

Another Recall at J&J — With More Likely to Come

WSJ Blogs, 13:26, 24 November 2010, 286 words, By Katherine Hobson, (English)

Johnson & Johnson announced another recall of Tylenol products today. This one's a bit different from other production-related recalls that have plagued the company recently. The almost 9.3 million bottles of three Tylenol Cold ...

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THE WALL STREET JOURNAL.
U.S. EDITION

Corporate News: Corporate Watch

784 words
23 November 2010
The Wall Street Journal
J
B2
English

TYSON

Meatpacker Reports

Record Profit for Quarter

Tyson Foods Inc. Monday reported record earnings for its fiscal fourth quarter as the largest U.S. meatpacker said it would counter higher grain costs through a mix of price increases and productivity improvements.

Retail meat prices have been pushing 10-year highs in the U.S., reflecting rising feed costs and a tight balance between supply and demand. Tyson executives project only modest increases in consumer and food service demand next year, with exports expected to keep domestic pricing trends intact.

Helping results were lower grain costs as the Springdale, Ark. company locked in prices ahead of a recent run-up in corn and other commodities.

For the quarter ended Oct. 2, Tyson reported a profit of $213 million, or 57 cents a share, compared with a prior-year loss of $457 million, or $1.23 a share, driven by a $560 million write-down at its beef business.

Revenue increased 3.2% to $7.44 billion even as the prior-year period included an additional week.

Tyson Chief Executive Donnie Smith warned feed costs, particularly for the poultry business, remain a challenge.

-- Mark Peters and Tess Stynes

J&J

McNeil Unit Recalls More

Children's Benadryl, Motrin

Johnson & Johnson recalled more children's Benadryl and Motrin after identifying additional manufacturing problems, but said the problems don't threaten the safety of consumers.

J&J is withdrawing about 4 million packages of children's Benadryl allergy tablets and about 800,000 bottles of junior-strength Motrin caplets from drugstores and suppliers because they were made under less-than-rigorous manufacturing standards. The products were made at J&J's Fort Washington, Pa., plant, before it was temporarily closed due to a string of quality issues, a spokeswoman said.

The company isn't asking consumers to return the popular over-the-counter medicines and says they can safely keep taking the drugs. J&J says the products passed its quality testing, and it hasn't received any reports of side effects.

The company's McNeil Consumer Healthcare unit disclosed the move on company websites Nov. 15, but J&J didn't issue a press release on the matter, as it has done with several of its recalls over the past year. A spokeswoman noted the recall didn't affect consumers.

-- Peter Loftus and Jonathan D. Rockoff

FREEPORT LNG

Macquarie Arm to Help

Firm Build Export Terminal

The North American energy marketing and trading arm of Macquarie Group Ltd. said it will help Freeport LNG Development LP build a $2 billion liquefied natural gas export terminal at its existing Texas import facility.

The announcement comes less than two weeks after a subsidiary of Cheniere Energy Inc. said it was working toward a deal to supply liquefied natural gas from its Sabine Pass LNG terminal in Louisiana to one of China's largest independently-owned natural gas companies.

Freeport LNG, whose investors include Dow Chemical Co. and ConocoPhillips, will seek approval from the Department of Energy and the Federal Energy Regulatory Commission and aim to have the facility exporting gas by early 2015. Once complete, the terminal will be able to liquefy up to 1.4 billion cubic feet of natural gas daily.

Under the agreement, Freeport LNG will remain the sole owner and operator of the plant.

Macquarie, meanwhile, will help fund construction and arrange gas supply agreements and sales for the terminal.

-- Ryan Dezember

TESCO

Retailer Aims to Boost

Its Sales in China

Tesco PLC said it aims to quadruple sales in China to GBP 4 billion, or $6.37 billion, over the next five years.

With its Chinese operations approaching profitability, the retailer said it aims to more than double its number of hypermarkets operating in the nation to more than 200, including 50 in Tesco shopping malls by the fiscal year ending in February 2015.

Tesco -- the world's third-largest retailer by sales, after U.S.-based Wal-Mart Stores Inc. and France's Carrefour SA -- said Monday that it expects to deliver significant profit in the next five years in China as stores mature and economies of scale are realized.

Sales at Chinese stores open at least a year rose 8.3% in the nine weeks to Oct. 31, the company said. Tesco posted sales of GBP 844 million in China in fiscal 2010.

The company doesn't report profit by country but said in October that it had a "small overall loss" in China in its fiscal first half. Tesco predicted that its Chinese operations will be profitable in the second half.

-- Kathy Gordon

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Health
J&J Recalls More Children's Benadryl and Motrin

By Peter Loftus And Jonathan D. Rockoff
430 words
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WSJO
English

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The company's McNeil Consumer Healthcare unit disclosed the move on company websites Nov. 15, but J&J didn't issue a press release on the matter, as it has done with several of its recalls over the past year. A spokeswoman noted the recall didn't affect consumers.

The withdrawal is the latest fall-out from the manufacturing problems at J&J, which have led to more than a half-dozen recalls of Benadryl, Motrin, Tylenol and over-the-counter medicines, some contact lenses and certain hip-replacement parts. The problems, which are costing J&J hundreds of millions of dollars in lost sales, also led to a shake-up of the company's manufacturing.

J&J's McNeil unit discovered the inadequate manufacturing processes as part of a review it conducted in the wake of the issues, the spokeswoman said.

The affected products are: Children's Benadryl Allergy Fastmelt Tablets, in cherry and grape flavors, which were distributed in the U.S., Canada, Belize, Barbados, Puerto Rico, St. Martin, and St. Thomas; and Junior Strength Motrin Caplets, 24-count, distributed in the U.S.

Various governmental entities are investigating J&J over its handling of the recalls, including a criminal probe by the U.S. Justice Department.

The Fort Washington plant is undergoing a refitting, and the company is shifting production of recalled over-the-counter medicines to other facilities. Grape-flavored children's Tylenol began returning to drugstore shelves this month. Other products will return through mid-2011.

Write to Jonathan D. Rockoff at jonathan.rockoff@wsj.com and Peter Loftus at peter.loftus@dowjones.com

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A.M. Vitals: Johnson & Johnson Recalls Kids' Benadryl, Motrin

WSJ Blogs, 07:42, 23 November 2010, 322 words, By Katherine Hobson, (English)

Another Recall: Even as some of its recalled kids' medicines make their way back to store shelves, Johnson & Johnson announced another recall -- this one of about 4.8 million packages of children's Benadryl tablets and ...

Document WCWSJB0020101123e6bn003bk

Kids' Tylenol is Back on Shelves, But Parents, Will You Buy It?

WSJ Blogs, 09:06, 18 November 2010, 173 words, By Katherine Hobson, (English)

More than 40 Johnson & Johnson's children's medicines have been absent from drugstores since May, when the company recalled themover manufacturing snafus.

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Corporate News: Tylenol for Kids Returns to Shelves

By Jonathan D. Rockoff
861 words
18 November 2010
The Wall Street Journal
J
B3
English

The first children's Tylenol products are returning to drugstore shelves after a long safety recall, and maker Johnson & Johnson now faces the tricky task of persuading parents to buy the pain reliever again.

Bottles of the grape-flavored version of children's Tylenol have begun reappearing in pharmacies across the country half a year after several J&J over-the-counter children's medicines were pulled because of manufacturing problems. The company began shipping one million bottles last month, and other recalled medicines will return through the middle of next year.

The recalls have cost the company hundreds of millions of dollars in lost sales and prompted a shake-up of manufacturing and management at its consumer-goods business. The quality problems included floating metal particles in the medicines and the potential for excessive concentrations of an active ingredient.

To get parents to return to Tylenol, J&J must combat not just the hit to its reputation but also the encroachment of rival brands, which have been taking over shelf space in drugstores. Cheaper private-label brands are also gaining amid the tough economy as sales of branded medicines drop. For example, private-label cough and cold remedy sales rose 6% from a year earlier to $2.4 billion during July, August and September, Nielsen Co. said.

Perrigo Co., a leading maker of store-brand nonprescription drugs, says it has gained nearly a 20% share in the market for acetaminophen pain relievers since the J&J recalls. Perrigo Chief Executive Joseph Papa told investors in May the company expects to retain about 50% of its market-share gains.

In general, loyalty to Tylenol's pain pills, a strong indication that customers will buy the product, dropped 7% in the past year, according to an annual survey in August of 35,000 Americans by marketing consultant Brand Keys Inc. Among over-the-counter pain medicines, Tylenol ranked behind rivals Advil, Aleve and Excedrin in terms of customer loyalty after trailing only Advil in 2009.

J&J must walk a messaging tightrope, marketing experts say, providing reassurance that it has fixed its problems without calling so much attention to them that safety concerns resurface.

"You don't want to always be apologizing, because that cues the wrong response. You want to be cuing the core emotional benefits that Tylenol delivers," said Rex Briggs, chief executive of Marketing Evolution, which has done consulting work for J&J.

J&J declined to comment about its plans.

At least initially, the reintroduction of Tylenol is low key. There are no signs in stores calling attention to the return, for instance. The grape version's red-and-purple packaging appears similar to the box before the recall. It pictures smiling mothers and children and says that mothers have "trusted" the medicine for 50 years.

But Tylenol rivals aren't going to make the products' return easy. Pfizer Inc.'s website for Advil notes that it was "not part of this year's pain reliever recalls" and refers to the children's and infants' versions of the pills as "relief you can trust."

In August, Novartis AG began giving away 250,000 bottles of its new Triaminic Fever Reducer Pain Reliever. Novartis described the medicine as the "only branded over-the-counter children's liquid acetaminophen product currently available nationwide in the U.S."

Advil and Triaminic benefited most from the J&J recalls, according to Bank of AmericaMerrill Lynch analysts. Advil had 11% to 12% of the market for children's liquid pain medicines in October, up from 1% before the recalls began, the analysts told investors recently. Triaminic's share jumped to as much as a fifth for children's cold, allergy and sinus medicines, they said.

Drugstores have given away much of Tylenol's shelf space to store brands. Stacey Swartz, owner of independent Neighborhood Pharmacy in Alexandria, Va., which got Tylenol back Wednesday, said she would wait to see how customers who have been buying store brands react to Tylenol's return before giving back all the shelf space it had.

Leslie Ann Hunt, a mother in New York City, says she doesn't see why she should pay more for Tylenol now that she is satisfied giving her seven-month-old son private-label pain relievers.

J&J has "been through this recall process and shown that their due diligence was no better than" makers of private-label brands, said Ms. Hunt, 39 years old.

Tylenol is a signature brand for J&J, which also sells prescription drugs and medical devices. The company's swift withdrawal of the medicine during a fatal tampering episode in 1982 endeared J&J and Tylenol to generations of consumers.

Some of that goodwill persists, according to a recent survey by marketing firm Relational Capital Group, even after the most recent recalls. The survey found that J&J and Tylenol still scored well above the average for most brands on measures of consumer attitudes.

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THE WALL STREET JOURNAL.

Management
Tylenol for Kids Returns to Shelves

By Jonathan D. Rockoff
1,074 words
18 November 2010
The Wall Street Journal Online
WSJO
English

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The recalls have cost the company hundreds of millions of dollars in lost sales and prompted a shake-up of manufacturing and management at its consumer-goods business. The quality problems included floating metal particles in the medicines and the potential for excessive concentrations of an active ingredient.

To get parents to return to Tylenol, J&J must combat not just the hit to its reputation but also the encroachment of rival brands, which have been taking over shelf space in drugstores and promoting themselves as safe and reliable. Cheaper private-label brands are also gaining amid the tough economy as sales of branded medicines drop. For example, private-label cough and cold remedy sales rose 6% from a year earlier to $2.4 billion during July, August and September, Nielsen Co. said.

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At chain drugstores, makers of over-the-counter medicines often pay for shelf space. But J&J will have to compete with rivals that also pay, as well as the stores' preference for private labels, to get space back, according to marketing experts. Pharmacies make higher margins on private-label medicines, though name brands command higher sales volume, pharmacists say.

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J&J has "been through this recall process and shown that their due diligence was no better than" makers of private-label brands, said Ms. Hunt, 39 years old, who describes herself as a longtime Tylenol user.

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Some of that goodwill persists, according to a recent survey by marketing firm Relational Capital Group, even after the most recent recalls, the temporary shutdown of a major manufacturing plant in the Philadelphia area and two congressional hearings. The survey found that J&J and Tylenol still scored well above the average for most brands on measures of consumer attitudes.

To some consumers, the manufacturing problems were "perceived as a short-term lapse in competence," said Chris Malone, chief advisory officer at Relational Capital Group, which questioned 1,000 adults across the U.S. in September and October. He shared the results with J&J and Advil maker Pfizer, but he said Relational Capital Group isn't working for either company.

That leftover regard gives J&J an opportunity to recapture customers if it can make the right appeals, according to marketing experts. After the poisoning episode, for instance, J&J reassured Tylenol customers and gave them a reason to buy the medicine by resuming sales only after introducing tamper-resistant bottles.

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Health
Pfizer Widens Recall of Lipitor Bottles

By Peter Loftus
453 words
29 October 2010
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The Wall Street Journal Online
WSJO
English

Pfizer Inc. again widened a recall of its blockbuster cholesterol-lowering drug Lipitor due to reports of musty or moldy odors associated with the product.

The New York drug maker said Friday it plans to recall about 38,000 bottles of Lipitor 40-milligram tablets that were distributed in the U.S. Pfizer cited two customer reports of an uncharacteristic odor related to the bottles, which Pfizer said were supplied by a third-party bottle manufacturer.

The latest incident follows two prior recalls of Lipitor implemented in August and earlier this month, which were also linked to complaints of unusual odor. About 332,000 bottles of Lipitor were recalled in those incidents combined.

Pfizer cautioned that additional recalls may be necessary because products manufactured before it made certain production changes could still be on the market.

The Pfizer recall continues a string of manufacturing-quality problems in the drug industry. Johnson & Johnson has made a series of recalls of over-the-counter medicines in the past year, including recalling Tylenol due to reports of musty or moldy odors. And this week GlaxoSmithKline PLC agreed to pay $750 million and plead guilty to a criminal charge to settle a government probe of manufacturing deficiencies at a plant in Puerto Rico, which distributed adulterated drugs.

Pfizer said Friday the odor is consistent with the presence of a chemical called 2,4,6 tribromoanisole, or TBA, which was found at a very low level in a complaint sample bottle during the probe that led to the first recall. TBA is used as a wood preservative on pallets to transport and store products.

The same chemical was implicated in J&J's Tylenol recalls linked to unusual odors. Pfizer said it stepped up its monitoring of possible TBA-related odor problems earlier this year.

The lots in the latest Lipitor recall were packaged and shipped before Pfizer made certain changes in August intended to avoid the odor problem.

Pfizer spokesman Ray Kerins said the company has taken steps to reduce risk of TBA contamination, including requiring the use of plastic pallets for transport of empty bottles.

Pfizer has identified the source of the problem as the bottle manufacturer's plant in Puerto Rico, which had shipped empty bottles to the Pfizer plant in Freiburg, Germany, for use in Pfizer products. Mr. Kerins said bottle production has been shifted to alternate third-party plants.

Lipitor is the best-selling prescription drug in the world, generating $5.57 billion in sales for the first half of 2010. Pfizer is scheduled to report third-quarter results next week.

Write to Peter Loftus at peter.loftus@dowjones.com

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Investor's Calendar
Investor's Calendar

264 words
24 October 2010
The Wall Street Journal Sunday
SNJR
1
English

-- THIS WEEK

-- Foreclosures Back On: Bank of America expects to have new affidavits submitted to the courts by Monday so pending foreclosure sales can continue in 23 states where a judge's approval is required.

-- Cheaper Talk: Verizon Wireless is expected to roll out Thursday a cheaper data plan for smartphones, with prices likely as low as $15 per month.

-- Cost Cutting: Insurer UnitedHealth Group will formally announce Wednesday an experimental program aimed at eliminating the incentive for doctors to choose cancer drugs based on profit.

-- iPad Expansion: Apple plans to start selling the iPad through Verizon and AT&T stores starting Thursday.

-- Earnings Roundup: Microsoft, Sprint Nextel, UBS, U.S. Steel and Visa are among those reporting.

-- LAST WEEK

-- Taxpayer Tab: Bailing out mortgage lenders Fannie Mae and Freddie Mac could cost taxpayers another $19 billion over the next three years, regulators said. But the total tab could nearly double if the U.S. economy slides back into recession.

-- Bank Results: It was a mixed bag for banks in the latest quarter. Wells Fargo and Citigroup reported higher profits. Morgan Stanley's earnings sank 67%, while Goldman Sachs Group's slumped a less-than-feared 40%. Meanwhile, Bank of America's loss widened to $7.3 billion.

-- Recalls: Johnson & Johnson said it's recalling more than 127,000 bottles of Tylenol 8-Hour caplets, after complaints about a musty or moldy odor. Graco Children's Products recalled two million strollers, after reports that four infants were strangled.

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THE WALL STREET JOURNAL.

Technology
Investor's Calendar

254 words
23 October 2010
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THIS WEEK

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THE WALL STREET JOURNAL.
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Earnings: Despite Recalls, J&J Profit Rises

By Jonathan D. Rockoff and Peter Loftus
577 words
20 October 2010
The Wall Street Journal
J
B5
English

Johnson & Johnson said Tuesday that Tylenol recalls depressed sales, but lower costs and a weaker dollar bolstered earnings and prompted the company to raise its full-year forecast.

The New Brunswick, N.J., company reported a third-quarter profit of $3.42 billion, or $1.23 a share, up 2.2% from $3.35 billion, or $1.20 a share, a year earlier.

The results suggested that J&J, though wounded, was weathering the sales hit from a series of recalls.

Manufacturing problems prompted closure of a key plant and more than a half-dozen recalls of over-the-counter medicines, some contact lenses and certain hip-replacement parts. On Monday, some musty-smelling Tylenol was withdrawn.

In the quarter, recalls cost the company $240 million in lost sales, Chief Financial Officer Dominic Caruso told analysts and investors.

In addition, J&J revenue has been hurt by a sluggish economy that caused some patients to put off knee replacements and other elective procedures, Mr. Caruso said. J&J's third-quarter revenue was $15 billion, 0.7% less than last year, and the company slightly lowered its sales forecast for 2010 to $62 billion.

Yet, the company, whose products range from Band-Aids to the Procrit anti-anemia drug, received a boost from the weaker dollar, a less-than-expected tax rate and the sale of a breast-cancer-testing business.

In July, J&J had cut its outlook for all of 2010 by 20 cents a share. Citing the foreign-exchange impact in particular, the company raised its full-year forecast Tuesday by five cents a share, to $4.70 to $4.80 a share.

Sheri McCoy, who heads J&J's pharmaceuticals group, said the launch of new therapies was making up for the costs of the health-care overhaul and impact of patent expirations.

The company will need new pharmaceuticals, such as rheumatoid arthritis treatment Simponi approved last year, to do well if it hopes to stop counting on lower expenses and higher margins for profit. By the end of the year, J&J could be seeking approval for five compounds, Ms. McCoy said.

J&J shares fell 57 cents to $63.29 in 4 p.m. New York Stock Exchange composite trading.

The medicine recalls caused U.S. sales of J&J's over-the-counter and nutritional products to plunge 40% to $438 million for the third quarter.

The overall consumer unit -- which had been J&J's star performer a couple years ago -- saw global sales drop 10.6% to $3.6 billion.

Gross margin rose to 30.7% from 29.4%.

Sales of medical devices rose 1% to $5.92 billion, a slowdown from recent periods and lighter than some analysts expected. Sales at the Cordis division, which makes artery-opening stent devices, fell 7%, while diabetes-care products saw a sales decline of 3%. Vision-care and certain surgical products posted sales gains.

J&J's pharmaceutical sales climbed 5% to $5.5 billion. Sales of anti-inflammatory drug Remicade rose 19% to $1.23 billion.

Other drugs posting sales gains included HIV treatment Prezista and attention-deficit disorder drug Concerta. Sales of anti-anemia drugs Procrit and Eprex dropped, hurt by a recent recall.

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THE WALL STREET JOURNAL.

Earnings
Abbott Profit Falls 40% on Acquisition, Recall Costs

By Peter Loftus
749 words
20 October 2010
15:35
The Wall Street Journal Online
WSJO
English

Abbott Laboratories reported a 40% drop in third-quarter earnings, weighed down by costs associated with layoffs, a baby-formula recall and the withdrawal of a diet drug due to safety concerns.

The costs more than offset a nearly 12% increase in revenue, fueled by rising sales of the anti-inflammatory drug Humira, cholesterol-lowering drugs and artery-opening stent devices. Abbott's earnings excluding the costs exceeded analysts' expectations, though the sales figure fell short--a scenario similar to what unfolded in rival Johnson & Johnson's earnings report Tuesday, when J&J cautioned that overall health-care spending growth was decelerating.

The sales shortfall stemmed partly from the September recall of about five million containers of Similac baby formula due to potential contamination by beetle parts or larvae. Abbott said the recall reduced third-quarter revenue by about $100 million. Analysts suggested currency-exchange rates also played a role.

"Still the sales number was weak," J.P. Morgan analyst Michael Weinstein wrote in a note to clients. Leerink Swann analyst Rick Wise said the company's cost controls bolstered earnings in the face of top-line pressure.

The Abbott Park, Ill., health-products company also raised the lower end of its 2010 earnings forecast range.

Abbott's diversified business lineup has cushioned it from some of the problems facing other large drug makers, such as patent expirations and generic competition. The company has made a series of acquisitions in recent years to help reduce its dependence on Humira for sales growth. In February, Abbott paid $6.1 billion in cash to acquire Solvay SA's pharmaceutical unit, and the company has expanded in emerging markets.

The company also is cutting costs. In September, Abbott announced it would eliminated about 3,000 jobs, or 3% of its global work force, primarily by reducing overlapping areas from the Solvay deal.

But like some other drug and health-products companies, Abbott has been stung by safety and quality problems. In addition to the Similac recall, Abbott earlier this month withdrew the diet drug Meridia from the market at the request of the Food and Drug Administration, after it was linked to increased risk for heart attacks and strokes.

Abbott also incurred costs associated with the recently enacted U.S. health-care overhaul and is facing pricing pressure from spending cuts by European national health programs. However, "despite these headwinds we delivered strong overall sales and [earnings] growth as well as gross margin expansion," Abbott Chief Financial Officer Thomas Freyman said on a conference call with analysts.

For the three months ended Sept. 30, Abbott earned $891 million, or 57 cents a share, down from $1.48 billion, or 95 cents a share, a year earlier.

Earnings were reduced by costs related to the Solvay acquisition and subsequent layoffs, the Similac recall and Meridia withdrawal. Excluding these costs, third-quarter earnings would have been $1.05 a share, a penny ahead of the mean estimate of analysts surveyed by Thomson Reuters and within Abbott's forecast range.

Sales rose 12% to $8.68 billion, short of the $8.9 billion expected by analysts. Currency-exchange trends cut sales growth by one percentage point, Abbott said. Some analysts had expected currency rates to boost sales.

Abbott's biggest unit, pharmaceuticals, posted sales of $4.9 billion, up 22% from a year earlier. Humira sales rose 13% to $1.68 billion, while combined sales of cholesterol drugs Trilipix and TriCor rose 22% to $404 million. Sales of anti-HIV drug Kaletra declined 7% to $328 million.

Sales of Abbott's nutritional products, which include Similac, declined 1.5% to $1.37 billion due to the product recall. Abbott has resumed production of a Similac powder product at the Michigan plant where the contamination was detected, and expects to return to normal supply levels in the coming months.

Abbott's diagnostics sales inched up less than 1% to $916 million. Sales of vascular products rose 19% to $790 million, helped by sales of its Xience stents.

For the fourth quarter, Abbott expects to earn $1.29 to $1.31 per share, excluding items, bracketing the current Street consensus.

For full-year 2010, Abbott now expects full-year earnings of $4.16 to $4.18 a share, excluding certain costs, versus a prior range of $4.13 to $4.18 a share.

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THE WALL STREET JOURNAL.

Earnings
Despite Recalls, J&J Ekes Out Net

By Jonathan D. Rockoff and Peter Loftus
590 words
20 October 2010
The Wall Street Journal Online
WSJO
English

Johnson & Johnson said Tuesday that Tylenol recalls depressed sales, but lower costs and a weaker dollar bolstered earnings and prompted the company to raise its full-year forecast.

The New Brunswick, N.J., company reported a third-quarter profit of $3.42 billion, or $1.23 a share, up 2.2% from $3.35 billion, or $1.20 a share, a year earlier.

The results suggested that J&J, though wounded, was weathering the sales hit from a series of recalls. Manufacturing problems prompted closure of a key plant and more than a half-dozen recalls of over-the-counter medicines, some contact lenses and certain hip-replacement parts. On Monday, some musty-smelling Tylenol was withdrawn.

In the quarter, recalls cost the company $240 million in lost sales, Chief Financial Officer Dominic Caruso told analysts and investors.

In addition, J&J revenue has been hurt by a sluggish economy that caused some patients to put off knee replacements and other elective procedures, Mr. Caruso said. J&J's third-quarter revenue was $15 billion, 0.7% less than last year, and the company slightly lowered its sales forecast for full-year 2010 to $62 billion.

