NYSE:WAG) has recently experienced a nearly 6% drop to around $45.20 per share, losing nearly $2.7 billion in market capitalization within just one trading day. The daily drop was caused by Walgreen Company (NYSE:WAG)'s recent third quarter earnings results, which missed analysts' estimates.

Should long-term investors consider this drop a buying opportunity? Let's find out.

Third quarter earnings results grew but missed estimates

Walgreen Company (NYSE:WAG)'s third quarter results are not declining or staying flat, the company actually managed to grow both its top line and bottom line. Net sales experienced a 3.2% growth; from $17.75 billion last year to more than $18.3 billion this year while the net income rose by 16.2% to $624 million. The diluted Earnings Per Share (EPS) came in at $0.65, 4.8% higher than last year EPS. These Include acquisition and Last In First Out (LIFO) accounting costs for Alliance Boots. Its adjusted EPS was much higher at $0.85. However, those results were lower than analysts' expectations of $18.43 billion in revenue and $0.91 EPS.

Greg Wasson, the company's President and CEO felt excited about the company's year-over-year gain in the retail pharmacy market share, from 18.4% to 19.2%. He was also bullish about the 18.1% growth in adjusted EPS, thanks to the company's cost control and the first year synergies with Alliance Boots of $125-$150 million and the earnings contribution from Alliance Boots.

10-year agreement and vertical integration with AmerisourceBergen Corp. (NYSE:ABC)

What might make investors bullish about the largest national drugstore is its recent 10-year agreement with AmerisourceBergen Corp. (NYSE:ABC) and the option to expand the business vertically with AmerisourceBergen Corp. (NYSE:ABC)'s stake. Walgreen Company (NYSE:WAG) currently distributed more than 80% of its own drugs, however, this agreement would let Walgreen utilize AmerisourceBergen's network for daily drug distribution. Moreover, Walgreen Company (NYSE:WAG) and Alliance Boots had the right to acquire up to 7% stake in AmerisourceBergen in the open market and warrants are exercisable for an additional 16% stake. With this vertical integration, all of these three businesses definitely have more bargaining power in the pharmaceutical sector and operate more efficiently.

Walgreen Company (NYSE:WAG)'s agreement with AmerisourceBergen Corp. (NYSE:ABC) represented a big customer loss for Cardinal Health Inc (NYSE:CAH) as Walgreen used to contribute more than $22.5 billion to its revenue, accounting for 21% of Cardinal Health Inc (NYSE:CAH)'s total revenue. While Cardinal Health could renew its contract with its biggest customer, CVS Caremark Corporation (NYSE:CVS), it lets AmerisourceBergen take away Walgreen, its second largest customer.

Many investors might consider the loss of big customer could harm Cardinal Health's overall

business, however, it has some positive consequences. When the Walgreen contract expires, Cardinal Health Inc (NYSE:CAH) would need lower inventory and account receivables. Because of the lower working capital needs, the company expects to generate an extra cash of $500 million. Moreover, as the Walgreen contract was a low margin business, the loss of Walgreen could push up Cardinal Health's distribution margin, from 1.6% to 2%.

Among the three companies, investors might like Cardinal Health Inc (NYSE:CAH) and Walgreen because of their decent dividend yields, at 2.6% and 2.3%, respectively, while the dividend yield of AmerisourceBergen Corp. (NYSE:ABC) is the lowest at 1.5%.

Of the trio, Walgreen Company (NYSE:WAG) is the most expensively valued. At $45.20 per share, it is worth $42.80 billion on the market. The market values Walgreen at 10.8 times its trailing (Earnings before interest, taxes, depreciation and amortization) EBITDA. AmerisourceBergen is trading at $53.60 per share, with the total market cap of $12.40 billion. It is valued at nearly 9 times its trailing EBITDA. Cardinal Health has the lowest EBITDA multiple. At $46.60 per share, it is worth $15.90 billion on the market. The market values Cardinal Health at 7.4 times its trailing EBITDA.

My Foolish take

Income investors might still consider both Cardinal Health Inc (NYSE:CAH) and Walgreen as long-term stocks for their portfolios due to their decent dividend yields. Cardinal Health, with the potential higher distribution margin with lower working capital needs and low valuation, could be a good buy for shareholders. Walgreen, with their global leading positions, the potential synergies with Alliance Boots and the vertical integration with AmerisourceBergen Corp. (NYSE:ABC) could also fit well in long-term investors' portfolios.

http://www.insidermonkey.com/blog/walgreen-company-wag-cardinal

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Investment adviser opposes McKesson CEO's re-election: WSJ
Reuters
1 July 2013

(Reuters) - A union pension adviser opposes the re-election of drug wholesaler McKesson Corp.'s (MCK.N) chief executive, citing excessive pay and the failure to heed a shareholder advisory vote to split the chairman and chief executive roles, the Wall Street Journal reported.

In a letter expected to be sent on Monday, CtW Investment Group urged McKesson's shareholders to vote against the re-election of CEO John Hammergren and directors Alton Irby III and Jane Shaw, the business daily said.

Irby and Shaw head the board's compensation and governance committees, respectively.

This is not the first time that CtW, which advises union pension funds, has targeted Hammergren. It successfully campaigned to force Hammergren to resign his board seat at Hewlett-Packard Co (HPQ.N) earlier this year.

HP's then chairman, Ray Lane, and another director also quit their posts in the shakeup at the No.1 personal computer maker's board in the aftermath of a failed $11 billion deal for Autonomy.

CtW says the funds it advises own a total of 1.4 million McKesson shares out of 228.5 million outstanding, according the Wall Street Journal.

In its letter, CtW opposed the re-election of Irby, the longtime chairman of McKesson's compensation committee, over what it said was "one of the most exorbitant CEO pay practices in the S&P 500", the daily reported.

Hammergren would have been paid $159 million had he voluntarily left the company in March, in what is said to be the largest ever pension benefit for an executive of a public company.

CtW and McKesson could not be immediately reached for comment outside regular business hours.

http://www.reuters.com/article/2013/07/01/us-mckesson-ctw-idUSBRE96006R20130701

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Final Glance: Pharmaceuticals companies
Associated Press
28 June 2013

NEW YORK (AP) — Shares of some top pharmaceuticals companies were mixed at the close of trading:

Baxter International Inc. fell $.43 or .6 percent, to $69.27.

Bristol-Myers Squibb Co. fell $1.61 or 3.5 percent, to $44.69.

Hospira rose $2.16 or 6.0 percent, to $38.31.

Johnson & Johnson fell $.85 or 1.0 percent, to $85.86.

Eli Lilly & Co. fell $.60 or 1.2 percent, to $49.12.

Merck fell $.83 or 1.8 percent, to $46.45.

Pfizer fell $.17 or .6 percent, to $28.01.

http://www.businessweek.com/ap/2013-06-28/final-glance-pharmaceuticals-companies

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