Yet, the company, whose products range from Band-Aids to the Procrit anti-anemia drug, received a boost from the weaker dollar, a less-than-expected tax rate and sale of a breast cancer-testing business.

In July, J&J had cut its outlook for all of 2010 by 20 cents a share. Citing the foreign-exchange impact in particular, the company raised its full-year forecast Tuesday by five cents a share, to $4.70 to $4.80 a share.

Sheri McCoy, who heads J&J's pharmaceuticals group, said the launch of new therapies was making up for the costs of the health-care overhaul and impact of patent expirations.

The company will need new pharmaceuticals, such as rheumatoid arthritis treatment Simponi approved last year, to do well if it hopes to stop counting on lower costs and higher margins for profit. By the end of the year, J&J could be seeking approval for five compounds, Ms. McCoy said.

J&J shares 57 cents to $63.29 in 4 p.m. New York Stock Exchange composite trading.

The medicine recalls caused U.S. sales of J&J's over-the-counter and nutritional products to plunge 40% to $438 million for the third quarter. The overall consumer unit—which had been J&J's star performer a couple years ago—saw global sales drop 10.6% to $3.6 billion.

Gross margin rose to 30.7% from 29.4%.

Sales of medical devices rose 1% to $5.92 billion, a slowdown from recent periods and lighter than some analysts expected. Sales at the Cordis division, which makes artery-opening stent devices, fell 7%, while diabetes-care products saw a sales decline of 3%. Vision-care and certain surgical products posted sales gains.

J&J's pharmaceutical sales climbed 5% to $5.5 billion. Sales of anti-inflammatory drug Remicade rose 19% to $1.23 billion. Other drugs posting sales gains included HIV treatment Prezista and attention-deficit disorder drug Concerta. Sales of anti-anemia drugs Procrit and Eprex dropped, hurt by a recent recall.

Write to Jonathan D. Rockoff at jonathan.rockoff@wsj.com and Peter Loftus at peter.loftus@dowjones.com

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THE WALL STREET JOURNAL.
EUROPE EDITION

Johnson & Johnson's profit edges higher

By Peter Loftus and Nathan Becker
495 words
20 October 2010
The Wall Street Journal Europe
WSJE
20
English

Johnson & Johnson's third-quarter earnings rose 2.2% as cost controls and lower taxes helped offset a sales decline due to the company's recent recalls of over-the-counter medicines.

The health-care products giant also raised its 2010 earnings outlook to $4.70 to $4.80 a share, up five cents from July's lowered target, citing foreign-exchange trends.

However, the company cautioned Tuesday that overall growth in health-care spending was slowing due to the sluggish economy, which is hurting sales in areas such as joint-replacement products. J&J's third-quarter revenue was lower than expected, and the company slightly lowered its full-year sales forecast.

J&J, whose products range from Band-Aids to the Procrit anemia drug, had lowered its 2010 profit forecast in July because of ongoing recalls of various OTC drugs such as Tylenol. The most significant was an April recall of more than 136 million bottles of liquid children's medicines due to problems including higher-than-appropriate concentrations of active ingredients and the presence of metal particles.

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The New Brunswick, N.J., company reported a profit of $3.42 billion, or $1.23 a share, up from $3.35 billion, or $1.20 a share, a year earlier. Revenue fell 0.7% to $14.98 billion. Analysts polled by Thomson Reuters had forecast earnings of $1.15 a share on $15.2 billion in revenue.

Gross margin rose to 30.7% from 29.4%.

The third-quarter profit was helped by a 1% decline in selling, marketing and administrative expenses, and an 11% drop in provision for income taxes.

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J&J's pharmaceutical sales climbed 5% to $5.5 billion. Sales of anti-inflammatory drug Remicade rose 19% to $1.23 billion. Other drugs posting sales gains included HIV treatment Prezista and attention-deficit-disorder drug Concerta. Sales of antianemia drugs Procrit and Eprex dropped, hurt by a recent recall.

J&J and other drug makers also have begun to incur costs associated with the U.S. health-care overhaul enacted earlier this year.

Another challenge is pricing pressure in Europe, where national health programs are cutting spending to close budget gaps.

Chief Financial Officer Dominic Caruso said he expects 2010 revenue of about $62 billion, down from a prior forecast of $62.5 billion.

Jon Kamp contributed to this article.

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THE WALL STREET JOURNAL.
U.S. EDITION

Corporate Watch

830 words
19 October 2010
The Wall Street Journal
J
B9
English

HARRAH'S

Casino Operator to Take

Portion of Company Private

Looking for more cash so that it can grow out of a mountain of debt amidst a still troubled U.S. gambling market, Harrah's Entertainment Inc. disclosed Monday its plans to sell a small portion of the company -- up to $575 million -- of stock in an initial public offering.

The company said in a filing that it will spend that money on several new projects in Las Vegas, as well as two planned casinos in Ohio, a state that authorized casino gambling for the first time last year.

The timing of the offering is dicey. Harrah's was caught with a massive debt load when its key casino markets -- including Las Vegas and Atlantic City -- took a nosedive not long after the company was taken private in a $27.8 billion buyout by private-equity firms TPG Capital LP and Apollo Global Management LP. To get through the difficult period, Harrah's has added cash, extended its debt maturities and shaved off some debt through a series of financial maneuvers. But it still remains among the most highly leveraged of all major casino companies, with $24 billion of debt. Analysts fear that prospects remain rocky as long as recovery in those gambling markets is uncertain.

-- Alexandra Berzon and A.D. Pruitt

GENERAL ELECTRIC

Company to Pump Funds,

Jobs into Appliances Unit

General Electric Co. on Monday announced significant new U.S. investment in its appliances division after spending much of 2008 trying to shed the unit.

The conglomerate said GE Appliances & Lighting will add 500 U.S. jobs by 2014 and invest $432 million to design and manufacture efficient and environmentally friendly refrigerators.

Combined with a previous announcement late last year, the appliances division has unveiled plans for about 1,300 new U.S. jobs by 2014 and over $1 billion in investment since GE pulled the division from the sales block in late 2008 for lack of an acceptable offer. A backup plan to spin off the unit was hobbled by the recession and credit crunch.

-- Bob Sechler

JOHNSON & JOHNSON

Tylenol 8-Hour Caplets

Recalled for Musty Odor

Johnson & Johnson said it's recalling more than 127,000 bottles of Tylenol 8-Hour caplets after a small number of complaints about a musty or moldy odor, continuing the health-care company's series of manufacturing quality problems.

The odor is thought to be caused by trace amounts of the chemical 2,4,6-tribromoanisole, J&J said. This is the same chemical J&J previously said was the culprit in recalls of certain Tylenol products beginning last year.

In the previous recalls, J&J had said the chemical came from wooden pallets used to transport product packaging. However, the company is still investigating the source of the chemical in the latest recall, said J&J spokeswoman Carol Goodrich. She said pallets used for products in the latest recall had been "heat-treated," a process designed to remove trace amounts of the chemical.

The recalled products were manufactured in March at the Fort Washington, Pa., plant of J&J's McNeil Consumer Healthcare unit. That plant has since been shut down and is undergoing a renovation to improve quality.

-- Peter Loftus and Kathy Shwiff

J.C. PENNEY

Department-Store Chain

Goes on Defense

J.C. Penney Co. has raised the drawbridge.

Two weeks after William Ackman's Pershing Square Capital Management and Steven Roth's Vornado Realty Trust announced they had bought more than 26% of the department-store chain's shares, Penney announced a plan to keep them from gaining more influence.

Penney adopted a so-called shareholder-rights plan -- critics call it a "poison pill" -- that would dilute Pershing's and Vornado's holding if they tried to increase their positions or force a takeover of the company.

The retailer said it enacted the one-year plan to "promote fair and equal treatment" of shareholders and "in light of recent rapid accumulations of the company's outstanding stock."

-- Rachel Dodes and Joann S. Lublin

VALE

Brazilian Mining Firm Plans

For Output Expansion

Convinced that commodity demand has recovered and prices will remain strong, Vale SA of Brazil said it was ramping up expansion plans and will spend $26 billion over the next two years on more than a dozen projects around the world.

The world's second-largest mining company by output said it will increase its fertilizer, iron ore, copper and coal production by expanding, improving and developing 18 projects by 2012. Chief Executive Roger Agnelli said the company will focus on organic production growth in Africa and on its sales in Asia.

"Africa is small today but will be very big in 10-15 years," he said Monday. "Asia accounts for 52% of our revenues. Asia will account for 80% in a few years."

-- Robert Guy Matthews

Document J000000020101019e6aj00038

That Familiar Musty Odor Hits J&J Again

WSJ Blogs, 07:45, 19 October 2010, 163 words, By Katherine Hobson, (English)

It's baaaaack! The musty or moldy odor that has prompted Johnson & Johnson to recall over-the-counter meds in the pastis now sparking a recall of more than 127,000 bottles of Tylenol 8-Hour caplets.

Document WCWSJB0020101019e6aj003pd

THE WALL STREET JOURNAL.

Health
Tylenol 8-Hour Caplets Recalled on Musty Odor

By Kathy Shwiff
198 words
18 October 2010
17:04
The Wall Street Journal Online
WSJO
English

A Johnson & Johnson unit said it is recalling more than 100,000 bottles of Tylenol 8-Hour caplets after a small number of complaints about a musty or moldy odor.

The odor is thought to be caused by trace amounts of a chemical called 2,4,6-tribromoanisole. The recall is for one product lot, which includes 127,728 bottles, according to a J&J spokesman.

The drug maker's McNeil Consumer Healthcare unit said the voluntary recall was a precaution and the risk of medical problems is remote. So far, effects have been temporary and not serious.

The latest recall follows a string of problems at McNeil, which makes Tylenol and other popular pain and cold medicines that have been recalled during the past year due to manufacturing problems. Recalls of more than 135 million medicine bottles and other over-the-counter drug products are expected to cost J&J hundreds of millions of dollars in lost sales, legal settlements and capital improvements. In addition, McNeil is under a federal criminal investigation.

Write to Kathy Shwiff at kathy.shwiff@dowjones.com

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THE WALL STREET JOURNAL.
U.S. EDITION

Keeping Tabs on Implants --- Registry to Monitor Problems With Hip, Knee Replacements

By Jon Kamp
629 words
13 October 2010
The Wall Street Journal
J
D3
English

An effort to track hundreds of thousands of replacement hip and knee surgeries across the U.S. each year will soon start gathering data, with the potential to uncover implant problems more quickly.

That could eventually mean more recalls in a $12 billion industry led by companies including Zimmer Holdings Inc., Johnson & Johnson and Stryker Corp. Still, manufacturers are backing the "American Joint Replacement Registry" and have chipped in start-up funding.

By joining voluntarily and influencing development, manufacturers may dodge having to face mandated rules down the road. They'll gain product-durability insight that could help as new, higher-priced devices need to be justified by comparative-effectiveness testing.

And the data collected by the registry could identify problems before recall-related costs balloon.

The registry "really can serve as a very robust early warning system," said Cheryl Blanchard, chief scientific officer at Zimmer and a member of the new joint registry's board.

Knee and hip replacement devices are approved by the Food and Drug Administration. But currently there is no big nationwide registry tracking long-term results for patients who have received the implants. By tracking when patients need repeat surgery to fix worn-out joints, the registry hopes to catch cases where parts wear out prematurely due to problems such as implant loosening or dislocation.

J&J recalled hip parts in August after a U.K. registry uncovered high repeat-surgery rates, and a Kaiser Permanente registry for its health system has played a role in several recalls. If the new registry reaches its goal of covering 90% of 5,000 U.S. hospitals that do joint surgery, it could be bigger than all other registries combined, dramatically expanding the surveillance net.

The project, an offshoot from the American Academy of Orthopaedic Surgeons, will get underway as a pilot program involving 15 hospitals this month. Initially it will track basic details about patients, doctors, hospitals and implants. The goal is for results to spur changes that improve patient outcomes.

The registry aims to start expanding next summer. In the meantime, registry officials are sorting out details about how hospitals will report data and who pays the costs. One idea is to ask insurance companies and Medicare to provide financial incentives for hospitals to participate, because insurers benefit from fewer patient complications.

Other countries, including Sweden and Australia, have well-regarded national registries. But it's been difficult to launch a broad orthopedic registry in the complicated U.S. system. "It's hard to herd the cats and get everybody moving in the same direction," said David Lewallen, a Mayo Clinic surgeon who chairs the new registry's board.

Another problem is that "most of the profession doesn't want a registry," said Jeffrey Lerner, chief executive of the ECRI Institute, a nonprofit research organization. Doctors and manufacturers fear possible repercussions from dredging up problems that could hurt business, he said.

Some experts also are concerned about who will have access to the data collected and how it will be used. Registries don't produce high-level medical evidence but instead generate raw information that can signal issues that require follow-up. The worry is that information could be wielded by insurers seeking to limit coverage, or in lawsuits and marketing efforts, without appropriate context.

Details are still being worked out, but addressing such concerns may mean allowing doctors, hospitals and manufacturers to see only data that relate to them, benchmarked against broader details.

The nonprofit registry is incorporated in Illinois, which has strong data-protection laws, Dr. Blanchard said. It also will produce detailed annual reports, Dr. Lewallen said.

Document J000000020101013e6ad0000w

Steel Cage Match: Advil vs. Tylenol Edition

WSJ Blogs, 15:42, 4 October 2010, 237 words, By Jonathan D. Rockoff, (English)

Just as Johnson & Johnson resumes shipping some recalled Tylenol, Pfizer said it would hand out free Advil. Pfizer announced Monday that it's giving away 500,000 free bottles of the painkiller to people who clear their medicine ...

Document WCWSJB0020101004e6a4005sf

THE WALL STREET JOURNAL.

Investor's Calendar
Government's TARP Program Expires

260 words
3 October 2010
The Wall Street Journal Online
WSJO
English

THIS WEEK

TARP Expires: The government's Troubled Asset Relief Program officially ends today, costing far less than originally expected and having largely achieved its goal of propping up the financial sector.

Reviving Lincoln: Ford is expected to unveil Monday a plan to create at least seven new or revamped Lincoln models over the next four years, and also pare its dealer network, as the auto maker seeks to revive the brand.

Back on Shelves: Johnson & Johnson will begin shipping this week bottles of grape-flavored children's liquid Tylenol, which has been off the market for months due to a recall.

iPad Expansion: Target starts carrying the Apple iPad today.

LAST WEEK

Discount Deal: Southwest Airlines agreed to buy AirTran for $1.4 billion, the first major merger between U.S. discount carriers.

AIG Sale: The U.S. government and American International Group agreed on a deal to sell the government's stake in the company earlier than expected, but it's a plan that remains fraught with risk.

Still Shopping: Consumer spending rose 0.4% in August, the same as in July.

Pricier Pads: Home prices rose for the fourth-straight month in July, but at a slower pace than in previous months.

Toy Recall: Mattel's Fisher-Price agreed to recall millions of kids' products, for a variety of potential risks, after a handful of injuries.

Forget Santa: Nintendo said its highly anticipated 3-D handheld videogame machine won't be available for sale until after the holidays.

Document WSJO000020101002e6a3004ph

Investor's Calendar
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266 words
3 October 2010
The Wall Street Journal Sunday
SNJR
1
English

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THE WALL STREET JOURNAL.
U.S. EDITION

J&J Told It Moved Too Late

By Jonathan D. Rockoff
662 words
1 October 2010
The Wall Street Journal
J
B1
English

WASHINGTON -- As Johnson & Johnson prepared to resume shipments of some children's Tylenol, federal regulators told a congressional committee that the company's over-the-counter medicines unit repeatedly failed to investigate and fix problems with its products.

Since May, Food and Drug Administration investigators have inspected three plants belonging to J&J's McNeil Consumer Healthcare unit, which makes Tylenol and other popular pain and cold medicines that have been recalled over the past year due to manufacturing problems.

The inspections revealed a recurring "failure to investigate and correct product problems in a prompt and thorough manner," Joshua Sharfstein, the agency's principal deputy commissioner, told lawmakers at the hearing Thursday. The problems that were uncovered were of "varying degrees of seriousness," he said.

J&J said it has taken a number of steps to fix its manufacturing problems. Among them, it recently established a team, headed by a company veteran, to oversee manufacturing and operations across all of J&J and to create uniform standards for all plants to follow. It has also developed a plan for correcting the issues at McNeil plants.

"We've learned a lot of lessons through this unfortunate situation," Chief Executive William Weldon testified at the hearing held by the House Committee on Oversight and Government Reform. "We will do everything in our power to make sure this never happens again."

The FDA is reviewing McNeil's plan for fixing its manufacturing problems, and the agency is also conducting a follow-up inspection of a plant in Las Piedras, Puerto Rico, Dr. Sharfstein said. "We intend to keep a close eye on these facilities until the company earns back our confidence," he told the committee.

Dr. Sharfstein's testimony suggests J&J faces additional close scrutiny from the agency. The New Brunswick, N.J., company makes prescription drugs and medical devices as well as consumer items like Johnson's baby powder and Band-Aids. On Tuesday, the FDA warned J&J and other companies against falsely claiming their mouthwash products remove plaque and prevent gum disease.

Over the past year, J&J has been buffeted by more than a half-dozen product recalls, which included some hip-replacement parts and certain contact lenses. Recalls of more than 135 million medicine bottles and other over-the-counter drug products are expected to cost J&J hundreds of millions of dollars in lost sales, legal settlements and capital improvements. In addition, McNeil is under a federal criminal investigation.

Thursday's hearing was the second by the Oversight Committee to explore McNeil's manufacturing problems. Members probed the company's handling of recalls of Motrin pills that dissolved slowly, children's Tylenol that could have been tainted with a harmful bacteria and bad-smelling Tylenol arthritis pills.

Committee members also asked why McNeil waited before pulling the products from the market, with Republicans and Democrats alike critical of how the company handled defective medicines. Republicans also faulted the FDA's oversight.

J&J CEO Weldon said McNeil should have moved more quickly to address its manufacturing problems, including determining the causes. "Going forward, should similar circumstances arise, they will be handled differently," he said.

Upgrading McNeil's plants and equipment will cost $100 million, Mr. Weldon told lawmakers. McNeil is refitting its plant in Fort Washington, Pa., which was shut down after an April 30 recall of many children's Tylenol products. The unit also has plants in Lancaster, Pa.; Lititz, Pa.; and Guelph, Ontario.

Next week, the Guelph plant will begin shipping grape-flavored liquid children's Tylenol, a company spokesman said. The company declined to forecast when the medicine will return to store shelves.

Earlier this month, the company said Colleen Goggins, the long-time chief of J&J's consumer group, will retire in March.

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THE WALL STREET JOURNAL.

Health
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By Jonathan D. Rockoff
666 words
1 October 2010
The Wall Street Journal Online
WSJO
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Write to Jonathan D. Rockoff at jonathan.rockoff@wsj.com

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THE WALL STREET JOURNAL.

Health
Shelved J&J Drug to Return

By Peter Loftus And Jonathan D. Rockoff
723 words
30 September 2010
The Wall Street Journal Online
WSJO
English

Johnson & Johnson said Wednesday that it plans to resume limited shipments next week of one of its children's medicines that has been off the market due to a recall.

In written testimony for delivery to a congressional committee Thursday, J&J Chief Executive William Weldon said nearly one million bottles of the medicine, which he didn't identify, will be available for release next week. J&J expects to distribute a total of four million bottles in the U.S. by the end of the year.

In April, J&J's McNeil Consumer Healthcare unit recalled about 136 million bottles of over-the-counter liquid children's medicines, including Tylenol and Benadryl brands, due to quality problems such as floating metal particles and excessive concentrations of an active ingredient.

J&J's handling of this and other product recalls has sparked a federal criminal investigation as well as a probe by the House Committee on Oversight and Government Reform. Mr. Weldon is scheduled to testify before the committee Thursday along with Colleen Goggins, head of J&J's consumer unit, whose planned retirement was announced earlier this month.

"I know that we let the public down," Mr. Weldon is expected to say, based on written testimony released by the committee. "We did not maintain our high quality standards, and as a result, children do not have access to our important medicines. I accept full accountability for the problems at McNeil, and I will take full accountability for fixing them."

Mr. Weldon said J&J is investing more than $100 million in facilities, equipment and other improvements to McNeil's operations.

A J&J spokesman declined to elaborate.

Thursday's hearing is the second that the Oversight Committee has held on J&J's production of popular over-the-counter medicines and the Food and Drug Administration's regulation of the company. In addition to focusing on the company's manufacturing woes, the committee also is expected to examine how McNeil handled quality issues with certain Motrin pills and bottles of children's Tylenol before issuing recalls last year.

Over the past year, J&J has issued more than a half-dozen recalls. The biggest was the April recall of Tylenol and other pain and cold medicines. Since then, other units have recalled some hip-replacement parts and certain contact lenses.

J&J has shuttered its plant in Fort Washington, Pa., which made many of the recalled medicines, and plans an extensive refitting. J&J has said the recall will reduce its 2010 sales by about $600 million.

Mr. Weldon has taken several steps to address the problems. He recently established a new team, headed by a J&J veteran, to oversee manufacturing company-wide. The company had said it planned to resume production of some recalled medicines at the end of this year, and it has been shifting production of the medicines to other facilities.

The problems affecting the company's children's medicines, including potential bacterial contamination and super potency, have angered some parents. Yet polling shows that many consumers still hold J&J in high regard.

"They seem to be a little Teflon," said Chris Malone, chief advisory officer of Relational Capital Group, a marketing-consulting firm.

When re-introducing the medicines, J&J can take advantage of its brand loyalty and many consumers' willingness to return to its products, marketing experts say. Still, the company will have to be careful to be seen as offering safe and quality medicines, not trying to serve its own interests.

Some marketing experts say J&J might want to update its brands in order to give consumers an added reason to return.

J&J must also deal with economic pressures constraining consumers. Private-label brands have been grabbing more market share during the economic downturn. During the four weeks ending Sept. 4, sales of store brands for over-the-counter health-care products grew 8.5% compared with a 0.4% decline for brands, according to Bank of AmericaMerrill Lynch.

Write to Peter Loftus at peter.loftus@dowjones.com and Jonathan D. Rockoff at jonathan.rockoff@wsj.com

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THE WALL STREET JOURNAL.
EUROPE EDITION

Quality control at J&J draws U.S. scrutiny

By Jonathan D. Rockoff
974 words
30 September 2010
The Wall Street Journal Europe
WSJE
24
English

Details have emerged in a recall of Johnson & Johnson's Tylenol products that are drawing new scrutiny to the company's handling of quality problems involving its popular over-the-counter medicines.

At issue is J&J's handling of events leading up to the recall last year of infant's and children's Tylenol, which were withdrawn because some samples from a batch of raw materials that the company had used to make the medicines tested positive for potentially harmful bacteria.

The company, which tests raw materials before using them, learned on April 14, 2009, that Burkholderia cepacia bacteria tainted some raw materials that were to be used to make children's and infant's Tylenol, according to an executive summary of J&J's investigation into the matter.

J&J didn't use these raw materials. But before discovering the contamination, the company had made some Tylenol from raw materials that had been received earlier from the same batch, the May 29, 2009, document said.

No bacteria were found in raw materials actually used in manufacturing, nor in the finished product, the company said.

J&J's McNeil Consumer Healthcare unit kept shipping the medicines until June 4, 2009, according to an email between McNeil staff. That was the day that investigators from the U.S. Food and Drug Administration cited the company for violating good manufacturing practices. In total, McNeil shipped more than eight million bottles, according to the McNeil staff email.

The company began recalling the bottles from wholesalers on Aug. 21, 2009, according to a letter sent to retailers, but it didn't make the recall public until September.

Before recalling the affected medicines, the company hired a contractor to see how many bottles remained on store shelves, according to communications from J&J staff and the contractor staff.

McNeil said it had "no basis to believe" that any of the Tylenol on the market contained B. cepacia given its testing of the raw materials, the finished medicines and, later, the recalled medicines. The FDA agreed the health risk was remote, the company said.

McNeil said it hired the contractor to determine how much of the affected medicine remained on the market to help it assess the kind of action it should take. On July 30, McNeil decided to recall the products and spent August finalizing the details of the recall with the FDA, the company said.

The bacteria aren't considered a threat to people in good health. But they can cause serious respiratory infections like pneumonia in patients suffering from weakened immune systems or such chronic lung diseases as cystic fibrosis, according to the U.S. Centers for Disease Control and Prevention. The FDA hasn't linked any serious side effects to the Tylenol, a spokeswoman said.

Since the FDA lacks the authority to mandate a recall, the agency's guidelines give drug companies latitude to determine what to do about defective medicines on the market depending on how much remains on sale and what the health risk may be. But the guidelines encourage companies to notify the agency "as soon as possible" when deciding to conduct a recall.

J&J's handling of problem Tylenol has become a focus of a congressional investigation into manufacturing problems. J&J has issued more than a half dozen recalls of popular over-the-counter medicines over the past year, and temporarily shuttered the Fort Washington, Pa., plant where it makes many Tylenol products.

How the company handled the September recall will likely be an issue when J&J Chief Executive William Weldon testifies Thursday before the House Committee on Oversight and Government Reform Thursday. In his invitation to Mr. Weldon, the committee's chairman, New York Democrat Edolphus Towns, asked whether J&J had tried to avoid recalling children's Tylenol in 2009.

New revelations could put a dent in J&J's reputation for corporate responsibility. The company cemented that reputation in 1982, after quickly recalling Tylenol because of a fatal tampering scare. J&J and its Tylenol brand still benefit from the reservoir of good will built up decades earlier, said Chris Malone, chief advisory officer of the Relational Capital Group, a marketing concern that recently surveyed consumer attitudes toward the company and Tylenol.

In an online survey of 1,042 people last July, consumers' loyalty to Tylenol and intent to purchase the medicine scored higher than its rival Advil despite the recalls, Mr. Malone said. But the high marks depended on perceptions that J&J acted in their best interests.

"If it became widely known and believed that Tylenol had failed on these critical expectations, consumer purchases and loyalty could be expected to drop significantly," Mr. Malone said.

The Tylenol recalls and the closing of a key plant have caused the company to lose hundreds of millions of dollars in sales. J&J's business benefits from its size and diversity, however. With $62 billion in revenue last year, the company doesn't depend on any particular product, even an iconic brand like Tylenol, which has about $1 billion in annual sales. J&J also sells prescription drugs and medical devices.

Its shares as of Tuesday had fallen 2.8% since April 30, when it announced its biggest recall, which involved 136 million bottles of children's and infants' Benadryl, Motrin, Tylenol and Zyrtec. By contrast, Dow Jones's U.S. Healthcare index was down 1.1%.

J&J said Wednesday that it plans to resume limited shipments next week of one of its children's medicineswhich it didn't namethat has been off the market for months.

Document WSJE000020100930e69u0001c

Grape Liquid Children's Tylenol Being Shipped Next Week, J&J Says

WSJ Blogs, 11:43, 30 September 2010, 181 words, By Katherine Hobson, (English)

We know you were at the edge of your seat during today's House Oversight Committeehearing on Johnson & Johnson's recent spate of recalls, waiting to hear which recalled children's medwill start shipping again next week.

Document WCWSJB0020100930e69u004k2

Ongoing Coverage of J&J's Appearance Before House Oversight Committee

WSJ Blogs, 08:42, 30 September 2010, 1241 words, By Peter Loftus, (English)

Johnson & Johnson CEO William Weldon will appear today before the House Oversight Committee to testify about the recalls and manufacturing problems that have recently plagued the drug maker.

Document WCWSJB0020100930e69u003kh

Ongoing Coverage of J&J's Appearance Before House Oversight Committee

WSJ Blogs, 08:28, 30 September 2010, 213 words, By Peter Loftus, (English)

Johnson & Johnson CEO William Weldon will appear today before the House Oversight Committee to testify about the recalls and manufacturing problems that have recently plagued the drug maker.

Document WCWSJB0020100930e69u003kd

THE WALL STREET JOURNAL.
U.S. EDITION

Corporate News: Shelved J&J Drug to Return --- Company to Resume Limited Shipping of One of Its Recalled Children's Products

By Peter Loftus and Jonathan D. Rockoff
536 words
30 September 2010
The Wall Street Journal
J
B4
English

Johnson & Johnson said Wednesday that it plans to resume limited shipments next week of one of its children's medicines that has been off the market due to a recall.

In written testimony for delivery to a congressional committee Thursday, J&J Chief Executive William Weldon said nearly one million bottles of the medicine, which he didn't identify, will be available for release next week. J&J expects to distribute a total of four million bottles in the U.S. by the end of the year.

In April, J&J's McNeil Consumer Healthcare unit recalled about 136 million bottles of over-the-counter liquid children's medicines, including Tylenol and Benadryl brands, due to quality problems such as floating metal particles and excessive concentrations of an active ingredient.

J&J's handling of this and other product recalls has sparked a federal criminal investigation as well as a probe by the House Committee on Oversight and Government Reform. Mr. Weldon is scheduled to testify before the committee Thursday along with Colleen Goggins, head of J&J's consumer unit, whose planned retirement was announced earlier this month.

"I know that we let the public down," Mr. Weldon is expected to say, based on written testimony released by the committee. "We did not maintain our high quality standards, and as a result, children do not have access to our important medicines. I accept full accountability for the problems at McNeil, and I will take full accountability for fixing them."

Mr. Weldon said J&J is investing more than $100 million in facilities, equipment and other improvements to McNeil's operations.

A J&J spokesman declined to elaborate.

Thursday's hearing is the second that the Oversight Committee has held on J&J's production of popular over-the-counter medicines and the Food and Drug Administration's regulation of the company. In addition to focusing on the company's manufacturing woes, the committee also is expected to examine how McNeil handled quality issues with certain Motrin pills and bottles of children's Tylenol before issuing recalls last year.

Over the past year, J&J has issued more than a half-dozen recalls. The biggest was the April recall of Tylenol and other pain and cold medicines. Since then, other units have recalled some hip-replacement parts and certain contact lenses.

J&J has shuttered its plant in Fort Washington, Pa., which made many of the recalled medicines, and plans an extensive refitting. J&J has said the recall will reduce its 2010 sales by about $600 million.

Mr. Weldon has taken several steps to address the problems. He recently established a new team, headed by a J&J veteran, to oversee manufacturing company-wide. The company had said it planned to resume production of some recalled medicines at the end of this year, and it has been shifting production of the medicines to other facilities.

Document J000000020100930e69u0000t

The Suspense is Killing Us: Which J&J Med Will Return to Shelves?

WSJ Blogs, 16:16, 29 September 2010, 281 words, By Katherine Hobson, (English)

Forget the premiere of "Law & Order: Los Angeles"! Our planned evening's entertainment: perusing the list of children's medicinesrecalled earlier this year by Johnson & Johnson and trying to figure out which one ...

Document WCWSJB0020100929e69t006mx

A. M. Vitals: J&J Documents Raise Questions About 2009 Recall

WSJ Blogs, 06:58, 29 September 2010, 268 words, By Katherine Hobson, (English)

J&J Recall Questions: Before the recall of children's medsthat has grabbed headlines this year, Johnson & Johnson last year issued a separate recall of infant's and children's Tylenol. Internal documents and emails ...

Document WCWSJB0020100929e69t002xl

THE WALL STREET JOURNAL.

Health
J&J's Quality Control Draws Scrutiny

By Jonathan D. Rockoff
1,274 words
28 September 2010
The Wall Street Journal Online
WSJO
English

Details have emerged in a recall of Johnson & Johnson's Tylenol products that are drawing new scrutiny to the company's handling of quality problems involving its popular over-the-counter medicines.

At issue is J&J's handling of events leading up to the recall last year of infant's and children's Tylenol, which were withdrawn because some samples from a batch of raw materials that the company had used to make the medicines tested positive for potentially harmful bacteria.

The company, which tests raw materials before using them, learned on April 14, 2009, that Burkholderia cepacia bacteria tainted some raw materials that were to be used to make children's and infant's Tylenol, according to an executive summary of J&J's investigation into the matter. J&J didn't use these raw materials. But before discovering the contamination, the company had made some Tylenol from raw materials that had been received earlier from the same batch, the May 29, 2009, document said.

No bacteria were found in raw materials actually used in manufacturing, nor in the finished product, the company said.

J&J's McNeil Consumer Healthcare unit kept shipping the medicines until June 4, 2009, according to an email between McNeil staff. That was the day that Food and Drug Administration investigators cited the company for violating good manufacturing practices. In total, McNeil shipped more than eight million bottles, according to the McNeil staff email.

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The bacteria aren't considered a threat to people in good health. But they can cause serious respiratory infections like pneumonia in patients suffering from weakened immune systems or such chronic lung diseases as cystic fibrosis, according to the Centers for Disease Control and Prevention. The Food and Drug Administration hasn't linked any serious side effects to the Tylenol, a spokeswoman said.

Since the FDA lacks the authority to mandate a recall, the agency's guidelines give drug companies latitude to determine what to do about defective medicines on the market depending on how much remains on sale and what the health risk may be. But the guidelines encourage companies to notify the agency "as soon as possible" when deciding to conduct a recall.

J&J's handling of problem Tylenol has become a focus of a congressional investigation into manufacturing problems. J&J has issued more than a half dozen recalls of popular over-the-counter medicines over the past year, and temporarily shuttered the Fort Washington, Pa., plant where it makes many Tylenol products.

How the company handled the September recall will likely be an issue when J&J Chief Executive William Weldon testifies before the House Committee on Oversight and Government Reform Thursday. In his invitation to Mr. Weldon, the committee's chairman, New York Democrat Edolphus Towns, asked whether J&J had tried to avoid recalling children's Tylenol in 2009.

New revelations could put a dent in J&J's reputation for corporate responsibility. The company cemented that reputation in 1982, after quickly recalling Tylenol because of a fatal tampering scare. J&J and its Tylenol brand still benefit from the reservoir of good will built up decades earlier, said Chris Malone, chief advisory officer of the Relational Capital Group, a marketing concern that recently surveyed consumer attitudes toward the company and Tylenol.

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Its shares are down 2.8% since April 30, when it announced its biggest recall, which involved 136 million bottles of children's and infants' Benadryl, Motrin, Tylenol and Zyrtec. By contrast, Dow Jones's U.S. Healthcare index was down 1.1%.

Mr. Weldon has apologized to consumers for the recalls of Tylenol and other over-the-counter medicines. The company is revamping its manufacturing side to make sure all its units follow company-wide standards.

Colleen Goggins, head of J&J's consumer group, recently said she would leave the company in March.

In the case of the children's Tylenol last year, FDA investigators discovered the contamination during an inspection and on June 4 cited McNeil for its handling of the contamination. The inspection report found that McNeil's testing of the raw materials wasn't "scientifically sound."

On June 4, the company stopped shipping Tylenol made from raw materials belonging to the batch that was found to have B. cepacia in some lots, according to email between McNeil staff.

The company also moved to assess how much of the affected Tylenol remained on sale, according to the documents.

"We may want to see if our sales group can do some discreet store visits to assess what is out there for a few stores across the country," a J&J quality staffer wrote in a June 23, 2009, email to a colleague.

The next day, a staffer at Inmar Inc., a contractor that helps drug makers retrieve recalled medicines that McNeil had previously used, emailed McNeil saying it could check about 400 stores for $20,000.

Inmar asked WIS International to help it with the Tylenol work, according to emails among WIS staff and WIS's instructions to its employees.

Inmar declined comment and WIS officials didn't immediately respond to a request for comment.

In a letter dated Sept. 11, 2009, McNeil told retailers that it had begun recalling the affected Tylenol bottles from wholesalers on Aug. 21.

McNeil notified doctors of the Tylenol recall on Sept. 18, 2009.

On Sept. 24, 2009, McNeil posted on its Tylenol website information about the recall of children's products, saying that "an unused portion of one inactive ingredient did not meet all quality standards."

Write to Jonathan D. Rockoff at jonathan.rockoff@wsj.com

Document WSJO000020100929e69s005bp

THE WALL STREET JOURNAL.
U.S. EDITION

Corporate News: Corporate Watch

717 words
27 September 2010
The Wall Street Journal
J
B3
English

UNITED BISCUITS

China's Bright Food

Is in Exclusive Deal Talks

Shanghai-based Bright Food (Group) Co. is in exclusive talks about a possible purchase of U.K. snacks and cookies maker United Biscuits (Holdings) Ltd., people familiar with the matter said.

One of the people said the acquisition, if it goes ahead, would be valued at more than GBP 2 billion, or about $3.2 billion. United Biscuits' owners, private equity-firms Blackstone Group LP of the U.S. and PAI Partners of France, paid GBP 1.6 billion for the company four years ago. Britain's Sunday Times earlier reported the talks.

Chinese state-owned Bright Food couldn't be reached Sunday.

Blackstone and PAI about two months ago hired Goldman Sachs Group Inc. and J.P. Morgan Chase & Co. to undertake a strategic review of United Biscuits. The company's brands include Carr's water crackers, Hula Hoops snacks and McVitie's biscuits.

United Biscuits is best positioned in Western Europe. Interest from global food companies in bidding for United Biscuits has been muted.

Bright Food is one of China's largest food conglomerates. The company operates more than 3,300 retail stores across China.

-- Marietta Cauchi

NETFLIX

Movie-Rental Firm Expands

NBC Universal License Deal

Subscription movie-rental company Netflix Inc. and General Electric Co.'s NBC Universal expanded their license agreement, allowing for more NBC television shows to be available through Netflix's online-streaming service.

Financial terms of the agreement weren't disclosed.

The deal, which makes Netflix a tougher competitor to pay-TV operators, expands its selection of NBC shows to include hits such as "30 Rock," "The Office" and "Law & Order: SVU." It also will include episodes of "Saturday Night Live."

Netflix has rocketed in popularity recently as consumers increasingly opt for its subscription-based rental service.

NBC Universal is a unit of GE, but cable company Comcast Corp. is in the process of acquiring 51% control of the business.

-- Nathan Becker

ANEMIA DRUGS

Amgen, J&J Recall Lots

Of Epogen and Procrit

Amgen Inc. is recalling certain lots of anemia drugs Epogen and Procrit, sold by Johnson & Johnson, because the vials may contain "extremely thin" glass flakes that are barely visible.

The recall includes about 200 lots of Epogen and 155 lots of Procrit. Both drugs are the same product, epoetin alfa, which Amgen makes and markets as Epogen for kidney-failure patients on dialysis, and has licensed other uses to J&J, which sells it as Procrit.

The removal of the affected lots shouldn't disrupt the supply of Epogen to patients, nor will it have a material financial impact on the company, Amgen spokeswoman Emma Hurley said. The drugs were made in Puerto Rico, she said.

J&J spokeswoman Lisa Vaga said "we believe the financial impact would not be significant." She said the company will do "everything we can to ensure customers and patients continue to have access to Procrit."

Amgen said the problem with the flakes occurs as a result of the interaction of the medications with glass vials over the shelf life of the product. In response, Amgen is reducing the shelf life of Epogen to 12 months, from 36 months, for single-dose vials and to 15 months for multiple-dose vials.

Furthermore, the company will begin using glass vials from one of its manufacturers "that doesn't exhibit the issue before the expiry date," Ms. Hurley said.

Amgen and J&J are sending letters and other communication to health-care professionals, distributors, wholesalers and pharmacies, with instructions for returning the products.

-- Thomas Gryta

CARGILL

Commodities Giant to Buy

A Unilever Unit in Brazil

Cargill Inc. agreed to buy the Brazilian tomato-product unit of Unilever for about 600 million Brazilian reals ($350 million).

Cargill said the deal shows its commitment to increasing its presence in Brazil, with the goal of becoming a leading food-product company in the country.

The deal gives the Minneapolis-based agribusiness giant some leading consumer brands for tomato sauce, paste and pulp, such as Pomarola, Pomodoro and Elefante. It also includes Unilever's site in Goiania, in Goias state, and a tomato-manufacturing plant.

-- Joan E. Solsman

Document J000000020100927e69r0002q

THE WALL STREET JOURNAL.

Business
Corporate Watch

860 words
26 September 2010
20:03
The Wall Street Journal Online
WSJO
English

United Biscuits

China's Bright Food Is in Exclusive Deal Talks

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United Biscuits is best positioned in Western Europe, which generates the bulk of its revenue, but has relatively little exposure to faster-growing emerging markets. Interest from global food companies in bidding for United Biscuits has been muted.

Bright Food is one of China's largest food-industry conglomerates. The company operates more than 3,300 retail stores across China.

Bright Food operates four listed companies. Among them is Bright Dairy & Food Co., which was among the more than 20 Chinese milk producers implicated in a 2008 scandal in which the industrial chemical melamine was added to milk powder that killed at least six children and sickened nearly 300,000 others. Bright Dairy and other companies apologized and recalled the tainted products.

Marietta Cauchi

Netflix

Movie-Rental Firm Expands NBC Universal License Deal

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The deal also provides access to episodes of "Battlestar Galactica," "Destination Truth" and "Eureka" from the Syfy network.

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Nathan Becker

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Amgen's sales of Epogen in the U.S. last year were $2.6 billion. J&J had global sales of Procrit—and a similar product called Eprex—of $2.2 billion last year.

The removal of the affected lots shouldn't disrupt the supply of Epogen to patients, nor will it have a material financial impact on the company, Amgen spokeswoman Emma Hurley said. The drugs were manufactured in Puerto Rico, she said.

J&J spokeswoman Lisa Vaga said "we believe the financial impact would not be significant." She said the company will do "everything we can to ensure customers and patients continue to have access to Procrit."

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Furthermore, the company will begin using glass vials from one of its manufacturers "that doesn't exhibit the issue before the expiry date," Ms. Hurley said.

Amgen and J&J are sending letters and other communication to health-care professionals, distributors, wholesalers and pharmacies, with instructions for returning the products.

Affected lot numbers and expiration dates can be found at the drugs' websites, www.epogen.com and www.procrit.com.

Thomas Gryta

Cargill

Commodities Giant to Buy A Unilever Unit in Brazil

Cargill Inc. agreed to buy the Brazilian tomato-product unit of Unilever for about 600 million Brazilian reals ($350 million).

Cargill said the deal shows its commitment to increasing its presence in Brazil, with the goal of becoming a leading food-product company in the country.

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Joan E. Solsman

Document WSJO000020100927e69r00231

THE WALL STREET JOURNAL.

Health
Amgen Recalls Some Procrit, Epogen

By Thomas Gryta
459 words
24 September 2010
09:52
The Wall Street Journal Online
WSJO
English

Amgen Inc. is recalling certain lots of anemia drugs Epogen and Procrit, sold by Johnson & Johnson, because they may contain "extremely thin" glass flakes that are barely visible.

The recall includes about 200 lots of Epogen, Amgen spokeswoman Emma Hurley said, but shouldn't disrupt the supply of the drug to patients, nor will it have a material financial impact on the company.

Both drugs are the same product, epoetin alfa, which Amgen produces and markets as Epogen for kidney-failure patients on dialysis and has licensed other uses of the drug to J&J, which sells it as Procrit.

Amgen said the problem with the flakes occurs as a result of the interaction of the medications with glass vials over the shelf life of the product. In response, Amgen is reducing the shelf life of Epogen to 12 months, from 36 months, for single-dose vials and 15 months for multiple-dose vials.

Furthermore, the company will begin using glass vials from one of its manufacturers "that doesn't exhibit the issue before the expiry date," Ms. Hurley said. The company uses multiple suppliers to provide glass vials, but it couldn't immediately comment on the source of the problematic vials.

J&J spokeswoman Lisa Vaga wouldn't comment on the financial impact of the recall, but she said the company will do "everything we can to ensure customers and patients continue to have access to Procrit."

Amgen's sales of Epogen in the U.S. last year were $2.6 billion. Johnson & Johnson had global sales of Procrit, and a similar product called Eprex, of $2.2 billion last year.

J&J has had a series of product recalls since late last year because of quality problems, which have tarnished its image and hurt its financial results. The company has battled the problems by improving quality-control measures and is refitting one of its plants related to the problems.

The recall is being conducted in cooperation with the Food and Drug Administration.

The glass flakes are barely visible in most cases, and the companies "found a low potential to impact patients who may have received the affected product" and have received no reports of problems that "can be directly attributed" to the problem.

Regardless, the companies warn that particles in an injectable product can cause serious side effects. Amgen and J&J are sending letters and other communication to health-care professionals, distributors, wholesalers and pharmacies, with instructions for returning the products.

Affected lot numbers and expiration dates can be found at the drugs' websites, www.epogen.com and www.procrit.com.

Write to Thomas Gryta at thomas.gryta@dowjones.com

Document WSJO000020100924e69o007ka

Amgen and J&J Anemia Drugs Recalled on Concerns of Glass Flakes

WSJ Blogs, 10:32, 24 September 2010, 219 words, By Katherine Hobson, (English)

It's been quite a week for recalls -- beetle partsin Abbott's Similac powdered formula, undeclared peanuts in Lobster Pooburned peanut candy (read that one to believe it) and now, tiny glass flakes in injectable anemia drugs.

Document WCWSJB0020100924e69o0050l

THE WALL STREET JOURNAL.

Health
Beetles Prompt Recall of Similac Baby Formula

By Jonathan D. Rockoff
695 words
23 September 2010
The Wall Street Journal Online
WSJO
English

Abbott Laboratories is recalling about five million containers of Similac powdered baby formula, after learning that beetles or their larvae could be in packages made at one of its U.S. production plants.

Abbott halted production of the powdered Similac at its Sturgis, Mich., plant late last week upon discovering common warehouse beetles in the production area during a routine check, a spokeswoman said Wednesday. The company recalled containers on store shelves in the U.S., Guam, Puerto Rico and some Caribbean countries because testing found contamination in 0.16% of products, she said. The recall doesn't affect liquid Similac.

The company said it expects $100 million in lost Similac sales in the third quarter. The company is waiting to estimate the expenses related to recalling the containers.

The Food and Drug Administration said the beetle parts didn't present a serious health threat. A baby taking the formula could develop a temporary case of gastrointestinal discomfort, namely nausea or diarrhea. "However, it's short-term, not life-threatening. It's something that if your infant is having some GI distress or refusing to eat, then you should consult your health-care provider," an FDA spokeswoman said.

Abbott hasn't received any reports of injuries, said Melissa Brotz, company spokeswoman. It did get two complaints from parents who noticed beetle parts in their formula containers, though the company hasn't confirmed the complaints, Ms. Brotz said. She said the company decided to recall the entire line of powdered Similac products made at the plant for precautionary reasons.

"Delivering anything less than the highest-quality infant formula is unacceptable to us, and we will do whatever is necessary to maintain the trust of parents in the coming weeks," Ms. Brotz said. For parents seeking information, the company has set up a website: www.similac.com/recall and a toll-free number: 1-800-986-8850.

The recall will clear store shelves of a sizeable portion of the nation's leading infant formula, though the company doesn't expect parents will have problems finding cans of powdered Similac made in its other plants, bottles containing the liquid version or alternatives until Abbott can replenish supplies over the next several weeks.

A number of companies have been recalling drugs and medical devices due to quality problems recently. Johnson & Johnson, in particular, has withdrawn children's Tylenol, some hip-replacement parts and certain contact lenses. An Iowa egg producer faced a congressional hearing Wednesday about a nationwide salmonella outbreak.

"Between the Tylenol recall and this, it's ridiculous. I cannot even give my kid formula without worrying there are insect parts in it," said Liza Lipp, of Plainview, N.Y., who discovered that she had three recalled Similac containers and called Abbott seeking to return them and get a refund.

Because her 7-month-old has done well on the powdered Similac, Ms. Lipp expressed concern that she'd have to switch her daughter to another brand if she can't find the formula, once an emergency supply of liquid Similac runs out. Ms. Lipp said she had used about half a container without any problem.

The Similac recall is expected to have a minor financial impact on Abbott, a suburban Chicago maker of prescription drugs and medical devices in addition to so-called nutritionals like Similac. Although the formula is a big part of Abbott's nutritionals business, less than $1.3 billion of the company's $30.8 billion revenue last year came from Similac sales in the U.S.

Aside from its Sturgis, Mich., facility, Abbott has three other nutritionals plants in the U.S., and has increased production there. It expects supplies in stores to begin returning to normal levels within a few weeks, Ms. Brotz said.

The Sturgis, Mich., facility is continuing to produce child nutritional products made on other lines at the plant unaffected by the beetle contamination, Ms. Brotz said. Those products include Alimentum, NeoSure and EleCare baby formulas.

Kevin Kingsburyand Peter Loftus contributed to this article.

Write to Jonathan D. Rockoff at jonathan.rockoff@wsj.com

Document WSJO000020100923e69n00004

THE WALL STREET JOURNAL.

Health

New Details on Defective Motrin; FDA Says It Wasn't Informed J&J Hired a Contractor to Buy Drug Off Store Shelves

By Jonathan D. Rockoff
653 words
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English

New details emerged Monday about Johnson & Johnson's efforts to buy up defective Motrin packages, the subject of a congressional investigation into whether the company sought to avoid a recall without the knowledge of the Food and Drug Administration.

Staff at J&J's McNeil Consumer Healthcare unit messaged each other in the spring and summer of 2009 that they'd kept an FDA official informed about the use of a contractor to buy defective Motrin off store shelves, according to emails and letters reviewed by The Wall Street Journal.

An FDA spokeswoman said the agency wasn't aware of the company's efforts. "Any effort to suggest to the contrary is based on quoting documents selectively and out of context," the spokeswoman said. After learning that McNeil had hired contractors to buy up the defective Motrin, the FDA advised McNeil to conduct a recall, the spokeswoman said. In July 2009, J&J recalled the Motrin.

J&J's McNeil unit has had manufacturing problems that forced the recall of popular over-the-counter medicines and the temporary shutdown of a Tylenol manufacturing plant. In November 2008, the company discovered that certain Motrin pills weren't dissolving quickly enough due to a formulation problem. The Motrin was made at a J&J plant in San Juan, Puerto Rico.

The House Committee on Oversight and Government Reform is investigating whether J&J tried to avoid recalling the medicines by hiring a contractor to buy them up.

Rep. Edolphus Towns, the committee's chairman, said he planned to ask J&J Chief Executive William Weldon about the matter during a hearing scheduled for Sept. 30. Rep. Darrell Issa, the ranking Republican on the committee, asked Rep. Towns last week to request testimony from the FDA also. The committee on Monday invited Joshua Sharfstein, FDA principal deputy commissioner, to testify and requested any communications between J&J employees and FDA staff in 2009 regarding the Motrin purchases.

In March and April 2009, McNeil staff described in messages to each other how they kept Maridalia Torres, director of the FDA's San Juan office, apprised of plans for handling the defective Motrin, according to company emails. None of the emails were from the FDA itself.

A sampling of stores was checked to see how much of the defective Motrin remained on store shelves before McNeil discussed with Ms. Torres whether there were so many of the pills on the market to warrant a formal recall, according to the emails.

In a letter and report sent to Ms. Torres dated April 21, 2009, the company said sampling suggested that about one percent of the defective Motrin remained on shelves. The defective products were removed during the visits, and all the remaining packages would be removed by July 15, the report said.

A McNeil staffer emailed colleagues on April 20 that the FDA's San Juan district director agreed the company could pull the remaining defective products from store shelves without conducting a recall, the message said.

Ms. Torres didn't immediately respond to a request for comment.

On May 27, 2009, a McNeil staffer emailed colleagues that the company had "negotiated an agreement" with the FDA that it didn't need to do a recall. "This was a major win for us as it limits the press that will be seen," the staffer wrote.

A J&J spokeswoman said McNeil "kept the FDA informed of its actions and removed the product from the market in a compliant manner. However, given the concerns highlighted by the congressional committee with respect to Motrin, moving forward we would look to handle things differently."

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Corporate News: New Details on Defective Motrin --- FDA Says It Wasn't Informed J&J Hired a Contractor to Buy Drug Off Store Shelves

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Ms. Torres didn't respond to a request for comment. The FDA declined further comment due to its ongoing criminal investigation of J&J's McNeil unit.

A J&J spokeswoman said McNeil "kept the FDA informed of its actions and removed the product from the market in a compliant manner.

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Health
J&J Consumer Chief to Retire

By Jonathan D. Rockoff And Peter Loftus
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The head of Johnson & Johnson's consumer unit will retire next year, after a string of manufacturing problems prompted a massive recall of children's Tylenol, causing hundreds of millions of dollars in lost sales.

Colleen Goggins, 56 years old, has overseen J&J's consumer business since 2001 and worked at the company since 1981. Before the manufacturing woes, she was considered a contender to succeed William Weldon as chief executive. But the recalls, which revealed serious quality problems in the over-the-counter drug business Ms. Goggins oversaw, were seen as hurting her chances.

In a statement Thursday, Mr. Weldon praised Ms. Goggins for developing the plan to fix the manufacturing problems and thanked her for contributing to J&J's success. He said Ms. Goggins chose to retire, effective March 1, 2011. J&J said Ms. Goggins wasn't available for an interview.

J&J announced the decision after congressional investigators on Thursday asked Mr. Weldon and Ms. Goggins to testify about the company's manufacturing problems, including answering questions about whether the company tried to avoid recalling children's Tylenol in 2009.

The House Committee on Oversight and Government Reform has been probing J&J's recalls of popular over-the-counter medicines. At a May hearing, lawmakers asked J&J to explain its hiring of a contractor to buy some defective Motrin products off store shelves, rather than conducting a recall. Mr. Weldon didn't attend that hearing because he was recovering from back surgery; Ms. Goggins did attend.

Emails obtained during the committee's investigation raised the question of whether the company sought to also avoid recalling children's Tylenol in the summer of 2009, according to Rep. Edolphus Towns, the committee chairman, in a letter on Thursday inviting Mr. Weldon and Ms. Goggins to testify Sept. 30.

In particular, Rep. Towns (D-N.Y.) cited an email from the contractor hired by J&J's McNeil Consumer Healthcare unit to buy up the defective Motrin eight-count packages.

That June 30, 2009, email, released by the committee, said J&J was "very pleased" with its Motrin work and asked the contractor to explore "another similar but potentially larger recall for July involving Children's Tylenol."

In November 2008, the company learned that certain Motrin pills weren't dissolving appropriately, due to a formulation problem. In a May 27, 2009, email, a McNeil staffer called an agreement with the Food and Drug Administration to do the Motrin purchases "a major win for us as it limits the press that will be seen."

J&J told the FDA that it hired the contractor for statistical sampling, Ms. Goggins testified in May. An FDA investigator later complained to a J&J employee that the company was effectively recalling the products without saying so, according to an email reviewed by The Wall Street Journal. In July 2009, the company recalled the defective Motrin.

A J&J spokesman said Mr. Weldon planned to testify at the hearing, and the participation of Ms. Goggins "is still being determined." A J&J spokeswoman declined to answer questions about the emails. Neither the contractor, Inmar Inc. of Winston-Salem, N.C., nor its unit that worked for J&J returned calls seeking comment. The FDA didn't provide answers to questions.

A series of product recalls since late last year due to quality problems have tarnished J&J's image and will cost the company an estimated $600 million in lost sales this year. Mr. Weldon has vowed to clean up the problems by improving quality-control measures, and he is also revamping the manufacturing operations companywide.

The biggest recall took place April 30, when the McNeil unit withdrew more than 135 million bottles of Benadryl, Zytech and other popular pain and cold medicines for children. Problems included floating metal particles and excessive concentrations of active ingredients in some products. The company also shut down a key manufacturing plant outside Philadelphia, where FDA investigators found bacteria in some raw materials.

Federal prosecutors also are investigating the J&J recalls.

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Consumer Chief At J&J to Leave

By Jonathan D. Rockoff and Peter Loftus
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English

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Management
J&J Chief Tends Corporate Wounds

By Joann S. Lublin And Jonathan D. Rockoff
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Management
English

At a recent town-hall meeting, Johnson &Johnson Chief Executive William Weldon sketched out for employees his plans for fixing the manufacturing problems that have prompted a string of recalls and triggered a criminal investigation.

Now, he faces the more difficult task of executing those plans and convincing the public that J&J has put its problems behind it. His success—or failure—may be among the most important legacies he leaves the company near the end of a four-decade career there.

Mr. Weldon, 61 years old, is expected to retire late next year, though the company doesn't have a mandatory retirement age. To resolve the pressing issues, he will likely draw on a careful, low-key approach to decision-making and the support of J&J's board, in keeping with his conservative style, people familiar with the situation say.

The New Brunswick, N.J., company has been struggling for months with manufacturing troubles at its McNeil Consumer Healthcare unit, which recalled Tylenol and other over-the-counter medicines and temporarily shut down a plant for refitting. To address the issues, Mr. Weldon established a companywide quality team, but singled out McNeil as the problem. He announced the quality team, and other parts of a reorganization, at the company town hall, two weeks ago.

Then, last week, J&J's Vision Care Inc. unit recalled 100,000 boxes of contact lenses sold in Asia and Europe, and the DePuy Orthopaedics Inc. subsidiary recalled two hip-repair implants. Those recalls are unrelated to the McNeil recalls, a company spokesman said.

A J&J spokesman said the company and Mr. Weldon declined to comment.

So far, it doesn't appear that the recalls will shorten Mr. Weldon's tenure as CEO, said a person familiar with the situation. J&J board members will probably ask Mr. Weldon "to stick around and fix" the problems that have triggered the recalls, the informed individual said.

Another person close to the situation said Mr. Weldon wouldn't want to leave J&J in the lurch. "There is a kind of competitive streak in him, and he feels he needs to fix" the situation, this person said.

Mr. Weldon also repeatedly has told fellow directors that his potential internal successors weren't ready to take over the corner office, according to this second person.

The problems are expected to cost J&J hundreds of millions of dollars in lost sales, legal settlements and capital improvements. Whether selling Band-Aids or drug-eluting stents, J&J depends heavily on its image for corporate responsibility, branding experts say.

Mr. Weldon, who joined the company in 1971 and became chief executive in 2002, has some tailwinds, too. J&J's stock has barely rippled with the newest disclosures. Portfolio managers such as Derek Taner, of Invesco Global Health Care Fund, say the financial hit has been relatively small for a company with $62 billion in sales last year. He is more concerned about other matters, such as tepid growth in some of the company's businesses and the impact of the economy.

The recalls make "good headlines, but from an investment standpoint the others matter more, and I think the stock's performance reflects that," said Mr. Taner, who said J&J is "well-managed." J&J is the fund's eighth-largest holding.

Nevertheless, the muted impact so far doesn't mean J&J is free and clear. The House Committee on Oversight and Government Reform is continuing its investigation, a spokeswoman for the committee said.

Similarly, the recalls haven't turned away some of J&J's most important customers. Mary O'Connor , chair of the Mayo Clinic Florida's orthopedic department and president of the American Association of Hip and Knee Surgeons, said she doesn't expect DePuy's recall Thursday to send physicians into the arms of rivals. "It's not like DePuy is the only company that has had a recall," said Dr. O'Connor, who said she has received royalties from DePuy and rival Zimmer Holdings Inc.

What's more, the Food and Drug Administration is weighing whether to bring criminal penalties against the McNeil unit. Agency investigators have found numerous manufacturing violations at McNeil plants. A senior FDA official told the Oversight Committee the agency had held a meeting with J&J officials to express concern about McNeil's commitment to quality.

The recall also might have hurt the chances that Colleen Goggins , chair of J&J's consumer group, will be picked as the next chief executive, according to one of the people familiar the situation. A J&J spokesman declined to comment.

Ms. Goggins has been among the leading contenders to succeed Mr. Weldon. However, she oversees the McNeil unit . Sheri McCoy, who chairs J&J's pharmaceuticals segment, and Alex Gorsky, head of medical devices and diagnostics, run larger operations . Ms. McCoy and Mr. Gorsky also are younger than Ms. Goggins .

J&J leaves a lot of authority in the hands of its 250 businesses. But senior management, drawing on a companywide credo that directs employees to put customers first, are responsible for establishing overall priorities, said Stephen Greyser , an emeritus professor at Harvard Business School, who studied J&J's successful handling of the deadly Tylenol poisonings in 1982.

Marketing-research company Vision Critical's survey of 10,800 people across the U.S. this spring, around the time of McNeil's biggest recall, found that J&J had the best reputation among 54 leading companies.

"But I don't think that goodwill is perpetual," said John Gilfeather, a specialist in corporate-reputation measurement at Vision Critical.

In recent weeks, Mr. Weldon has begun giving interviews in which he has acknowledged letting down J&J's customers and has vowed to regain their trust and confidence.

"You earn your trust through your actions, and you lose it through your actions," he said in an interview with The Wall Street Journal. "Over time, we feel we will be able to re-establish trust and confidence."

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J&J chief tends to woes, legacy

By Joann S. Lublin and Jonathan D. Rockoff
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30 August 2010
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At a town hall meeting recently, Johnson &Johnson Chief Executive William Weldon sketched out for employees his plans for fixing the manufacturing problems that have prompted a string of recalls and triggered a criminal investigation.

Now, he faces the more difficult task of executing those plans and convincing the public that J&J has put its problems behind it. His success -- or failure -- may be among the most important legacies he leaves the company near the end of a four-decade career there.

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Health
J&J Latest Recall: Hip-Repair Implants

By Jonathan D. Rockoff And Jon Kamp
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English

(See Correction & Amplification below .)

Johnson & Johnson pulled two hip-repair implants off the market Thursday, the latest in a string of products recalled because of quality problems.

J&J's DePuy Orthopaedics Inc. unit said Thursday it is recalling the hip implants because too many patients needed surgeries to replace the devices. The unit had sold about 93,000 of the devices before phasing out production last year. The company said it's withdrawing the "very few" left on the market because new data indicated surgeons needed to replace them at a rate more than twice the industry average.

The latest recall deepens concern about quality controls at the company. This week, J&J's Vision Care Inc. unit withdrew about 100,000 boxes of contact lenses sold in Asia and Europe because a manufacturing problem prompted some customers to complain of pain, stinging or redness. Since September, the McNeil Consumer Healthcare unit has issued a series of recalls pulling more than 136 million bottles of Tylenol and other over-the-counter medicines off the shelves.

"Is this it, or is there more coming?" asked Les Funtleyder, portfolio manager of the Miller Tabak Health Care Transformation mutual fund, who is planning on buying J&J shares when his fund starts Sept. 13 but is keeping an eye out for more problems.

The over-the-counter recalls will cost J&J an estimated $600 million in lost sales this year, not including an undisclosed sum to refit a key Tylenol manufacturing plant that will be shut down about a year, and to upgrade others. DePuy's recall could cost J&J an additional $1.2 billion over five years for the cost of patient medical care and legal liability, Wells Fargo analyst Larry Biegelsen estimated in a note to investors.

The company's 2009 reported revenue was $62 billion. J&J stock fell 18 cents to $57.80 in 4 p.m. composite trading on the New York Stock Exchange.

J&J Chief Executive William Weldon recently established a team overseeing quality across the company's supply chain to address the manufacturing issues.

Mr. Weldon said in an interview last week that McNeil's troubles, in particular, have taught the company lessons and it would work hard to fix the issues inside the unit and anywhere else at J&J.

Mr. Weldon said the manufacturing problems were isolated to McNeil, which he called an outlier. Yet since then, two more J&J units have issued recalls.

Mr. Weldon wasn't saying the rest of the company was perfect or that it couldn't improve, a spokesman said Thursday, but that J&J had an outstanding record of supplying products overall.

Manufacturing experts say it's difficult for even the most committed companies to avoid periodic issues arising during production, especially for a firm like J&J that makes a mix of consumer goods, drugs and medical devices and leaves a lot of autonomy to its subsidiaries. Yet, the experts say the stream of problems suggests that J&J managers aren't striking the right balance between ensuring quality and controlling costs.

"It must have to do with the people they've got, and their awareness of quality, and their concern about cost and all the issues, trying to balance quality and cost," said Stephen Byrn, who teaches courses on drug and

medical-device manufacturing at Purdue University and helped found its master's program on quality for health-care products.

J&J's decision to issue the recalls reflects the company's "commitment to do what's in the best interest of those who use our products," the J&J spokesman said. He added that Mr. Weldon had said he didn't believe cost-cutting played a role in any of McNeil's problems.

DePuy, based in Warsaw, Ind., sells several kinds of hip implants. The recalled devices were especially popular for use in younger patients because the devices were thought to be more stable and less susceptible to dislocations than competing products, the company said.

The two recalled products are the ASR XL Acetabular System and ASR Hip Resurfacing System. The ASR Hip Resurfacing System wasn't approved in the U.S. and was only sold outside the country. DePuy sold ASR hip parts in the U.S. for an average price of $6,465 each last year, according to Orthopedic Network News, a newsletter that surveys hospitals to track device prices.

Under generally accepted standards, no more than 5% of patients should have a revision within five years, DePuy said. But new, unpublished data from the National Joint Registry of England and Wales found that the two implants had rates of 12% and 13%, the company said.

The two systems relied on all-metal implants or caps to replace the ball-and-socket in hip joints, rather than using plastic or ceramic surfaces. Such metal-on-metal implants have drawn scrutiny because wear can kick up metal debris that damages surrounding muscle and tissue in some patients, thereby requiring that the implants be replaced earlier than usual.

Surgeons have been warning about the problems with metal-on-metal implants. They try to avoid redoing the hip operations because "revision" surgeries carry risks and successive implants don't tend to fit as well as the first ones.

Revision surgeries "are technically more difficult, they take longer, the patient is more at risk of complications and the recovery is more prolonged," said Mary O'Connor, who chairs the orthopedic department at Mayo Clinic Florida and is president of the American Association of Hip and Knee Surgeons.

Revision surgeries are also expensive. They cost $20,800, about a fifth, or $4,000, more than the typical cost of procedures putting in the implants, according to the Agency for Healthcare Research and Quality.

DePuy advised doctors to monitor patients with the recalled implants. Dr. Henrik Malchau, an orthopedic surgeon at Massachusetts General Hospital who has done the revision operations in DePuy patients, said he wouldn't replace the recalled devices unless tests showed high ion levels in a patient's blood and damaged soft tissue. "Any surgical intervention is associated with complication and risk of death," he said.

DePuy said it would cover reasonable costs of monitoring and treatment, including revisions, associated with the recall, and that it will pick up all costs, including those that Medicare would pay.

J&J declined to cite 2009 revenue figures for the recalled hip parts. The company's DePuy franchise posted $5.37 billion in world-wide sales last year, accounting for nearly 9% of total J&J sales. DePuy is one of the largest makers of replacement orthopedic joints, where it competes closely with Zimmer Holdings Inc. and Stryker Corp.

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Correction & Amplification

Johnson & Johnson's DePuy unit sold replacement-hip systems, which included recalled ASR parts, in the U.S. for an average price of $6,465 each last year, according to the price-tracking newsletter Orthopedic Network News. This article incorrectly lists this figure as an average price for ASR parts only.

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Large Stock Focus
Cephalon Drops 2%; J&J Skids

By Donna Kardos Yesalavich
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NEW YORK—Blue-chip stocks fell Thursday, with declines in Cisco Systems, International Business Machines and J.P. Morgan Chase pushing the Dow Jones Industrial Average below the psychologically important 10000 mark on continued worries about economic growth.

The Dow dropped 74.25 points, or 0.7%, to 9985.81, its lowest close since July 6. Thursday marked the measure's fifth decline out of the past six sessions. It is now off 4.6% for the month and 4.2% for the year.

Cisco was the Dow's worst performer, with a drop of 51 cents, or 2.4%, to $20.70. IBM dropped 2.49, or 2%, to 122.78, contributing nearly 19 points to the price-weighted index's decline. J.P. Morgan slipped 60 cents, or 1.7%, to 35.63.

The Nasdaq Composite Index lost 22.85, or 1.1%, to 2118.69, the measure's fifth-lowest close this year. The Standard & Poor's 500-stock index shed 8.11, or 0.8%, to 1047.22, its sixth-lowest close this year. The declines came as investors grew increasingly nervous ahead of the government's Friday release of its revised estimate for second-quarter gross domestic product, in addition to a speech from Federal Reserve Chairman Ben Bernanke at the central bank's annual meeting in Jackson Hole, Wyo.

"The market is set up to be in a nervous position in light of the GDP number," said Douglas Guffy, senior portfolio manager at Baird Investment Management, noting economists are expecting the GDP estimate to be slashed to 1.3% from 2.4%.

3Par fell 73 cents, or 2.7%, to 26.03 after personal-computer maker Dell said 3Par accepted its revised merger agreement for $24.30 a share, topping the $24 offer made earlier this week by rival Hewlett-Packard. However, 3Par's shares rose 1.7% in after-hours trading as H-P accelerated the bidding war after Thursday's close, boosting its offer for the data-storage company 11% over Dell's latest offer. In the regular session, H-P slipped two cents, or 0.1%, to 38.22, and Dell declined three cents, or 0.3%, to 11.75.

Guess tumbled 4.09, or 11%, to 34.14. The apparel manufacturer's fiscal second-quarter profit rose 12%, but it only affirmed its targets for the year, which disappointed the market.

Cephalon dropped 1.17, or 2%, to 56.63. The biopharmaceutical company said Chairman and Chief Executive Frank Baldino Jr. will take a temporary medical leave of absence and is expected to return to the company later this year.

Patterson declined 1.31, or 4.9%, to 25.36. The wholesaler of dental, veterinary and other products posted a 20% jump in fiscal first-quarter profit on widened margins, but revenue increased by less than analysts expected.

Signet Jewelers added 1.30, or 4.7%, to 28.72. The jewelry retailer's fiscal second-quarter earnings jumped 47%, beating analysts' estimates, as same-store sales gains at its U.S. brands such as Kay Jewelers and Jared the Galleria of Jewelry added to the top line.

American depositary shares of Toyota Motor slipped 34 cents, or 0.5%, to 68.72. The auto maker announced it would conduct a safety recall involving about 1.3 million Corollas sold in the U.S. and Canada to address some engine-control modules that may have been improperly manufactured.

Stryker dropped 24 cents, or 0.6%, to 42.88 after the company agreed to pay Massachusetts $1.4 million to settle allegations it improperly marketed two orthopedic products. Under the settlement, filed Wednesday in Suffolk

Superior Court, Stryker will pay $325,000 in civil penalties; $875,000 to fund efforts to combat unlawful marketing and on programs to benefit health-care consumers; and $150,000 to cover attorney fees and investigative costs.

Johnson & Johnson edged down 18 cents, or 0.3%, to 57.80. The drug giant's orthopaedic-device unit announced recalls of some hip-replacement devices because of data on the rate of second surgeries needed. The recall, which J&J called voluntary, comes amid a string of quality-control problems at its non-prescription-drug operations.

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THE WALL STREET JOURNAL.
EUROPE EDITION

J&J's DePuy unit issues recall for two hip implants

By Jonathan D. Rockoff and Jon Kamp
531 words
27 August 2010
The Wall Street Journal Europe
WSJE
19
English

Johnson &Johnson recalled two of its hip implants because too many patients needed surgeries replacing the devices, in the latest in a string of recalls that have dogged the U.S. health-care company.

Surgeons had been raising concerns about the need to replace the ASR XL Acetabluar System and the ASR Hip Resurfacing System earlier than usual. Last year, J&J's DePuy Orthopaedics Inc. unit said it would phase out production of the implants because of declining sales and a desire to focus on developing newer products. The unit said Thursday it's withdrawing the "very few" left on the market because new data pointed to high re-do rates.

The recall was the latest for J&J, which sells many well-known health-care products.

Just this week, J&J's Vision Care Inc. unit withdrew about 100,000 boxes of contact lenses sold in Asia and Europe because a manufacturing problem prompted some customers to complain of pain, stinging or redness. Since September, the McNeil Consumer Healthcare unit has issued a series of recalls pulling more than 136 million bottles of Tylenol and other over-the-counter medicines. That unit shut down and is refitting a key manufacturing plant, while upgrading its others.

Unlike the earlier withdrawals, DePuy's involved serious consequences for patients who will have to be monitored to see if they need risky surgeries taking out and replacing the recalled implants.

J&J has an "outstanding record" of providing safe and effective products, and its decision to issue the recalls reflects the company's "commitment to do what's in the best interest of those who use our products," a spokesman said Thursday.

DePuy, based in Warsaw, Ind., sells several kinds of hip implants. The company has sold 93,000 of the recalled units, since they went on the market early this decade. They were especially popular for use in younger patients because the devices were thought to be more stable and less susceptible to dislocations than competing products, the company said. The ASR Hip Resurfacing System wasn't approved in the U.S. and was only sold outside the country.

The two systems relied on all-metal implants or caps to replace the ball-and-socket in hip joints, rather than using plastic or ceramic surfaces. Such metal-on-metal implants have drawn scrutiny because wear can kick up metal debris that damages surrounding muscle and tissue in some patients, thereby requiring that the implants be replaced earlier than usual.

Surgeons try to avoid redoing the hip operations because "revision" surgeries carry such risks as blood clots, infections and fractures; in addition, successive implants don't tend to fit as well as the first ones. Under generally accepted standards, no more than 5% of hip implants should require revision after five years, DePuy said. But new, unpublished data from the National Joint Registry of England and Wales found that the two implants had rates of 12% and 13%, the company said.

Document WSJE000020100827e68r0000a

A. M. Vitals: Latest J&J Recall Involves Two DePuy Hip Implants

WSJ Blogs, 06:37, 27 August 2010, 372 words, By Katherine Hobson, (English)

Pulling Implants: If you're keeping tabs on Johnson & Johnson's string of recalls, here's another: the company's DePuy Orthopaedics unit is pulling two hip implants because of unusually high replacement rates, the ...

Document WCWSJB0020100827e68r002pc

THE WALL STREET JOURNAL.
U.S. EDITION

J&J's Latest Recall: Hip-Repair Implants

By Jonathan D. Rockoff and Jon Kamp
1,127 words
27 August 2010
The Wall Street Journal
J
B1
English

Corrections &Amplifications

Johnson &Johnson's DePuy unit sold replacement-hip systems, which included recalled ASR parts, in the U.S. for an average price of $6,465 each last year, according to the price-tracking newsletter Orthopedic Network News. A Friday Corporate News article incorrectly listed this figure as an average price for ASR parts only.

(WSJ August 28, 2010)

(END)

Johnson &Johnson pulled two hip-repair implants off the market Thursday, the latest in a string of products recalled because of quality problems.

J&J's DePuy Orthopaedics Inc. unit said Thursday it is recalling the hip implants because too many patients needed surgeries to replace the devices. The unit had sold about 93,000 of the devices before phasing out production last year. The company said it is withdrawing the "very few" left on the market because new data indicated surgeons needed to replace them at a rate more than twice the industry average.

The latest recall deepens concern about quality controls at the company. This week, J&J's Vision Care Inc. unit withdrew about 100,000 boxes of contact lenses sold in Asia and Europe because a manufacturing problem prompted some customers to complain of pain, stinging or redness. Since September, the McNeil Consumer Healthcare unit has issued a series of recalls pulling more than 136 million bottles of Tylenol and other over-the-counter medicines off the shelves.

"Is this it, or is there more coming?" asked Les Funtleyder, portfolio manager of the Miller Tabak Health Care Transformation mutual fund, who is planning on buying J&J shares when his fund starts Sept. 13 but is keeping an eye out for more problems.

The over-the-counter recalls will cost J&J an estimated $600 million in lost sales this year, not including an undisclosed sum to refit a key Tylenol manufacturing plant that will be shut down in about a year and to upgrade others. DePuy's recall could cost J&J an additional $1.2 billion over five years for the cost of patient medical care and legal liability, Wells Fargo analyst Larry Biegelsen estimated in a note to investors.

The company's 2009 reported revenue was $62 billion. J&J shares fell 18 cents to $57.80 in 4 p.m. composite trading on the New York Stock Exchange.

J&J Chief Executive William Weldon recently established a team overseeing quality across the company's supply chain to address the manufacturing issues. Mr. Weldon said in an interview last week that McNeil's troubles, in particular, have taught the company lessons and it would work hard to fix the issues inside the unit and anywhere else at J&J.

Mr. Weldon said the manufacturing problems were isolated to McNeil, which he called an outlier. Yet since then, two more J&J units have issued recalls.

Mr. Weldon wasn't saying the rest of the company was perfect or it couldn't improve, a spokesman said Thursday, but that J&J had an outstanding record of supplying products overall.

Manufacturing experts say it's difficult for even the most committed companies to avoid periodic issues arising during production, especially for a firm like J&J that makes a mix of consumer goods, drugs and medical devices and leaves a lot of autonomy to its subsidiaries. Yet, the experts say the stream of problems suggests that J&J managers aren't striking the right balance between ensuring quality and controlling costs.

J&J's decision to issue the recalls reflects the company's "commitment to do what's in the best interest of those who use our products," the J&J spokesman said. He added that Mr. Weldon had said he didn't believe cost cutting played a role in any of McNeil's problems.

DePuy, based in Warsaw, Ind., sells several kinds of hip implants. The recalled devices were especially popular for use in younger patients because the devices were thought to be more stable and less susceptible to dislocations than competing products, the company said.

The two recalled products are the ASR XL Acetabular System and ASR Hip Resurfacing System. The ASR Hip Resurfacing System wasn't approved in the U.S. and was only sold outside the country. DePuy sold ASR hip parts in the U.S. for an average price of $6,465 each last year, according to Orthopedic Network News, a newsletter that surveys hospitals to track device prices.

Under generally accepted standards, no more than 5% of patients should have a revision within five years, DePuy said. But new, unpublished data from the National Joint Registry of England and Wales found that the two implants had revision rates of 12% and 13%, the company said.

The two systems relied on all-metal implants or caps to replace the ball-and-socket in hip joints, rather than using plastic or ceramic surfaces. Such metal-on-metal implants have drawn scrutiny because wear can kick up metal debris that damages surrounding muscle and tissue in some patients, thereby requiring that the implants be replaced earlier than usual.

Surgeons have been warning about the problems with metal-on-metal implants. They try to avoid redoing the hip operations because "revision" surgeries carry risks and successive implants don't tend to fit as well as the first ones.

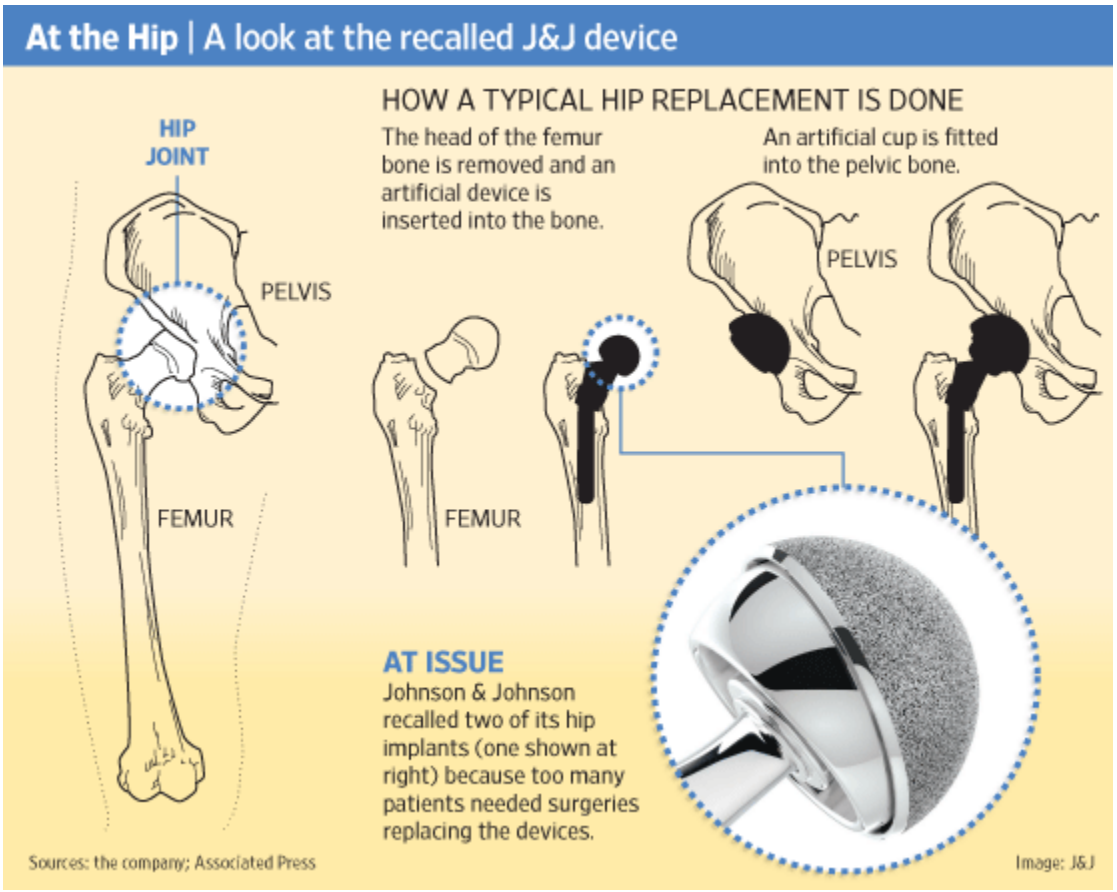
Revision surgeries "are technically more difficult, they take longer, the patient is more at risk of complications and the recovery is more prolonged," said Mary O'Connor, who chairs the orthopedic department at Mayo Clinic Florida and is president of the American Association of Hip and Knee Surgeons.

Revision surgeries are also expensive. They cost $20,800, about one-fifth, or $4,000, more than the typical cost of procedures putting in the implants, according to the Agency for Healthcare Research and Quality.

DePuy advised doctors to monitor patients with the recalled implants. Dr. Henrik Malchau, an orthopedic surgeon at Massachusetts General Hospital who has done the revision operations in DePuy patients, said he wouldn't replace the recalled devices unless tests showed high ion levels in a patient's blood and damaged soft tissue.

DePuy said it would cover reasonable costs of monitoring and treatment, including revisions, associated with the recall, and will pick up all costs, including those that Medicare would pay.

J&J declined to cite 2009 revenue figures for the recalled hip parts. DePuy is one of the largest makers of replacement orthopedic joints, where it competes closely with Zimmer Holdings Inc. and Stryker Corp.



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THE WALL STREET JOURNAL.
U.S. EDITION

Media &Marketing

J&J Contact Lenses Recalled --- Eye-Care Unit's Action Affects 100,000 Boxes of Lenses in Asia and Europe

By Jonathan D. Rockoff and Jon Kamp
492 words
24 August 2010
The Wall Street Journal
J
B7
English

Johnson &Johnson, which is trying to fix problems making Tylenol and other popular over-the-counter medicines, said Monday it was recalling about 100,000 boxes of contact lenses sold in Asia and Europe because of a manufacturing problem.

J&J's Vision Care Inc. unit recalled the "1-Day Acuvue TruEye" lenses after customers in Japan complained about experiencing pain, stinging or redness after inserting the lenses, the company said. Two lens customers were treated with medication, a spokesman said.

The eye-care unit traced the issue to the lens-rinsing process used on a particular line at a plant in Ireland that made the select lots, the company said. The unit described the manufacturing problem as isolated to the recalled lots and said the company had already taken corrective action.

J&J has been struggling with manufacturing problems in recent months. In March, the U.S. Food and Drug Administration sent a warning letter to the company's Advanced Sterilization Products subsidiary, saying it needed to do more to fix issues with certain sterilization devices. Advanced Sterilization Products said it was taking aggressive action.

The production woes have been most acute at J&J's McNeil Consumer Healthcare unit, which makes Benadryl, Motrin, Tylenol and Zyrtec medicines. The company recalled some of the over-the-counter drugs after customers reported a musty smell, and other products after patients complained about finding foreign materials.

The company has estimated the recalls could cost it $600 million in lost sales this year, and executives have acknowledged the withdrawals have damaged its once-sterling reputation with customers.

To fix the problems, McNeil temporarily shut a plant in Fort Washington, Pa., and is refitting it while upgrading other facilities. In addition, J&J is establishing a team to oversee manufacturing quality and compliance across the company. The team's leader will report directly to J&J Chief Executive William Weldon.

Manufacturing can be a highly complex process, and issues can periodically arise, according to experts. Mr. Weldon, in an interview describing the reorganization last week, said manufacturing problems were isolated to McNeil. "McNeil is an outlier when you look across J&J," he said. "This is not a systemic issue across J&J. We have an outstanding record."

Vision Care said it has pulled affected contact lenses off the market and suspended shipments of affected lots still in its control. It would be unlikely if anyone who used the affected lenses experienced any long-term health consequences, the company said.

The unit sells a different version of the 1-Day Acuvue TruEye lenses -- made with a different silicone hydrogel material -- in the U.S., according to the company.

Document J000000020100824e68o00035

THE WALL STREET JOURNAL.

Health

J&J Contact Lenses Recalled; Eye-Care Unit's Action Affects 100,000 Boxes of Lenses in Asia and Europe

By Jonathan D. Rockoff And Jon Kamp
549 words
24 August 2010
The Wall Street Journal Online
WSJO
English

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The unit sells a different version of the 1-Day Acuvue TruEye lenses—made with a different silicone hydrogel material—in the U.S., according to the company.

Contact lenses are a small portion of sales at J&J, a huge health-care conglomerate based in New Brunswick, N.J., selling medical devices, drugs and consumer products. A spokesman said the financial impact from the lens recall "is not considered significant."

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THE WALL STREET JOURNAL.

Business

J&J, Bruised by Recalls, Aims Higher; CEO Weldon Offers Prescription to Regain Consumers' Trust by Revamping Drug Manufacturing, Adding Quality Overseer

By Jonathan D. Rockoff
619 words
19 August 2010
The Wall Street Journal Online
WSJO
Health Edition
English

Johnson &Johnson is reorganizing its manufacturing side and creating a new position reporting directly to the chief executive to ensure quality production across the company, Chief Executive William Weldon said in an interview Wednesday.

J&J's McNeil Consumer Healthcare unit has been bedeviled by manufacturing problems that triggered a massive recall of children's Tylenol and other over-the-counter medicines earlier this year, and forced the temporary shutdown of a key plant.

Mr. Weldon acknowledged customers were smarting from the recalls, and vowed to regain their trust and confidence once the recalled medicines return to the market starting the end of this year. The company is refitting its shuttered plant in Fort Washington, Pa., and plans to invest "more heavily" in upgrading other McNeil facilities, he said.

"We've learned a lot of lessons from this, and we're working hard to make sure we get things right, not only at McNeil but across the company," Mr. Weldon said.

He said the problems at McNeil were limited to the unit—he called McNeil an "outlier" in the company. But McNeil's troubles showed the benefits of creating a companywide operations unit to ensure quality and compliance and share expertise and best practices, he said. J&J had begun looking at its manufacturing and quality framework across the company 1½ years ago, he said.

Ajit Shetty, a J&J veteran running the corporate oversight group, will be in charge of operations for the company's pharmaceuticals, medical device and consumer segments. The chief quality officers for each of the business groups will report into Mr. Shetty's new organization, as will the managers of the 120 J&J manufacturing facilities world-wide, Mr. Weldon said. J&J's units will retain responsibility for the quality and compliance of their products, a spokesman said.

"The people who use our products are our first priority, and we've let them down," Mr. Weldon said. He acknowledged the recalls have sapped trust and confidence in J&J, and said the company has "a lot to do to earn that back."

The recalls at the McNeil unit have prompted a congressional investigation, and the Food and Drug Administration has said it is considering criminal penalties.

FDA investigators have found numerous violations of good manufacturing practices at McNeil plants in recent months. Certain Tylenol, Motrin and Benadryl products made at a J&J plant in Puerto Rico were recalled starting late last year because a chemical used to treat wooden pallets in the factory gave some products a musty smell.

J&J temporarily shut down the Fort Washington plant on April 30 after consumers complained about "foreign materials, black or dark specks" in medicine bottles. That same day, J&J recalled liquid Benadryl, Motrin, Tylenol and Zyrtec medicines for children made at the plant, saying they could contain metallic particles or high concentrations of active ingredient due to manufacturing problems.

The recall lowered J&J's sales in the second quarter by $200 million and will cost the company an estimated $600 million in lost sales for the full year. The company hasn't estimated the full financial impact.

J&J plans to make the recalled medicines at other facilities, and will start production of some of the medicines toward the end of this year. The Fort Washington plant won't reopen until the second half of next year, Mr. Weldon said.

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THE WALL STREET JOURNAL.
EUROPE EDITION

J&J, hit by recalls, revamps factories

By Jonathan D. Rockoff
442 words
19 August 2010
The Wall Street Journal Europe
WSJE
UK22
English

Johnson &Johnson, which has been bedeviled by product recalls, is reorganizing its manufacturing side and creating a new position to oversee production quality across the company, Chief Executive William Weldon said Wednesday.

Manufacturing problems at J&J's McNeil Consumer Healthcare unit triggered a massive recall of children's Tylenol and other over-the-counter medicines earlier this year and forced the temporary shutdown of a key plant. The problems put a dent in J&J's reputation with consumers, and will cost the company an estimated $600 million in lost sales for the year.

Mr. Weldon acknowledged customers were smarting from the recalls, and said the company was exploring steps to regain their confidence once the medicines return to the market starting at the end of this year, although he said it's too early to elaborate.

Currently, the company is refitting its shuttered plant in Fort Washington, Pa., and it plans to invest "more heavily" in upgrading other McNeil facilities, he said. "We've learned a lot of lessons from this, and we're working hard to make sure we get things right, not only at McNeil but across the company," Mr. Weldon said.

The challenges are great. J&J, based in New Brunswick, N.J., makes well-known health-care products from consumer goods like Band-Aids to Cypher drug-eluting stents. Yet, like others in the industry, it has stumbled recently with manufacturing quality.

In recent months, FDA investigators found numerous violations of good manufacturing practices at McNeil plants. Certain Tylenol, Motrin and Benadryl products made at a J&J plant in Puerto Rico were recalled starting late last year because a chemical used to treat wooden pallets in the factory gave some products a musty smell.

J&J temporarily shut down the Fort Washington plant on April 30 after consumers complained about "foreign materials, black or dark specks" in medicine bottles. That same day, J&J recalled liquid Benadryl, Motrin, Tylenol and Zyrtec medicines for children made at the plant because they could contain metallic particles or high concentrations of active ingredient due to manufacturing problems.

Ajit Shetty, a J&J veteran who had been overseeing operations in the company's pharmaceuticals group, will add the medical-device and consumer groups to his portfolio. The chief quality officers for each of the business groups will report into Mr. Shetty's new organization, as will the managers of the 120 J&J manufacturing facilities world-wide, Mr. Weldon said.

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THE WALL STREET JOURNAL.
U.S. EDITION

J&J, Bruised by Recalls, Aims Higher --- CEO Weldon Offers Prescription to Regain Consumers' Trust by Revamping Drug Manufacturing, Adding Quality Overseer

By Jonathan D. Rockoff
881 words
19 August 2010
The Wall Street Journal
J
B10
English

Johnson &Johnson, which has been bedeviled by product recalls, is reorganizing its manufacturing side and creating a new position to oversee production quality across the company, Chief Executive William Weldon said Wednesday.

Manufacturing problems at J&J's McNeil Consumer Healthcare unit triggered a massive recall of children's Tylenol and other over-the-counter medicines earlier this year, and forced the temporary shutdown of a key plant. The problems put a dent in J&J's reputation with consumers, and will cost the company an estimated $600 million in lost sales for the year.

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Currently, the company is refitting its shuttered plant in Fort Washington, Pa., and it plans to invest "more heavily" in upgrading other McNeil facilities, he said.

"We've learned a lot of lessons from this, and we're working hard to make sure we get things right, not only at McNeil but across the company," Mr. Weldon said.

The challenges are great. J&J, based in New Brunswick, N.J., makes well-known health-care products from consumer goods like Band-Aids to Cypher drug-eluting stents. The company endeared itself to millions of customers with a swift recall of Tylenol in 1982, amid a poisoning scare. Yet, like others in the industry, it has stumbled recently with manufacturing quality.

In recent months, FDA investigators found numerous violations of good manufacturing practices at McNeil plants. Certain Tylenol, Motrin and Benadryl products made at a J&J plant in Puerto Rico were recalled starting late last year because a chemical used to treat wooden pallets in the factory gave some products a musty smell.

J&J temporarily shut down the Fort Washington plant on April 30 after consumers complained about "foreign materials, black or dark specks" in medicine bottles. That same day, J&J recalled liquid Benadryl, Motrin, Tylenol and Zyrtec medicines for children made at the plant because they could contain metallic particles or high concentrations of active ingredient due to manufacturing problems.

"The people who use our products are our first priority, and we've let them down," Mr. Weldon said. He acknowledged the recalls have sapped trust in J&J, and said the company has "a lot to do to earn that back."

Mr. Weldon said the problems were limited to the McNeil unit -- he called McNeil an "outlier" in the company -- and noted the company isn't remaking plants outside McNeil's, except as part of its routine quality and compliance efforts.

J&J tends to leave much authority in the hands of its sprawling units. Yet J&J had begun looking at its manufacturing and quality framework across the company 1 1/2 years ago, Mr. Weldon said. McNeil's troubles, he said, underscored the benefits of creating a companywide operations team to ensure quality.

Ajit Shetty, a J&J veteran running the corporate oversight group, will be in charge of operations for the company's pharmaceuticals, medical device and consumer segments. The chief quality officers for each of the business groups will report into Mr. Shetty's new organization, as will the managers of the 120 J&J manufacturing facilities

world-wide, Mr. Weldon said. J&J's units will retain responsibility for the quality and compliance of their products, a spokesman said.

"It's the right move," said Prabir Basu, a former Pfizer Inc. manufacturing official who now heads the nonprofit National Institute for Pharmaceutical Technology and Education.

Establishing a companywide team will help ensure that all units follow the same quality standards without letting their guard down as McNeil appeared to have done, Mr. Basu said. Still, the mere presence of the team, he added, "will not be enough. They have to develop the same quality standards. They have to make sure the same quality standards apply to all divisions."

Persuading customers to return could also be thorny. "I don't think I'll ever get it out of my head that I was giving tainted medicine to my babies. It's something you never forgive or forget," said Leslie DeBauge, a New York City mother of a 2 1/2-year-old girl and 4-year-old boy. She ordered children's Advil online, and has been buying store-brand versions of children's Tylenol and Benadryl.

A spokeswoman for the House Oversight and Government Reform Committee, which has been investigating the recalls, said the probe was ongoing. The FDA declined comment.

J&J plans to make the recalled medicines at other facilities, and will start production of some of the medicines toward the end of this year. The Fort Washington plant won't reopen until the second half of next year, Mr. Weldon said. The company hasn't estimated what the full financial impact would be.

Document J000000020100819e68j0003u

THE WALL STREET JOURNAL.

Health
J&J Says Multiple States Inquired About Recall

By Peter Loftus
363 words
11 August 2010
17:23
The Wall Street Journal Online
WSJO
English

Johnson & Johnson said Wednesday "multiple" U.S. state attorneys general have inquired about its series of recalls of over-the-counter medicines.

The New Brunswick, N.J., health-care company said in a regulatory filing Wednesday it received "civil investigative demands" from the state authorities in connection with the recalls.

J&J didn't identify the states. A spokesman couldn't immediately be reached.

J&J previously disclosed it had received grand-jury subpoenas from the U.S. Attorney's Office in Philadelphia. In the regulatory filing Wednesday, J&J said these subpoenas requested "documents broadly relating to recent recalls of various products" of J&J's McNeil Consumer Healthcare unit, as well as the U.S. Food and Drug Administration inspections of company manufacturing plants in Fort Washington, Pa., and Lancaster, Pa.

J&J said Wednesday it is cooperating with the U.S. Attorney's Office in responding to the subpoenas.

In a blow to J&J's reputation and financial results, its McNeil Consumer Healthcare unit has issued several recalls since late 2009 of over-the-counter medicines including those bearing the Tylenol, Motrin and Benadryl brands. The most significant was an April recall of more than 136 million bottles of liquid children's medicines due to quality problems such as higher-than-appropriate concentrations of active ingredient and the presence of metal particles.

J&J has suspended production at the Fort Washington plant. The FDA has identified problems at another J&J plant in Lancaster.

The recalls contributed to J&J's recent reduction of its 2010 earnings forecast.

Members of Congress also have been investigating J&J's actions surrounding the recalls, and multiple lawsuits seeking class-action status have been filed in connection with the recalls.

One lawsuit filed by a shareholder in late July in New Jersey state court seeks to compel inspection of company "books and records with respect to certain product recalls and various manufacturing plants," J&J said Wednesday.

Write to Peter Loftus at peter.loftus@dowjones.com

Document WSJO000020100811e68b009vm

Why Novartis's Triaminic Giveaway Reminds Us of the Tour de France

WSJ Blogs, 15:37, 28 July 2010, 320 words, By Katherine Hobson, (English)

Parents grieving the absence of the children's liquid Tylenol recalledby Johnson & Johnson are being targeted by Novartis with a massive giveaway. Next month the drug maker is giving away as many as 250,000 bottles of its new ...

Document WCWSJB0020100728e67s005v5

THE WALL STREET JOURNAL.

Health
FDA Report Details JNJ's Quality Issues

By Jonathan D. Rockoff
431 words
22 July 2010
The Wall Street Journal Online
WSJO
English

New details emerged about quality-control issues at the third Johnson & Johnson plant to be cited by regulators in recent months.

The Lancaster, Pa., plant, which makes heartburn medicines Pepcid and Mylanta, failed to look into consumers' complaints that various kinds of Pepcid tablets were mixed up in bottles, according to a Food and Drug Administration inspection report released Wednesday. Consumers had complained about finding mint and berry flavors or maximum and regular strength tablets of Pepcid in the same bottle.

The facility failed to check the quality of some Mylanta products after various equipment failed during manufacturing of the antacid, the report said. In addition, FDA investigators said in the report that they had to make repeated requests for various manufacturing records and wait days to get the documents, which industry standards say should be readily accessible.

The inspection took place June 22 to July 9, according to the report.

The Lancaster plant is owned by a joint venture between J&J and Merck & Co. A spokeswoman for the venture said Wednesday it provided a large volume of documents to investigators as quickly as possible and will promptly address issues the FDA cited.

J&J's McNeil unit, which operates the Lancaster plant, has endured a string of recalls of various over-the-counter medicines due to quality issues.

Inadequate follow-up of complaints was cited by FDA investigators during an inspection of a J&J plant in Fort Washington, Pa., in April. Investigators cited the plant for failing to investigate and fix problems that led consumers to complain about "foreign materials, black or dark specks" in medicine bottles from June 2009 to April 2010.

The Fort Washington plant was shut on April 30 amid a recall of liquid Benadryl, Motrin, Tylenol and Zyrtec medicines for children that could contain metallic particles or high concentrations of active ingredient due to manufacturing problems.

That recall lowered second-quarter sales by $200 million and will cost the company an estimated $600 million in lost sales for the full year, J&J said Tuesday. The company says it will refit the Fort Washington plant and revamp its operations before reopening it.

The FDA has also identified problems at J&J's manufacturing plant in Las Piedras, Puerto Rico, which recalled certain Tylenol, Motrin and Benadryl products because a chemical used to treat wooden pallets in the factory gave some products a musty smell.

Write to Jonathan D. Rockoff at jonathan.rockoff@wsj.com

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THE WALL STREET JOURNAL.

Earnings
J&J Cuts Outlook Due to Recalls

By Peter Loftus
788 words
20 July 2010
08:10
The Wall Street Journal Online
WSJO
English

Johnson & Johnson's second-quarter profit rose 7.5%, but the health-care conglomerate lowered its forecast of full-year earnings due to its recalls of over-the-counter medicines and increased pressure on prescription-drug prices in Europe.

J&J, of New Brunswick, N.J., also disclosed it has received a subpoena from a federal grand jury in Philadelphia, seeking information related to the recalls. J&J said it is cooperating; a spokeswoman for the U.S. Attorney's Office in Philadelphia declined comment.

J&J shares declined $1.42, or 2.4%, to $58.15 Tuesday morning.

In a blow to J&J's reputation and financial results, its McNeil Consumer Healthcare unit has issued several recalls since late 2009 of over-the-counter medicines, including those bearing the Tylenol, Motrin and Benadryl brands. The most significant was an April recall of more than 136 million bottles of liquid children's medicines due to quality problems such as higher-than-appropriate concentrations of active ingredient and the presence of metal particles.

"Remedial actions to address the product quality issue at McNeil Consumer Healthcare are ongoing and of high importance," J&J Chief Executive William Weldon said in a press release Tuesday.

J&J has suspended operations at its Fort Washington, Pa., plant, the primary source of the children's medicines, and is working to upgrade it. This will contribute to an estimated $600 million reduction to J&J's 2010 sales, said Chief Financial Officer Dominic Caruso. The company plans to shift production of the affected products to other plants, but that probably won't get under way until next year.

J&J's handling of issues related to the recall has prompted investigations by members of Congress and the U.S. Food and Drug Administration. An FDA official has said the agency is weighing the possibility of pursuing criminal penalties against the company.

The FDA also has identified problems at other J&J manufacturing plants, one in Puerto Rico and another in Lancaster, Pa.

The recall's impact on second-quarter financial results was significant, cutting sales by about $200 million and earnings by about 5 cents a share. In the U.S., combined sales of over-the-counter medicines and nutritionals—which encompass McNeil—dropped 27.5% to $492 million. J&J's consumer-products unit saw sales decline 5.4% to $3.6 billion world-wide.

Despite the recall, J&J still was able to post improved second-quarter results. Net income rose to $3.45 billion, or $1.23 a share, from $3.21 billion, or $1.15 a share, a year earlier. The latest quarter included a gain of 2 cents a share from settlements of litigation; excluding this, earnings would have been $1.21 a share, matching the mean estimate of analysts surveyed by Thomson Reuters.

Second-quarter sales rose slightly to $15.3 billion from $15.2 billion a year earlier, but fell short of the Thomson estimate of $15.6 billion. The effects of currency-exchange rates contributed only about 0.5 percentage points of the growth, less than in recent quarters due to the strengthening of the dollar.

J&J was able to offset some of the pain from the over-the-counter recalls with gains in its medical-device and diagnostics unit. Sales rose 4% to $6.1 billion. The company's Ethicon surgical products and vision-care products contributed to the growth, while its drug-coated stent franchise continued to be hurt by competition.

Sales for J&J's pharmaceutical unit rose 1% to $5.6 billion. The anti-inflammatory drug Remicade had sales of $1.1 billion, up 2.5%, while sales of the oral formulation of antipsychotic Risperdal and antiseizure drug Topamax declined due to generic competition. J&J said sales of newly launched prescription drugs, including the Stelara treatment for psoriasis, posted strong growth.

But a looming threat to pharmaceutical sales growth is coming from budget austerity measures taken by certain European countries such as Greece and Spain, which have reduced their payments for prescription drugs. Mr. Caruso said the pricing pressure in Europe is accelerating and is expected to cut about $200 million from 2010 sales.

J&J said it now expects 2010 earnings of $4.65 to $4.75 a share, excluding certain items, down from a previous forecast of $4.80 to $4.90 a share. J&J also cited unfavorable changes in foreign currency-exchange rates for the adjustment.

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THE WALL STREET JOURNAL.

Health

J&J Says FDA Finds Problems at a Third Drug-Making Facility

By Jonathan D. Rockoff

392 words
20 July 2010
The Wall Street Journal Online
WSJO
English

Regulators have found manufacturing problems at a third Johnson & Johnson drug-making plant, according to the company, which had already recalled several of its over-the-counter medicines due to manufacturing issues at two other facilities, one of which it closed.

The Food and Drug Administration recently inspected J&J's Lancaster, Pa., plant, and reported manufacturing problems to J&J, the company said Monday. A company spokeswoman declined to specify the date of the inspection or provide a copy of the inspection report. The company said it is taking the FDA's issues "seriously" and will address them "as rapidly as possible."

FDA spokeswoman said the agency was reviewing the findings and couldn't make them public yet.

The Lancaster plant is among four J&J facilities making over-the-counter pain and cold medicines, in addition to factories in Fort Washington, Pa.; Las Piedras, Puerto Rico; and Guelph, Ontario.

The plant in Lancaster is owned by a joint venture with Merck & Co., but is operated by J&J's McNeil unit. Among the products made there are heartburn medicines Pepcid and Mylanta.

In April, J&J's McNeil Consumer Healthcare unit shut down its plant in Fort Washington, where it made Tylenol, Motrin and other liquid products for children, saying some of its products might contain tiny metallic particles. Last week, the company said the plant might remain closed at least through the middle of next year as its equipment is replaced and operations revamped.

The FDA has also found violations of good manufacturing practices—including failure to appropriately investigate a musty smell or odor eventually traced to a chemical used to treat wooden pallets used to transport and store products—at the company's plant in Las Piedras, Puerto Rico. That plant, which makes Tylenol, Benadryl and Motrin, is still operational.

Due to manufacturing problems at its plants, J&J has issued six recalls of over-the-counter medicines since last September. Analysts say the company could lose at least $500 million in sales while the company works to move production of recalled Benadryl, Motrin, Tylenol and Zyrtec medicines to other plants.

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Document WSJO000020100719e67k00b42

J&J's 2010 Price Tag for Recalls: $600 Million. But What About Reputation?

WSJ Blogs, 12:53, 20 July 2010, 323 words, By, (English)

How much will Johnson & Johnson's series of product recalls ultimately cost the company?We got a partial answer today, when the company released second-quarter earnings. J&J said the recalls by its McNeil Consumer Healthcare ...

Document WCWSJB0020100720e67k005eh

THE WALL STREET JOURNAL.

Ahead of the Tape
Ahead of the Tape
Time for a Johnson & Johnson First-Aid Plan

By Jonathan D. Rockoff
423 words
19 July 2010
The Wall Street Journal Online
WSJO
English

Manufacturing problems at Tylenol plants have given Johnson & Johnson a headache.

The company has had six drug recalls since September, temporarily shut a particularly problematic drug-making factory, and sent an executive to testify before a congressional committee. When the health-care giant reports second-quarter earnings on Tuesday, investors need to get a sense not just of the financial hit but also of how the company will contain reputational damage.

J&J has so far offered little guidance, except to say the recalled products average $650 million in annual sales and the shuttered plant won't reopen at least through the middle of next year. Chief Financial Officer Dominic Caruso didn't speak at a yearly business review in June, even though he was scheduled to give remarks.

The company certainly needed time to get a handle on the extent of the problem. Only last Thursday did its McNeil Consumer Healthcare unit send to regulators a plan for fixing its shuttered Fort Washington, Pa., plant. That day, the company also said it was working to begin making the medicines in other plants—and that production of some of the drugs might resume later this year.

But investors can't be asked to wait too long, especially since the stock has underperformed the broader market the past year. Analysts are worried the Fort Washington plant mightn't reopen until the second half of 2011,and that the problems with children's Tylenol could damp sales of Tylenol to adults. They speculate lost revenue will be $500 million or more.

That may sound like chump change, given that J&J last year generated revenue of about $62 billion. And in any other quarter, Benadryl, Zyrtec and the other over-the-counter medicines subject to recalls would be an afterthought.

But the over-the-counter medicine franchise is central to J&J's image. In fact, J&J owes much of its reputation for putting customers first to its decisive handling of a Tylenol poisoning scare in 1982. The string of recent problems has raised investor concerns that the company's storied management might have lost its golden touch.

Tuesday's earnings are the perfect opportunity for management to show that it knows how to treat this ailment and keep it from turning into a more serious condition.

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THE WALL STREET JOURNAL.

Health
J&J Submits Plan to Fix Tylenol Plant Problems

By Jonathan D. Rockoff
407 words
15 July 2010
17:36
The Wall Street Journal Online
WSJO
English

Johnson & Johnson told regulators Thursday how it plans to correct problems at a troubled Tylenol plant, and said the plant might remain closed until well into next year.

J&J's McNeil Consumer Healthcare unit shut down the Fort Washington, Pa., plant due to manufacturing problems on April 30, the same day it recalled certain Benadryl, Motrin, Tylenol and Zyrtec medicines for infants and children that the company said could contain tiny metallic particles.

Also that day, the Food and Drug Administration found numerous violations of good manufacturing practices at the plant.

On Thursday, J&J's McNeil unit submitted to the FDA its plan for addressing the violations. The company didn't release the plan but said it planned to remake the factory, install new equipment and redo its operations.

The company said in a statement that it will make a "significant investment" in refitting the plant and that it will be out of service for a "protracted period of time." J&J didn't specify the time or cost, although a spokeswoman said the plant might remain closed at least through the middle of next year.

Analysts say the Fort Washington plant might not reopen until the second half of next year, and the company could lose $500 million in revenue or more.

The company's statement indicated that some of the medicines made at the plant might go on sale before the end of this year because the company is working to shift their production to other facilities.

J&J's McNeil unit is eliminating about 300 jobs as part of its makeover of the plant. The company said it has been giving employees regular pay and benefits since the plant's closure in April and will continue to do so through at least mid-September, then give the laid-off workers a severance package. Some might be rehired, McNeil said.

The company has issued six recalls of various over-the-counter cold and pain medicines since last September. It had shuffled management and hired an outside expert to help it upgrade the plant, and it has been improving processes and training employees. The House Committee on Oversight and Government Reform is investigating, and the FDA is weighing whether to seek criminal penalties.

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THE WALL STREET JOURNAL.

Health
J&J Starts Disclosing Drug Unit's Payments to Doctors

By Peter Loftus
962 words
9 July 2010
The Wall Street Journal Online
WSJO
English

Johnson & Johnson publicly disclosed for the first time payments it made to doctors, becoming the latest drug maker to try to improve transparency of its marketing practices.

But if investors want to browse the J&J data or look at the big picture, they are in for some work. The information about J&J's payments to individual doctors is spread across at least three reports posted on websites of the various operating companies of J&J's pharmaceutical unit. And J&J isn't publicly disclosing aggregate numbers for how much it spent or how many doctors received money, as some rivals have done.

"It's not all in one place," said Allan Coukell, director of the Pew Prescription Project, which has advocated for increased disclosure of industry payments to doctors. "We would have rather seen the multiple J&J sites consolidated into one. That said, I give them credit for doing what they've done. We applaud any company that takes voluntary steps towards this kind of disclosure."

J&J's pharmaceutical divisions began posting the names of doctors and the amounts they received from J&J on several company websites on June 30, said spokesman Mark Wolfe. The data cover payments made to doctors during the first three months of this year.

Based on the information released by J&J, payments to doctors by the company's Ortho-McNeil-Janssen division over the three-month period totaled $1.76 million, according to calculations by Obsidian HDS LLC, which aggregates physician-payment data. The total for J&J's Centocor Ortho Biotech unit was $658,111, and the total for the company's Tibotec unit was $433,250, according to Wall Street Journal calculations.

Like other drug makers, J&J, of New Brunswick, N.J., pays doctors and health-care professionals to serve as consultants for research, safety surveillance and other matters, and to speak to other doctors about uses of its products.

Such practices, however, have come under fire in recent years from critics who say the payments can taint drug research and medical practice.

Advocates for the disclosure say making public the payments will foster greater accountability, and inform patients as to whether their doctors have financial relationships with manufacturers of the products they prescribe.

Drug companies have defended the payments as necessary to gain insight into drug research and clinical practices.

The new health-care overhaul law requires makers of prescription drugs and medical devices to report physician-payment data to the government, which the U.S. Department of Health and Human Services will consolidate and make available on a public website. The requirement for annual reporting is to begin in 2013.

J&J and several other drug manufacturers had already pledged to publicly disclose physician-payment data before the law was enacted. Eli Lilly & Co., Pfizer Inc., GlaxoSmithKline PLC, Merck & Co. and Cephalon Inc. have begun posting payment data online. Some, including Pfizer, Lilly and Cephalon, have been required to post such payment information under terms of settlements of government investigations of marketing practices.

J&J announced in May 2009 that it would voluntarily begin disclosing physician payments in the first half of 2010 on the respective websites of its U.S. pharmaceutical divisions, which include Ortho-McNeil-Janssen, Centocor Ortho Biotech and Tibotec. The company said it would expand its reporting to include its medical-device and diagnostics unit next year.

"We have an ongoing commitment to ethical and transparent interactions with medical professionals," Mr. Wolfe said.

The new data cover payments exceeding $25 made directly and indirectly to U.S. physicians for participation in a speakers bureau or for providing consulting services in support of one of J&J's U.S.-marketed products. J&J will post the reports quarterly, beginning in September.

The longest report, at 18 pages, was for J&J's Ortho-McNeil-Janssen unit, which markets antipsychotic Risperdal, pain drug Duragesic and Concerta for attention deficit hyperactivity disorder, or ADHD. Many doctors listed received several thousand dollars each from J&J, and at least a few exceeded $20,000.

Some companies have disclosed aggregate numbers for physician payments. Pfizer, for instance, said in March it paid $35 million to about 4,500 health-care providers in the second half of 2009. In December, Glaxo said it paid $14.6 million to 3,700 health professionals in the second quarter of 2009.

But J&J isn't releasing any aggregate numbers, spokesman Mr. Wolfe said. "There are no aggregates as each link represents an individual legal entity that provided payments to U.S. physicians during the first quarter of 2010," he said.

Separately J&J's McNeil Consumer Healthcare unit said Thursday it is recalling 21 lots of over-the-counter medicines including Benadryl Allergy Ultratab, Children's Tylenol Meltaways, Motrin IB, Tylenol Extra Strength and Tylenol PM. The lots were manufactured at a J&J plant in Puerto Rico and were distributed there, as well as in the U.S., Fiji, Guatemala, the Dominican Republic, Trinidad and Tobago and Jamaica.

The J&J unit said the latest recall is a follow-up to one announced in January, which included certain lots of Tylenol, Motrin, Benadryl, Rolaids and other brands. The January recall was prompted by consumer complaints about musty odors, which McNeil linked to trace amounts of a chemical, known as 2,4,6-tribromoanisole, or TBA, used in wooden pallets involved in storing and transporting packaging materials for the products.

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THE WALL STREET JOURNAL.

Health
J&J Unit Widens Recall of Over-the-Counter Medicines

By Peter Loftus
571 words
8 July 2010
15:38
The Wall Street Journal Online
WSJO
English

Johnson & Johnson's troubled McNeil Consumer Healthcare unit again widened its recall of over-the-counter medicines, including Tylenol, Motrin and Benadryl, due to reports of musty or moldy odors linked to trace amounts of a chemical.

The latest recall continues a string of quality-control problems with J&J's nonprescription drugs, hurting sales and damaging the company's reputation, with no clear resolution in sight. J&J has come under scrutiny by congressional investigators and the Food and Drug Administration, which has said it may pursue criminal penalties against the company in connection with the recalls.

"Looks like more of the same," said Miller Tabak analyst Les Funtleyder, adding that it isn't clear what has caused McNeil's quality-control breakdowns, what the company is doing to fix them and when the company will put the problems behind it.

McNeil issued a separate recall in April covering more than 136 million bottles of liquid children's medicines, including Tylenol and Motrin brands, because of quality problems, including higher-than-appropriate concentrations of active ingredients. McNeil has suspended operations at the primary manufacturing plant for those products, in Fort Washington, Pa., while it takes steps to correct the problems.

The company has said it plans to submit a comprehensive action plan on quality improvements to the FDA by next Thursday. McNeil reiterated Thursday that the risk of serious adverse medical events from the recalled products is remote. However, it said consumers should stop using those products and contact McNeil for a refund or replacement.

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On Thursday, McNeil said it widened the January recall as a precautionary move after an internal review found that some packaging materials used in the lots were shipped and stored in the same type of wooden pallets implicated in the earlier recalls. McNeil previously widened the TBA-related recall in June, recalling five lots of products including Benadryl and Tylenol, saying they were inadvertently omitted from the initial recall action.

The company has said some consumers complained of gastrointestinal problems, including vomiting, as a result of the odors.

McNeil recalled certain lots of Tylenol arthritis pain caplets in late 2009 as a result of the odor problem. A spokeswoman declined to say how many bottles and boxes are involved.

J&J's shares, which have risen about 7.5% over the past year, were up 77 cents, or 1.3%., at $61.38 in 4 p.m. composite trading on the New York Stock Exchange.

Kathy Shwiff contributed to this article.

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THE WALL STREET JOURNAL.

Health

J&J Plant Involved in Recall to Stay Closed

By Jonathan D. Rockoff And Kathy Shwiff
391 words
24 June 2010
21:05
The Wall Street Journal Online
WSJO
English

Johnson & Johnson said it doesn't expect to resume before the end of this year making children's Tylenol and other medicines at the Fort Washington, Pa., plant that suspended production amid manufacturing problems that sparked a recall.

J&J's McNeil Consumer Healthcare unit halted work at the plant in late April, after learning that certain over-the-counter children's medicines could contain tiny metallic particles. The plant had made a range of products for kids and adults, including Tylenol, Benadryl, St. Joseph aspirin, Motrin and Zyrtec.

The products generate about $650 million in yearly sales, the company said. While their absence won't financially devastate a drug-and-device giant with sales last year of $62 billion, the recall has marred J&J's image. Analysts say the company faces not only an extensive undertaking to return the plant to compliance but also to restore the reputation of the recalled medicines.

On Thursday, J&J didn't give a timetable for restarting production at the plant, but the fact that the company ruled out doing so this year suggests the necessary fixes will be extensive. The company said it is in the midst of conducting a "comprehensive quality assessment" of its manufacturing operations and has identified fixes.

The April 30 recall involved more than 136 million bottles of pain and cold medicines for children and infants. It was the McNeil unit's fifth recall since last fall, and has prompted investigations by the Food and Drug Administration and the House Committee on Oversight and Government Reform.

The FDA has said the risk of harm from the defective medicines is remote, and has not reported any links between the products and reports of serious side effects.

J&J had said it's taken other significant steps to address the manufacturing problems at its McNeil unit, including replacing managers, hiring an outside consultant, and improving processes and employee training.

J&J's shares were at $59.65, up 5 cents, in after-hours trading. The stock, which recently traded under $58 for the first time in a year, has performed worse than other major drug makers during the past month as concerns linger over the recalls.

Document WSJO000020100625e66p001md

THE WALL STREET JOURNAL.
U.S. EDITION

Corporate News: J&J Adds More Medicines to Recall

249 words
16 June 2010
The Wall Street Journal
J
B2
English

A Johnson &Johnson unit recalled more medicines omitted from a wide recall in January, the third time it has broadened the recall of drugs made at its Puerto Rico plant to include more of the over-the-counter products.

Tuesday's recall comprises four lots of 100-count bottles of Benadryl Allergy Ultratab tablets sold in the U.S., and one lot of 50-count Extra Strength Tylenol Rapid Release Gels.

The action follows J&J's McNeil Consumer Healthcare unit's withdrawal of a wide range of Motrin, Tylenol, Benadryl, Rolaids, Simply Sleep and St. Joseph aspirin products. The unit began recalling medicines made at its Las Piedras, Puerto Rico, plant last November, after consumers complained about a moldy, musty or mildew-like odor that could cause nausea, stomach pain or diarrhea. In December, the company first expanded that recall.

The products recalled Tuesday were inadvertently omitted from the first recall due to "technical and clerical errors," a McNeil spokeswoman said. The unit discovered the mistake as part of its ongoing effort to fix the odor problem, which the company attributes to the presence of trace amounts of a chemical sometimes applied to the wood pallets use in manufacturing.

The company says its analysis shows the risk of serious side-effects is remote.

J&J's McNeil unit has been struggling with manufacturing problems at its plants.

Document J000000020100616e66g00020

THE WALL STREET JOURNAL.

Health
J&J Recalls More Medicine

By Jonathan D. Rockoff And Joan E. Solsman
315 words
16 June 2010
The Wall Street Journal Online
WSJO
English

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The company says its analysis shows the risk of serious side-effects is remote.

J&J's McNeil unit has been struggling with manufacturing problems at its plants. On April 30, it recalled children's Tylenol and other children's medicines made at its facility in Fort Washington, Pa., because the bottles could contain tiny metallic particles. Shortly after that recall, the unit discovered it had inadvertently neglected to include one version of Children's Zyrtec.

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THE WALL STREET JOURNAL.

Health

Memos to J&J Gave Details Of Motrin Buys

By Jonathan D. Rockoff
438 words
12 June 2010
The Wall Street Journal Online
WSJO
English

New details emerged Friday about a Johnson & Johnson unit's hiring of a contractor to buy defective Motrin at stores, an episode that has drawn scrutiny from congressional investigators probing whether the company tried to avoid a recall.

J&J's McNeil Consumer Healthcare unit hired a contractor to buy packages of the painkiller at retail stores after discovering in November 2008 that some of the medicines had problems dissolving. Contract workers were subsequently told to act like customers when making the purchases and not indicate they were conducting a recall, according to a memo shown at a House Committee on Oversight and Government Reform hearing last month.

Internal emails reviewed by The Wall Street Journal indicate some J&J employees knew the effort aimed to avoid raising suspicion of a recall. Last spring, J&J employees exchanged emails with a contractor specializing in product retrievals, Inmar Inc. of Winston-Salem, N.C., that discussed details of the operation.

An April 1, 2009, email from Rob Small, Inmar's director of field operations and transportation, sent to four J&J employees said workers could tell stores their purchases involved "random quality and/or packaging checks."or are "purchasing some samples" as part of a look at product packaging.According to Inmar's website, Mr. Small is now senior director, supply chain consulting

The memo to contract workers was sent from an entity called "WIS" that was working for a client called "CSCS" on behalf of J&J. Inmar has a CSCS unit, according to the company's its website.

Neither Inmar nor Mr. Small responded to requests for comment. A J&J spokeswoman declined to identify the contractors. She said the company kept the FDA and wholesalers informed of its actions and said J&J wanted to remove the affected product "with as little disruption and consumer confusion as possible" given the lack of a safety risk. She said a subcontractor without direct contact with McNeil was responsible for the memo to contract workers and McNeil didn't have any knowledge of it.

On July 16, 2009, a Food and Drug Administration investigator said in an email to a J&J employee that it seemed the company "is doing a recall even though you are calling it a 'retrieval.'" The agency investigator recommended the company conduct a recall.

That same month, J&J's McNeil unit recalled 88,104 packages of Motrin.

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THE WALL STREET JOURNAL.
U.S. EDITION

Media &Marketing
J&J Recall Probe Expands to Others

By Jonathan D. Rockoff
546 words
3 June 2010
The Wall Street Journal
J
B9
English

A Congressional probe of a Johnson &Johnson unit's manufacturing problems is spreading beyond the company's recent recall of its children's medicines to withdrawals of other over-the-counter products.

The House Committee on Oversight and Government Reform asked Blacksmith Brands on Tuesday for further information about its recall last week of PediaCare cough and cold medicines. Those products were made by J&J at the same Fort Washington, Pa., plant that produced children's Tylenol and other recalled kids drugs.

J&J's McNeil Consumer Healthcare unit had recalled certain Benadryl, Motrin, Tylenol and Zyrtec pain and cold medicines for children on April 30 because of manufacturing problems including the potential for metal particles in the products. J&J has temporarily shut the plant.

A spokesman for Blacksmith Brands, of Tarrytown, N.Y., called the committee's request standard in the event of recalls and said the company would cooperate. Blacksmith Brands bought the four recalled PediaCare products from J&J's McNeil Consumer Healthcare unit last year, and had arranged prior to the recall for other plants to make them starting in July.

The House committee also had sought information from WIS International, a merchandising consultant, as part of its examination of McNeil's handling of defective Motrin pain relief pills, according to a person familiar with the investigation.

In 2008, J&J's McNeil unit discovered that some of the pills weren't dissolving correctly. It hired a contractor to purchase the product from store shelves, according to documents released at the Congressional committee hearing last week.

The contractor advised its workers to buy up the Motrin packages, and to act like customers, making no reference to this being a recall, according to a memo released at the hearing.

In July 2009, McNeil issued a recall of the Motrin product.

Colleen Goggins, who oversees J&J's consumer group, told lawmakers last week that the company didn't have "any intent to mislead or hide anything" and that it had told the FDA it had hired a contractor to statistically sample the products. A J&J spokeswoman said it is looking into the contractor's work and would report back to the committee.

She wouldn't comment on whether WIS International was the contractor in the memo.

An entity called "WIS" is named in the contractor's memo.

Officials at the company did not return messages left Wednesday seeking comment. On Tuesday, Dave Haller, vice president of sales, account management and marketing, said: "We don't comment on activities for our clients, and Johnson &Johnson is not a client of ours." He would not say whether J&J or one of its units had been a client in the past.

WIS International, which has headquarters in San Diego, Calif., and Mississauga, Ontario, counts inventory on behalf of retailers, hospitals and other kinds of firms. It also helps manufacturers recall tainted products from retail store shelves.

The company's website says it has "worked on recalls and product purchases ranging from a few hundred stores to nearly 60,000."

Document J000000020100603e6630001w

THE WALL STREET JOURNAL.

Management
J&J Probe Expands to Other Products

By Jonathan D. Rockoff
543 words
2 June 2010
18:11
The Wall Street Journal Online
WSJO
English

A Congressional probe of a Johnson & Johnson unit's manufacturing problems is spreading beyond the company's recent recall of its children's medicines to withdrawals of other over-the-counter products.

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A spokesman for Blacksmith Brands, of Tarrytown, N.Y., called the committee's request standard in the event of recalls and said the company would cooperate. Blacksmith Brands bought the four recalled PediaCare products from J&J's McNeil unit last year, and had arranged prior to the recall for other plants to make them starting in July.

The House committee sought information from WIS International, a merchandising consultant, as part of its examination of McNeil's handling of defective Motrin pain relief pills, according to a person familiar with the investigation.

In 2008, J&J's McNeil unit discovered that some of the pills weren't dissolving correctly. It hired a contractor to purchase the product from store shelves, according to documents released at the Congressional committee hearing last week.

The contractor advised its workers to buy up the Motrin packages, and to act like customers, making no reference to this being a recall, according to a memo released at the hearing.

In July 2009, McNeil issued a recall of the Motrin product.

Colleen Goggins, who oversees J&J's consumer group, told lawmakers last week that the company didn't have "any intent to mislead or hide anything" and that it had told the FDA it had hired a contractor to statistically sample the products. A J&J spokeswoman said it is looking into the contractor's work and would report back to the committee.

She wouldn't comment on whether WIS International was the contractor in the memo.

An entity called "WIS" is named in the contractor's memo.

Officials at the company did not return messages left Wednesday seeking comment. On Tuesday, Dave Haller, vice president of sales, account management and marketing, said: "We don't comment on activities for our clients, and Johnson & Johnson is not a client of ours." He would not say whether J&J or one of its units had been a client in the past.

WIS International, which has headquarters in San Diego, Calif., and Mississauga, Ontario, counts inventory on behalf of retailers, hospitals and other kinds of firms. It also helps manufacturers recall tainted products from retail store shelves.

The company's website says it has "worked on recalls and product purchases ranging from a few hundred stores to nearly 60,000."

Write to Jonathan D. Rockoff at jonathan.rockoff@wsj.com

Document WSJO000020100603e6630005l

A. M. Vitals: More J&J Products Scrutinized By Congress

WSJ Blogs, 06:42, 3 June 2010, 313 words, By Katherine Hobson, (English)

Probe Widens: More Johnson & Johnson-made products are facing congressional scrutiny, with a House committee probing recalls of PediaCare cough and cold products and the pain reliever Motrin, the WSJ reports. The committee is seeking ...

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THE WALL STREET JOURNAL.

Health
More Children's Medicine Made at J&J Facility Is Recalled

By Jonathan D. Rockoff
662 words
29 May 2010
The Wall Street Journal Online
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English

Four children's cough and cold medicines made at a Johnson & Johnson plant shuttered because of manufacturing problems were recalled Friday, a month after different kids' medicines made at the facility were withdrawn.

Blacksmith Brands, which sells the PediaCare cough and cold medicines made at the plant in Fort Washington, Pa., said on its website that it was issuing the recall for precautionary reasons. It said it hasn't received any complaints or reports of side effects connected to the PediaCare products.

The new recall, which a Blacksmith Brands spokesman said affects at most 100,000 bottles, comes a day after Johnson & Johnson was grilled at a congressional hearing over manufacturing lapses at the plant and how its McNeil Consumer Healthcare unit has handled recalls of over-the-counter medicines.

The latest recall affects PediaCare's Multi-Symptom Cold, Long Acting Cough, Decongestant, and Allergy and Cold medicines. Blacksmith Brands said it has told retailers to take the four products from store shelves and advised parents to stop using the bottles.

The four PediaCare medicines had been owned by J&J, which sold them to Blacksmith Brands in November along with several other over-the-counter consumer products. That was after regulators found several violations of good-manufacturing practices at the Fort Washington plant. The private-equity firm Charlesbank Capital Partners formed Blacksmith, of Tarrytown, N.Y., shortly before the purchase of the products. Blacksmith had long planned for two other manufacturing plants to take over production of its PediaCare products starting in July, a spokesman said.

In an interview Friday before the Blacksmith Brands announcement, Rep. Edolphus Towns (D., N.Y.), chairman of the House Oversight and Government Reform Committee, vowed to step up a probe of the J&J unit's history of handling defective drugs, indicating the company faces protracted public scrutiny of its manufacturing problems.

Rep. Towns said he wanted to investigate McNeil's role in a contractor's apparent effort in late 2008 to buy up defective Motrin pills off retail shelves. Regulators discovered the contractor's work, and the company issued a recall in July 2009.

A McNeil spokeswoman said the company also planned to look into the contractor's work and report back to the committee.

The Oversight Committee hearing was called as a result of the McNeil unit's recall on April 30 of certain Benadryl, Motrin, Tylenol and Zyrtec medicines for infants and children. The Food and Drug Administration says that recall, though not posing much of a safety risk, indicated systemic compliance problems inside J&J's McNeil unit.

Mr. Towns said the committee would continue investigating the problems and also wants to examine whether the FDA needs more staff and the power to order a recall. Now, companies must volunteer to conduct a recall. The committee also wants to make sure the recent recall was aggressive enough, Rep. Towns added, expressing concern that some parents might not have gotten the message after the company announced the action late on a Friday.

"We cannot take this lightly, and I want J&J to know we are not," Rep. Towns said.

The unnamed contractor's work involving defective Motrin emerged during the hearing when lawmakers cited FDA documents and a memo from the contractor to its workers.

The McNeil unit hired the contractor after discovering in late 2008 that some Motrin wasn't dissolving correctly, according to the materials. The company told the FDA it had hired the contractor for statistical sampling, the FDA documents said.

Colleen Goggins, world-wide chairwoman of J&J's consumer group, told lawmakers the New Brunswick, N.J., company kept the FDA fully informed of its actions and didn't have "any intent to mislead or hide anything." She said she didn't know what the McNeil unit told the contractor to do.

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Corporate News: More Medicine Made at J&J Plant Is Recalled

By Jonathan D. Rockoff
555 words
29 May 2010
The Wall Street Journal
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English

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THE WALL STREET JOURNAL.

Health

FDA Weighing Penalties Against J&J; Unit's Manufacturing Deficiencies Could Draw Criminal Action From Agency

By Jennifer Corbett Dooren And Jonathan D. Rockoff
1,139 words
28 May 2010
The Wall Street Journal Online
WSJO
English

WASHINGTON—The Food and Drug Administration said it is weighing whether to seek criminal penalties against the Johnson & Johnson unit that made children's Tylenol and other over-the-counter kids' medicines recalled last month.

Joshua Sharfstein, the FDA's principal deputy commissioner, told lawmakers at a hearing Thursday that J&J's McNeil Consumer Healthcare unit had a "pattern of noncompliance" with good manufacturing practices. He said regulators were considering such punitive measures as "seizure, injunction or criminal penalties." The FDA's criminal investigations office is looking into the matter, an aide said.

The hearing veered into a new controversy when lawmakers pressed J&J to explain why, after the company discovered some defective Motrin products, a contractor sent out workers to buy all the available product off retail shelves. Under pressure from the FDA, the company issued a recall of 88,104 packages of Motrin in July 2009. "I don't think we fully understood what was going on," Dr. Sharfstein said.

Dr. Sharfstein said the agency was now working well with J&J and its McNeil unit, but he described a history of troubles getting the unit to fix violations.

Colleen Goggins, who oversees J&J's consumer business, said in her testimony to the House Committee on Oversight and Government Reform that the company kept the FDA fully informed of its actions and didn't have "any intent to mislead or hide anything."

The hearing probed into the problems at J&J's McNeil unit, which was responsible for managing the plant at Fort Washington, Pa., where the recalled children's medicines were manufactured. The New Brunswick, N.J., health-care giant generally leaves much discretion to its 250 far-flung units.

But the corporate parent has been "very involved" in last month's recall, a J&J spokesman said Thursday. Chief Executive William Weldon posted an open letter to customers on J&J's company blog, and the company has used the site to pass on further updates.

Ms. Goggins told the committee that the company "will expend whatever resources are necessary to ensure that this facility provides once again high quality medicines."

Regarding the possibility of criminal action, she said, "My major concern right now is remediating our plants to the highest level of quality and getting our products back on the shelves for consumers who need them."

The manufacturing lapses also have occurred amid cost-cutting and consolidation of some functions, reflecting broader pharmaceutical industry efforts to reduce expenses. J&J executives, for instance, recently moved to standardize compensation across the company.

Last year, J&J announced plans to cut 8,200 jobs, or 7% of its work force, as part of a broad restructuring that aims to achieve $1.7 billion in yearly savings by 2011.

At Thursday's hearing, Ms. Goggins said cost-cutting didn't affect quality control at the Fort Washington facility. She said the head count among Fort Washington's quality staff was flat from 2006 to 2009, while the plant's quality-control spending during that time rose 17%.

The consumer business's overall spending on property, plant and equipment fell to $439 million last year from $499 million the year before.

Last year, J&J's consumer business, which includes the McNeil unit and other companies, had $15.8 billion in sales and $2.48 billion in profit.

The recall announced on April 30 involved more than 136 million bottles of Benadryl, Motrin, Tylenol and Zyrtec for children and infants, according to the FDA. Some of the pain and cold medicines might have had more active ingredient than approved, the company said, while others might have had metallic particles in them. FDA investigators found bacteria in some raw materials.

The company shut down the Fort Washington plant until it could fix manufacturing problems there.

Dr. Sharfstein criticized the unit for waiting a year to notify the FDA of musty odor problems with adult Tylenol pills made at a Puerto Rico plant, later traced to a pesticide used on the wooden pallets storing empty bottles and prompting a recall.

In February, the FDA sought out J&J officials for a meeting "so they would be on notice" about the agency's concerns about the McNeil unit's commitment to quality, Dr. Sharfstein said.

J&J's McNeil unit had learned in November 2008 that certain Motrin pills wouldn't dissolve appropriately due to a formulation problem, reducing their effectiveness. The company put a hold on lots at its distribution center, and hired a contractor to sample some of the eight-count packages on store shelves to see if a recall was necessary, according to an FDA PowerPoint document about the company's handling of the issue that was released at Thursday's hearing.

But the contractor appeared to do more than buy a few samples. The contractor instructed workers to visit all of the stores "on your schedule to locate and purchase" all of the Motrin eight-count packages, according to a memo shown at the House committee hearing. The memo said "you should simply 'act' like a regular customer in making these purchases," and advised the workers not to talk about a recall.

Ms. Goggins said she didn't know what instructions had been given to the contractor. She said the company had told the FDA it was hiring the contractor for statistical sampling. It's unclear what prompted the contractor to direct its workers to buy up all packages on store shelves.

In the case of the recalled Tylenol and other children's medicines, the FDA said the risk of harm was remote, but urged parents to throw them away or return them. The agency is investigating reports of serious side effects, but has not found any links so far, Dr. Sharfstein said.

The House Oversight Committee had asked J&J's chief executive, Mr. Weldon, to testify. He couldn't attend due to a health issue. Ms. Goggins, a top lieutenant and potential successor, spoke in his stead.

Ms. Goggins is a longtime J&J employee. She joined the company in 1981 and became worldwide chairwoman of its consumer group in 2001.

She described a wide range of actions the company has taken to address the manufacturing problems. She outlined widespread personnel changes at the McNeil unit and the over-the-counter medicines group, including replacing manufacturing and quality officials in both. The company also hired an outside consultant expert in manufacturing quality practices.

Alicia Mundy contributed to this article.

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FDA Weighing Penalties Against J&J --- Unit's Manufacturing Deficiencies Could Draw Criminal Action From Agency

By Jennifer Corbett Dooren and Jonathan D. Rockoff
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WASHINGTON -- The Food and Drug Administration said it is weighing whether to seek criminal penalties against the Johnson &Johnson unit that made children's Tylenol and other over-the-counter kids' medicines recalled last month.

Joshua Sharfstein, the FDA's principal deputy commissioner, told lawmakers at a hearing Thursday that J&J's McNeil Consumer Healthcare unit had a "pattern of noncompliance" with good manufacturing practices. He said regulators were considering such punitive measures as "seizure, injunction or criminal penalties." The FDA's criminal investigations office is looking into the matter, an aide said.

The hearing veered into a new controversy when lawmakers pressed J&J to explain why, after the company discovered some defective Motrin products, a contractor sent out workers to buy all the available product off retail shelves. Under pressure from the FDA, the company issued a recall of 88,104 packages of Motrin in July 2009. "I don't think we fully understood what was going on," Dr. Sharfstein said.

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The hearing probed into the problems at J&J's McNeil unit, which was responsible for managing the plant at Fort Washington, Pa., where the recalled children's medicines were manufactured. The New Brunswick, N.J., health-care giant generally leaves much discretion to its 250 far-flung units.

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Ms. Goggins told the committee that the company "will expend whatever resources are necessary to ensure that this facility provides once again high quality medicines."

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Alicia Mundy contributed to this article.

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Health
J&J Lapses Are Cited In Drugs for Children

By Jonathan D. Rockoff
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English

Johnson & Johnson, under fire for recent recalls of over-the-counter medicines, had a number of serious quality control problems in manufacturing children's drugs, according to a Wall Street Journal review of company and regulator documents.

At the Fort Washington, Pa., plant where J&J's McNeil Consumer Healthcare unit manufactured bottles of Tylenol, Benadryl, Motrin and Zyrtec, officials didn't take basic steps required by regulators to assure its children's medicines met government-approved specifications for purity, potency and quality, according to manufacturing experts consulted by the Journal about the contents of the documents.

A Food and Drug Administration inspection report, dated April 30, cites incidents of mishandling of materials, lax documentation and inadequate investigation of consumer complaints.

A company document dated that same day traced metal flakes found in infants' Tylenol to the company's machinery. The company shut down the Fort Washington plant until it can fix the problems.

The FDA will review the company's plans to fix the problems before the plant reopens, said Elaine Gansz Bobo, an agency spokeswoman. A reopening could be weeks or months away, she said.

"There are systemic quality problems there that need to be addressed," Ms. Bobo said, adding that the FDA is evaluating the plant's suppliers and investigating other McNeil plants.

J&J said on its website Tuesday that its McNeil unit was taking steps to "bring its operation back to a level of quality that Johnson & Johnson demands of its companies." Before the recall, it hired an outside expert to help it fix problems at the Fort Washington plant. The unit is also improving processes and training employees, and plans to conduct a full assessment of the plant. The company said it wouldn't comment for this story beyond what it posted.

The extent of the manufacturing problems at the plant—and the adequacy of the FDA's oversight—will be the subject of a hearing scheduled for Thursday by the House Committee on Oversight and Government Reform. Colleen Goggins, who heads J&J's consumer business, is expected to testify.

To assure the quality of drugs, federal law requires companies to follow general ground rules called "current good manufacturing practices." Drug makers put in place detailed procedures designed to meet these standards based on FDA regulations and guidance, and accepted industry practices.

FDA investigators frequently find violations of good manufacturing practices during inspections, although usually not the range of problems found at the Fort Washington plant, according to drug-making experts. Shutdowns of manufacturing plants are rare but not unheard of. Genzyme Corp. last year temporarily shut down its main manufacturing facility in Allston, Mass., after the company said it detected a virus in one of the plant's bioreactors.

The J&J recall that was announced April 30 affected certain liquid pain and cold medicines for infants and children. J&J's McNeil Healthcare unit said some of the recalled products might contain more active ingredient than approved, while others might have metallic particles. FDA investigators also found bacteria in raw materials at the plant.

The FDA is continuing its investigation of whether serious side effects reported to the agency were caused by the recalled medicines. The agency has said the chance of harm to consumers from the recalled medicines is remote.

The shutdown is costly to the company, and J&J officials have said it's not unreasonable that it could cost north of $200 milion.

J&J's McNeil Consumer Healthcare unit is part of the company's over-the-counter medicines and nutritionals franchise, which is the largest segment of J&J's consumer business. Last year, that consumer business had $15.8 billion of sales, with $5.6 billion coming from sales of the over-the-counter franchise, according to the company's annual report.

The recall was the J&J unit's fifth since last September.

J&J has a reputation for corporate responsibility, which it cemented in 1982 when it quickly recalled all Tylenol products amid a poisoning scare and didn't resume sales until it could package them in new, tamper-resistant bottles.

The report from the FDA's routine visit to the Fort Washington plant last month—which concluded April 30, the day of the recall—cited 20 violations of good manufacturing practices.

For example, the FDA found that the plant handled raw materials improperly. Good manufacturing practices require plants to test raw materials before using them. The plant sampled 14 out of a total of 350 bags of raw material, according to an unredacted copy of the FDA inspection report reviewed by the Journal. The report said the plant should have sampled at least 19 bags.

The standards also require plants to keep tested ingredients separate from those yet to be examined. Some manufacturers store the raw materials in different rooms; others keep the ingredients in different parts of the same room separated by a line on the floor, said Stephen Hoag, who teaches pharmaceutical manufacturing at the University of Maryland's pharmacy school.

FDA investigators found that the Fort Washington plant kept tested and untested raw materials together.

Plant workers also used the wrong drum of acetaminophen when making a batch of infants' Tylenol drops, according to the FDA inspection report. "A mix-up occurred and a partial drum weighing less than the required amount was used instead of the correct drum," investigators wrote.

In addition, the FDA cited the Fort Washington plant for failing to take corrective action after receiving 46 consumer complaints regarding "foreign materials, black or dark specks" from June 2009 to April 2010.

Good manufacturing practices require companies to promptly look into complaints after receiving a significant number and fix any problems, said David Lebo, a former production official at J&J who now teaches pharmaceutical manufacturing at Temple University.

In one investigation by McNeil, metal flakes found in five batches of Tylenol infants' drops were tied to pistons that were used during processing, according to a company document dated April 30. It isn't known whether the company's investigation was related to consumer complaints, or whether the company corrected the flaking problem.

Pistons typically pump liquid medicines through manufacturing plants, drug-making experts say. It isn't uncommon for metals to flake off the pistons, the experts say, and some manufacturers install magnets to filter out the shavings.

The FDA also cited the Fort Washington plant for releasing batches of cherry-flavored infants' Tylenol after testing showed that there were related batches the agency termed "super potent." The company failed to conduct a "thorough investigation or any additional analytical testing," the inspection report said.

According to notes a company employee took during the FDA's visit to the plant, which were reviewed by the Journal, investigators asked why the company released seven batches after three related batches failed testing.

A company employee said that the batches were released because they passed tests and were distinct from the other batches, the notes say. (The notes don't specify if the batches were the same ones for which the agency cited McNeil, but the unredacted FDA inspection report refers to the same number of released batches.)

A spokesman for Rep. Edolphus Towns (D - N.Y.), chairman of the Oversight Committee, said the plant's violations were "deeply troubling" and indicated a systemic problem. The committee is going to look into whether the problems at the plant extended to other plants run by J&J's McNeil unit.

Write to Jonathan D. Rockoff at jonathan.rockoff@wsj.com

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J&J Lapses Are Cited In Drugs For Kids

By Jonathan D. Rockoff
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In addition, the FDA cited the Fort Washington plant for failing to take corrective action after receiving 46 consumer complaints regarding "foreign materials, black or dark specks" from June 2009 to April 2010.

Good manufacturing practices require companies to promptly look into complaints after receiving a significant number and fix any problems, said David Lebo, a former production official at J&J who now teaches pharmaceutical manufacturing at Temple University.

In one investigation by McNeil, metal flakes found in five batches of Tylenol infants' drops were tied to pistons that were used during processing, according to a company document dated April 30. It isn't known whether the company's investigation was related to consumer complaints, or whether the company corrected the flaking problem

Pistons typically pump liquid medicines through manufacturing plants, drug-making experts say. It isn't uncommon for metals to flake off the pistons, the experts say, and some manufacturers install magnets to filter out the shavings.

The FDA also cited the Fort Washington plant for releasing batches of cherry-flavored infants' Tylenol after testing showed that there were related batches the agency termed "super potent." The company failed to conduct a "thorough investigation or any additional analytical testing," the inspection report said.

According to notes a company employee took during the FDA's visit to the plant, which were reviewed by the Journal, investigators asked why the company released seven batches after three related batches failed testing.

A company employee said that the batches were released because they passed tests and were distinct from the other batches, the notes say. (The notes don't specify if the batches were the same ones for which the agency cited McNeil, but the unredacted FDA inspection report refers to the same number of released batches.)

Document J000000020100527e65r0003y

THE WALL STREET JOURNAL.

Health
J&J Unit Warned of Problems in Sterilization Devices

By Jennifer Corbett Dooren
469 words
26 May 2010
The Wall Street Journal Online
WSJO
English

WASHINGTON—The Food and Drug Administration warned a Johnson & Johnson unit about failures to properly handle and correct problems reported with certain sterilization devices.

The March 12 warning letter was released Tuesday and relates to devices made by Advanced Sterilization Products, an Irvine, Calif., company that's part of Ethicon Inc., which is a unit of J&J. The letter stemmed from an FDA plant inspection that was conducted from June through September 2009.

The letter discussed several consumer complaints relating to the company's Sterrad and other devices, some of which included reports that the sterilizers emitted an oil mist. The problems were first reported in 2007.

The FDA said actions taken by the company were "inadequate" to correct and prevent recurrence of the events. Other reported problems included small cracks in devices that allowed customers to come in contact with hydrogen peroxide used in one type of device.

The FDA said Advanced Sterilization Products attempted to fix the reported problems by recalling and taking what's known in the industry as a field action to fix the problems. However, the FDA said an assessment wasn't conducted to see if the corrections were effective.

In a statement, ASP said it "has aggressively implemented a number of specific corrective actions to address deficiencies in some of our internal processes, and we continue to work with the agency to address and quickly resolve any outstanding issues." The company noted the letter didn't cite any product "performance, efficacy or safety issues."

In the letter, the FDA requested that a third party audit ASP's manufacturing plant to look at quality-assurance systems and report to the agency by Aug. 1, 2010. Follow-up reports are being requested each year through 2012.

The warning letter adds to problems faced by J&J, which is coping with a wide-ranging recall of liquid Tylenol and other children's products after manufacturing problems at its Fort Washington, Pa., plant. A top company executive is scheduled to testify Thursday before the House Committee on Oversight and Government Reform as part the panel's investigation into the recall, along with a top FDA official.

On Tuesday, the J&J unit that makes Tylenol outlined plans to address quality issues that stemmed from the recall. McNeil Consumer Healthcare said it is improving processes and employee training in the company's manufacturing and quality operations. The company said it has made "significant organizational changes" and, even before the most recent recall was announced, retained a third-party expert to assist in identifying corrective actions that it needs to take.

John Kell contributed to this article.

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THE WALL STREET JOURNAL.
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Corporate News: J&J Notes Troubles In Medicine Recall

By Jonathan D. Rockoff
489 words
19 May 2010
The Wall Street Journal
J
B3
English

New details about problems with Johnson &Johnson's production and recall of certain children's medicines are emerging as the company faces growing scrutiny in Washington, D.C.

Some samples of recalled infants' Tylenol were tested to contain as much as 24% more active ingredient than shown on the label, according to a letter that J&J's McNeil Consumer Healthcare sent to doctors and poison-control officials and reviewed by The Wall Street Journal.

The company said the suspect medicines hadn't reached the marketplace, and its testing of other batches that had been released to the market didn't find any problems. "But we cannot confirm that all the individual bottles were within specification or that 24% would have been the maximum," according to the letter, which didn't indicate when or how the testing was done.

The letter was dated May 1, the day after J&J recalled certain children's and infant's Benadryl, Motrin, Tylenol and Zyrtec cold and pain medicines after discovering unspecified manufacturing problems. The company said at the time that the medicines could contain higher concentrations of medicine than they should, among other potential issues, but didn't specify an amount.

The J&J unit neglected to include one version of Children's Zyrtec in the recall for five days, according to an email sent to its over-the-counter sales force. It told its sales force on May 5 that the 1 milligram grape version of children's Zyrtec "was inadvertently not included" in the recall and requested sales staff alert retailers to the need to take the bottles off store shelves and return them with the other recalled products.

A spokeswoman said the company's "health assessment" indicates the chance that the recalled medicines will cause harm is remote.

She also said that the company promptly added the grape-flavored Zyrtec to its recall list "after discovering it was inadvertently omitted from the original list," and has not added any other products since then.

The FDA is investigating whether similar problems exist at two other manufacturing plants run by J&J's McNeil unit. The House Committee on Oversight and Government Reform is also investigating.

Excessive use of acetaminophen can cause liver damage. But Ian Paul, an associate pediatrics professor at Pennsylvania State University College of Medicine, said a day or two of taking a 24% higher concentration of acetaminophen "wouldn't cause a problem."

The FDA must approve a dosage based on clinical testing that shows it is safe and effective. Drug makers determine how much active and other ingredients a medicine contains. The FDA requires the companies periodically test the drugs to make sure they meet the specified levels, and agency inspections look to see that the levels are met.

Document J000000020100519e65j0002u

Some Infant Tylenol Recalled by J&J Had Too Much of Active Ingredient

WSJ Blogs, 06:57, 19 May 2010, 219 words, By Katherine Hobson, (English)

We now know a bit more about the problems with children's medications recalled by Johnson &Johnson: some samples of recalled infant Tylenol contained as much as 24% more of the active ingredient, acetaminophen, as they were ...

Document WCWSJB0020100519e65j002ux

THE WALL STREET JOURNAL.

Health
J&J Details Medicine-Recall Troubles

By Jonathan D. Rockoff
700 words
18 May 2010
17:51
The Wall Street Journal Online
WSJO
English

New details about problems with Johnson & Johnson's production and recall of certain children's medicines are emerging as the company faces growing scrutiny in Washington, D.C.

Some samples of recalled infants' Tylenol were tested to contain as much as 24% more active ingredient than shown on the label, according to a letter that J&J's McNeil Consumer Healthcare unit sent to doctors and poison-control officials that was reviewed by The Wall Street Journal.

The company said the suspect medicines hadn't reached the marketplace, and its testing of other batches that had been released to the market didn't find any problems. "But we cannot confirm that all the individual bottles were within specification or that 24% would have been the maximum," according to the letter, which didn't indicate when or how the testing was done.

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The J&J unit inadvertently neglected to include one version of Children's Zyrtec in the recall for five days, according to an email sent to the company's over-the-counter sales force. It told its sales force on May 5 that the 1 milligram grape version of children's Zyrtec "was inadvertently not included" in the recall.

The email attributed the mistake to a clerical error, and told sales staff to alert customers immediately to the need to take the bottles off store shelves and return them with the other recalled products.

A spokeswoman for J&J's McNeil unit said the company sent the letter about infant Tylenol to health-care professionals in connection with the recall, and its "health assessment" indicates the chance that the recalled medicines will cause harm is remote.

She also said that the company promptly added the grape-flavored Zyrtec to its recall list "after discovering it was inadvertently omitted from the original list," and has not added any other products since then.

In conjunction with the April 30 recall, J&J's McNeil unit shut down the Fort Washington, Penn., plant that made the recalled products until it could fix the manufacturing issues and assure quality production. The company said that in addition to overly high concentrations of ingredients, the recalled liquid products may contain inappropriate levels of inactive ingredients or tiny metallic particles left as a residue from the manufacturing process.

A Food and Drug Administration inspection of the plant had also found bacteria in raw materials set aside for use to make several lots of Tylenol.

The FDA is investigating whether similar problems exist at two other manufacturing plants run by J&J's McNeil unit. The House Committee on Oversight and Government Reform is also investigating. "What we have uncovered so far is very troubling," said Rep. Edolphus Towns (D., N.Y.), the committee's chairman. The committee will hold a hearing May 27.

Excessive use of acetaminophen can cause liver damage. But Ian Paul, an associate pediatrics professor at Pennsylvania State University College of Medicine who works with the American Academy of Pediatrics, said children would have to take the higher concentrations over a long period of time in order to be harmed.

A day or two of taking Tylenol with 24% higher concentration of acetaminophen "wouldn't cause a problem," said Dr. Paul, who researches the safety and efficacy of over-the-counter children's medicines.

The FDA must approve a dosage based on clinical testing that shows it is safe and effective. Drug makers determine how much active and other ingredients a medicine contains. The FDA requires the companies periodically test the drugs to make sure they meet the specified levels, and agency inspections look to see that the company is meeting the levels.

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THE WALL STREET JOURNAL.

Health

FDA Widens Probe of J&J's McNeil Unit; Inquiry Follows Recent Recall of Over 40 Children's Medicines Because of Manufacturing Problems

By Jonathan D. Rockoff
585 words
18 May 2010
00:33
The Wall Street Journal Online
WSJO
English

The Food and Drug Administration has widened its investigation into the recent recall of certain Johnson & Johnson children's medicines and is now inquiring into manufacturing across the company's consumer health-care unit.

J&J's McNeil Consumer Healthcare makes a range of products for adults and kids, notably Benadryl, St. Joseph aspirin, Motrin, Tylenol and Zyrtec.

On April 30, the company recalled a number of over-the-counter medicines for children and infants after receiving complaints from consumers and discovering manufacturing problems. The company also closed the plant in Fort Washington, Pa., that made the recalled products until it fixes the issues and can assure quality production.

The recall of the liquid children's medicines was the third by the J&J unit since last September. An FDA spokeswoman said there had been no specific complaints about products from other McNeil facilities. But given the history of recent recalls, the FDA wanted to make sure there weren't any similar manufacturing problems and to identify any steps the agency must take to prevent the problems from recurring.

Besides Fort Washington, J&J's McNeil unit has plants in Lancaster, Pa., and Las Piedras, Puerto Rico.

"We're doing our due diligence," said FDA spokeswoman Elaine Gansz Bobo.

The J&J unit "is conducting a comprehensive quality assessment across its manufacturing operations and continues to cooperate with the FDA," a company spokeswoman said.

Some parents say the recall has weakened J&J's reputation for quality. The recall has also prompted a congressional investigation of the company's handling of consumer complaints and the adequacy of the FDA's inspections. The House Committee on Oversight and Government Reform has asked J&J Chief Executive William Weldon to testify at a hearing on May 27.

The FDA and J&J have told the committee they will cooperate and are in the process of answering its questions, and the committee expects that Mr. Weldon will attend, said Kurt Bardella, a spokesman for Rep. Darrell Issa (R., Calif.), the panel's ranking Republican.

A J&J spokesman said the company is communicating with the committee and will respond appropriately to the panel's request but declined to say if Mr. Weldon will appear.

The recall last month involved more than 40 different Tylenol, Benadryl, Motrin and Zyrtec products for children and infants. Some of the medicines had higher concentrations of active ingredient than specified, and some products may contain tiny metallic particles left as a residue from the manufacturing process, according to J&J's McNeil unit.

The FDA conducted a routine inspection of the Fort Washington plant last month. Agency inspectors found that the J&J unit received 46 complaints from consumers between June 2009 and April 2010 regarding "foreign materials, black or dark specks" in certain medicines. The FDA also said bacteria contaminated raw materials to be used to make several lots of Tylenol products for children.

FDA has begun to review all complaints it has received to determine whether the recalled products caused any serious side effects. The agency has said the chances that the recalled products could cause harm were remote, but warned parents not to use the products as a precaution.

Write to Jonathan D. Rockoff at jonathan.rockoff@wsj.com

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THE WALL STREET JOURNAL.
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Corporate News: FDA Widens J&J Inquiry

By Jennifer Corbett Dooren
534 words
18 May 2010
The Wall Street Journal
J
B4
English

WASHINGTON -- The Food and Drug Administration has widened its investigation into the recent recall of certain Johnson &Johnson children's medicines and is now inquiring into manufacturing across the company's consumer health-care unit.

J&J's McNeil Consumer Healthcare makes a range of products for adults and kids, notably Benadryl, St. Joseph aspirin, Motrin, Tylenol and Zyrtec.

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A J&J spokesman said it will respond appropriately to the panel's request but declined to say if Mr. Weldon will appear.

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The FDA conducted a routine inspection of the Fort Washington plant last month. Agency inspectors found that the J&J unit received 46 complaints from consumers between June 2009 and April 2010 regarding "foreign materials, black or dark specks" in certain medicines. The agency also said bacteria contaminated raw materials to be used to make several lots of Tylenol products for children.

The FDA has begun to review all complaints it has received to determine whether the recalled products caused any serious side effects.

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THE WALL STREET JOURNAL.

Health
House Committee Seeks CEO Testimony at Hearing on J&J Recall

By Jonathan D. Rockoff
278 words
14 May 2010
16:57
The Wall Street Journal Online
WSJO
English

A House committee has asked Johnson & Johnson Chief Executive William Weldon to testify at a coming hearing on the company's recent recall of over-the-counter children's medicines.

The House Committee on Oversight and Government Reform plans to hold a hearing May 27 on the recall of certain Tylenol, Motrin, Benadryl and Zyrtec bottles for children and infants. The committee is investigating the company's response to consumer complaints of foreign matter in certain products and the adequacy of regulators' inspections.

The Oversight Committee's invitation said the hearing "will examine the circumstances surrounding your recall of over 40 variations of infant and children's medicines."

Mr. Weldon posted a letter to customers on J&J's blog May 7 expressing "great concern" about the recall by the company's McNeil Consumer Healthcare unit. "You can be confident that we will make whatever changes are needed at McNeil to fully restore the quality of manufacturing," he wrote.

A J&J spokesman said the company is "communicating with the committee and will respond appropriately" to its request.

The Food and Drug Administration says the chance of harm from the recalled products is remote but is warning parents not to use them. J&J has suspended all manufacturing at the Fort Washington, Pa., plant that made the products. FDA inspectors on a routine inspection of the plant found bacteria in raw materials to be used to make several lots of Tylenol products for children and infants.

Write to Jonathan D. Rockoff at jonathan.rockoff@wsj.com

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THE WALL STREET JOURNAL.

Health
House to Examine Medicines Recall

By Jonathan D. Rockoff And Jennifer Corbett Dooren
447 words
5 May 2010
17:29
The Wall Street Journal Online
WSJO
English

The House Committee on Oversight and Government Reform is opening an investigation into conflicting accounts of what prompted a Johnson & Johnson unit's recent recall of children's over-the-counter medicines, as well as how the company handled consumer complaints about foreign matter in the bottles.

The committee will seek a chronology of events leading up to the recent recall, a spokesman for Rep. Darrell Issa, the ranking Republican on the committee, said Wednesday. It will also seek copies of investigation reports by the Food and Drug Administration and J&J's McNeil Consumer Healthcare unit, the spokesman said.

The committee will examine the "adequacy of FDA's inspection procedures," according to a statement issued by Rep. Edolphus Towns, the Democratic chairman, and Rep. Issa. It plans to ask the FDA for its procedures governing routine inspections of over-the-counter drug makers and recalls, said Kurt Bardella, Rep. Issa's spokesman.

J&J declined to comment. The FDA said in a statement it recognizes "the committee's interest in this case" and looks forward to cooperating" with the investigation.

The recall over the weekend involved more than 40 different Tylenol, Benadryl, Motrin and Zyrtec products for children and infants.

Some of the medicines had higher concentrations of the active ingredient than specified, according to the company, and some products may contain tiny metallic particles left as a residue from the manufacturing process.

It was the latest in a string of recalls at the McNeil unit.

J&J's McNeil made the liquids at a Fort Washington, Pa., plant that the company has temporarily shut down until it fixes the manufacturing problems and can assure quality production.

The company said it launched the recall after consumer complaints spurred an internal investigation that discovered manufacturing problems. An FDA spokeswoman gave a different account, saying a routine inspection last month found problems at the plant and the company decided to issue a recall after the regulators reported their findings.

FDA inspectors said bacteria contaminated raw materials to be used to make several lots of Tylenol products for children. FDA also said that the J&J unit received 46 complaints from consumers between June 2009 and April 2010 regarding "foreign materials, black or dark specks" in the medicines.

The committee helped lead House investigations into gas-pedal problems on Toyota Motor Corp. vehicles as well as the National Highway Traffic Safety Administration's probe of the safety troubles.

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THE WALL STREET JOURNAL.

Health
FDA Ties Tylenol Recall to Contamination

By Jonathan D. Rockoff And Jennifer Corbett Dooren
512 words
5 May 2010
The Wall Street Journal Online
WSJO
English

Raw materials that were to be used to make several lots of the Tylenol products for children and infants that were recalled over the weekend were contaminated, the Food and Drug Administration said Tuesday.

Johnson & Johnson recalled about 1,500 lots of bottled products, including pediatric versions of Tylenol, Motrin, Zyrtec and Benadryl. The company's McNeil Consumer Healthcare unit said it was withdrawing the over-the-counter products, starting late Friday, because of manufacturing problems at its Fort Washington, Pa., plant.

The FDA inspected the manufacturing plant during a routine visit between April 19 and April 30.

Agency inspectors found that raw materials set aside for use to make several lots were contaminated with gram-negative bacteria, according to the inspection report. Such organisms are so named because they don't pick up the purplish dye used in the test to distinguish them from gram-positive bacteria. Both kinds of bacteria can cause infections.

FDA officials said the company may have used the contaminated inactive ingredients in manufacturing, but the company's testing of finished products didn't turn up contamination.

"The findings are serious, but we cannot say yet whether further action by the FDA is warranted," Deborah Autor, the FDA's director of compliance, said in a conference call with reporters.

Some of the liquid products may contain a higher concentration of their active ingredient than they should, while others may contain inappropriate levels of inactive ingredients or tiny metallic particles left as a residue from the manufacturing process, according to the company. The FDA report cited 46 consumer complaints regarding "foreign materials, black or dark specks" that were reported to the company between June 2009 and April 2010.

A spokeswoman for J&J's McNeil unit said the company has halted production at one plant. Other plants also make the medicines, and there are lots from those plants that weren't recalled and remain on store shelves. The spokeswoman declined to comment on the cost of the recall to the company or the source of the raw materials.

In a separate statement, she said that the J&J unit's own reviews had turned up some of the quality issues that the FDA observed and that McNeil won't restart operations at the Fort Washington plant until it fixes the problems and can be assured of product quality.

"We have no higher concern than providing parents with the highest quality products for their children," the company's statement said.

FDA Commissioner Margaret Hamburg said the potential for harm is remote. Still, she urged parents to avoid giving the medicines for precautionary reasons. "There are many alternative versions of these medicines available in generic form," she said.

To assist parents, the company has set up a hot line at 888-222-6036 and a website at www.mcneilproductrecall.com.

Write to Jonathan D. Rockoff at jonathan.rockoff@wsj.com and Jennifer Corbett Dooren at jennifer.corbett-dooren@dowjones.com

Document WSJO000020100504e655009fe

FDA Commissioner: Use Generic Alternatives to Recalled J&J Meds

WSJ Blogs, 06:21, 5 May 2010, 255 words, By Katherine Hobson, (English)

The head of the FDA yesterday urged parents to use generic alternatives to the Johnson &Johnson children's medicines being recalled for manufacturing problems, the WSJ reports.

Document WCWSJB0020100505e655002gx

THE WALL STREET JOURNAL.
U.S. EDITION

Corporate News: FDA Ties Recall of Tylenol To Contaminated Materials

By Jonathan D. Rockoff and Jennifer Corbett Dooren
519 words
5 May 2010
The Wall Street Journal
J
B3
English

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A spokeswoman for J&J's McNeil unit said the company has halted production at one plant.

Other plants also make the medicines, and there are lots from those plants that weren't recalled and remain in stores.

The spokeswoman declined to comment on the cost of the recall to the company or the source of the raw materials. But J&J Vice President of Investor Relations Louise Mehrotra said sales and earnings would be hurt because it has stopped shipment of the products.

The company spokeswoman said that the J&J unit's own reviews had turned up some of the quality issues that the FDA has observed and that McNeil won't restart operations at the Fort Washington plant until it fixes the problems and can be assured of product quality.

"We have no higher concern than providing parents with the highest quality products for their children," the company's statement said.

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Document J000000020100505e6550004g

THE WALL STREET JOURNAL.

Health

Consumers Helped Spur J&J Recall of Children's Medicine

By Ron Winslow And Avery Johnson
866 words
3 May 2010
The Wall Street Journal Online
WSJO
English

Consumer complaints about certain over-the-counter children's medications spurred an investigation that led to a recall of more than 40 different products because of manufacturing problems, according to officials at a unit of Johnson & Johnson.

The recall, announced over the weekend by the company and the U.S. Food and Drug Administration, prompted drug stores and other merchants to pull the medicines off their shelves and caused concern among parents who took steps to avoid giving the products—largely pain and allergy remedies—to their children.

A spokesman for J&J's McNeil Consumer Healthcare unit wasn't more specific about what issues consumers raised that led to the internal probe. "We always receive some consumer inquiries about our products and those inquiries led to the investigation that ultimately led to this recall," the spokesman, Marc Boston, said in an email.

The company said there haven't been any serious side effects reported, and the company and the FDA said the potential for harm is remote. Still, the company and the agency said the products shouldn't be given to children for precautionary reasons.

The recall involved at least 1,000 lots of products, including various pediatric versions of Tylenol, Motrin, Zyrtec and Benadryl. Some of the liquid formulations may contain a higher concentration of their active ingredient than they should while others may contain inactive ingredients at inappropriate levels, or tiny metallic particles that are a residue of the manufacturing process, the company said.

The medicines were sold in the U.S. and Canada as well as in countries as far away as Fiji and Kuwait. All were made at a factory in Fort Washington, Pa., the FDA and the company said. Neither the company nor the FDA could say how many bottles of medicine were involved.

At English Drug, an independent pharmacy in Bethel, Conn., staffers removed several products from the store's shelves Sunday morning after learning about the recall on the Internet. "These are very popular products, but we pulled them" out of safety concerns for consumers, said Denise McMahon, a pharmacist at the store.

In New York City, Natalia Carin said she gave recently gave her 2-year-old son Cole children's Zyrtec and Motrin. He appears to be fine, she said. But, she added, "I'd like some information about what kind of substance this was and how dangerous it might be and what we can expect."

Kenneth Polin, a pediatrician at Town and Country Pediatrics, with offices in Chicago and its suburbs, had heard from few worried parents Sunday, but says his advice is to turn to generic versions of the medicines. He recommended that before consumers buy a generic, they make sure to ask a pharmacist whether or not J&J manufactured it.

Overall, he said he is encouraged that no children so far are reported to have taken ill. "If the child looks good, they are good," he said.

But for Julia Reid, 31 years old, of New York City, the recall casts a pall over all of the products. Last week, she bought infant Tylenol to give her younger daughter, Maggie, when she gets her first vaccines at her 2-month-old checkup next week. "I'm not going to use anything until the problem is resolved," she says. When Maggie gets her shots, "I'll just have to deal with a very upset baby."

The recall is another dent in J&J's reputation as a model of corporate responsiveness. That harks back to the deadly Tylenol poisonings in the early 1980s, when the company reacted swiftly to recall the product and inform the public.

But more recently U.S. regulators have criticized J&J's handling of product-quality issues, because of a widening series of recalls of over-the-counter medicines that accelerated late last year. In November, the company recalled a limited number of certain bottles of Tylenol arthritis-pain caplets after identifying an uncharacteristic smell or taste associated with the products. The company said a small number of consumers had reported nausea and related symptoms.

But in December, J&J had to expand the recall to include all lots of the product. A month later, J&J widened the recall again to include other brands such as Motrin and Benadryl. That resulted in the FDA sending J&J a warning letter saying the company had violated good-manufacturing rules at its Las Piedras, Puerto Rico, plant, which caused the product problems.

All of the recalls may be causing some confusion in the marketplace. Ms. McMahon, the pharmacist at English Drug, said she had several customers come in Sunday looking for the adult Tylenol arthritis-pain pills who told her they had been removed from store shelves elsewhere. Those products aren't part of the current recall. English Drug sold out of that product.

Jonathan D. Rockoff and Peter Loftus contributed to this article.

Write to Ron Winslow at ron.winslow@wsj.com and Avery Johnson at avery.johnson@WSJ.com

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THE WALL STREET JOURNAL.
EUROPE EDITION

J&J recalls children's medicines --- After consumers complain, an inquiry into manufacturing spurs the product withdrawals

By Ron Winslow and Avery Johnson
751 words
3 May 2010
The Wall Street Journal Europe
WSJE
18
English

Drug stores and other merchants scrambled to pull certain children's over-the-counter medications off U.S. shelves after a Johnson &Johnson unit decided to recall the products over manufacturing lapses.

Parents similarly took steps to avoid giving the products -- largely pain and allergy medicines -- to their children, although no cases of harm related to the products have been reported.

J&J's McNeil Consumer Healthcare unit is withdrawing various pediatric versions of Tylenol, Motrin and Zyrtec among other products for infants and children, the U.S. Food and Drug Administration said Saturday. Some of the liquid formulations may contain a higher concentration of their active ingredient while others may contain inactive ingredients at inappropriate levels, or tiny metallic particles that are a residue of the manufacturing process, the company said.

A spokesman for J&J said consumer complaints sparked an inquiry into manufacturing processes, and the inquiry led to the recall. He wasn't more specific. The company said there haven't been any serious side effects reported, and both the company and the FDA said the potential for harm is remote. Still, the company and the agency said the products shouldn't be given to children for precautionary reasons.

All told, at least 1,000 lots of more than 40 different products are involved. They were sold in the U.S. and Canada as well as countries as far away as Fiji and Kuwait. All were made at a factory in Fort Washington, Pa., the FDA and the company said. Neither the company nor the FDA could say how many bottles of medicine were involved.

At English Drug, an independent pharmacy in Bethel, Conn., staffers removed several products from shelves Sunday morning after learning about the recall on the Internet. "These are very popular products, but we pulled them" out of safety concerns for consumers, said Denise McMahon, a pharmacist at the store.

In New York City, Natalia Carin said she recently gave her two-year-old son Cole children's Zyrtec and Motrin. He appears to be fine, she said. But, she added, "I'd like some information about what kind of substance this was and how dangerous it might be and what we can expect. It's just a worry about the unknown and what sort of long-term effects this could have."

Kenneth Polin, a pediatrician at Town &Country Pediatrics in Chicago, said he had only gotten one phone call from a worried parent, but added that his advice is for parents to turn to generic versions of the medicines. He suggested consumers make sure to ask a pharmacist whether or not Johnson &Johnson manufactured a generic before buying it.

Overall, he said he is encouraged that no children so far are reported to have taken ill. "If the child looks good, they are good," he says.

The recall is another dent in J&J's reputation as a model of corporate responsiveness. That harks back to the deadly Tylenol poisonings in the early 1980s, when the company reacted swiftly to recall the product and inform the public.

But more recently U.S. regulators have criticized J&J's handling of product-quality issues, because of a widening series of recalls of over-the-counter medicines that accelerated late last year. In November, the company recalled a limited number of certain bottles of Tylenol arthritis-pain caplets after identifying an uncharacteristic smell or

taste associated with the products, which the company said led to a small number of consumers reporting nausea and related symptoms.

At the time, the company said the recall affected only certain lots of the arthritis-pain caplets, but in December, J&J expanded the recall to include all lots of the Tylenol arthritis-pain product. A month later, J&J widened the recall again to include other brands such as Motrin and Benadryl.

This time, the FDA sent J&J a warning letter saying the company had violated good-manufacturing rules at its Las Piedras, Puerto Rico, plant, which caused the product problems. The FDA said the contamination was first noted in 2008 and recurred in 2009, and accused J&J of not conducting a timely, comprehensive investigation.

Jonathan D. Rockoff and Peter Loftus contributed to this article.

Document WSJE000020100503e65300018

Recall Roundup: J&J Pulling Children's Tylenol, Motrin, Other Meds

WSJ Blogs, 06:59, 3 May 2010, 257 words, By Katherine Hobson, (English)

Johnson &Johnson is on the recall hot seat - again. More than 40 different products, mostly children's pain and allergy remedies, are being yanked from shelves after J&J and the FDA announced late Friday that some may contain ...

Document WCWSJB0020100503e653001xi

THE WALL STREET JOURNAL.

U.S.
Johnson & Johnson Recalls Children's Medicines

By Jonathan D. Rockoff
838 words
2 May 2010
12:56
The Wall Street Journal Online
WSJO
English

A Johnson & Johnson unit is recalling more than 1,000 lots of certain over-the-counter infant and children's products, including various pediatric formulations of bottled Tylenol, Motrin and Zyrtec, the Food and Drug Administration said Saturday.

J&J's McNeil Consumer Healthcare unit is withdrawing the liquid products due to manufacturing problems, according to the FDA. Some of the medicines may contain a higher concentration of their active ingredient than they should, while others may contain inactive ingredients at levels the company deems inappropriate, or tiny metallic particles, a McNeil spokeswoman said.

The company said there haven't been any serious side effects reported, and both the company and the FDA said the potential for harm is remote. Still, the company and the agency said the products shouldn't be given to children for precautionary reasons.

The recalled lots cover certain kinds of Tylenol infants' drops, Children's Tylenol Suspension, Children's Tylenol Plus Suspension, Concentrated Motrin Infants' Drops, Children's Motrin Suspension, Children's Zyrtec Sugar-Free Dye-Free and Children's Benadryl Allergy. A total of 53 different products are involved.

Neither J&J nor the FDA could say how many individual bottles are subject to the recall. The children and infant's medicines were sold in the U.S. and Canada as well as countries as far away as Fiji and Kuwait. All were made at a factory in Fort Washington, Pa., the FDA and the company said.

The FDA has launched an investigation. "We want to be certain that consumers discontinue using these products and that they know what to do if they have concerns about a specific product," FDA Commissioner Margaret Hamburg said in a statement. "While the potential for serious health problems is remote, Americans deserve medications that are safe, effective and of the highest quality."

For its part, J&J's McNeil Consumer Healthcare unit said it was conducting a "comprehensive quality assessment across its manufacturing operations" and has already identified fixes it will put in place before resuming manufacturing at its problem factory.

The recall was announced Friday night. The FDA and J&J gave differing explanations for the late notice. According to FDA's Ms. Bobo, a routine inspection by the agency turned up the manufacturing problems, and the agency detailed those problems to the company in a letter sent Friday morning. That prompted the company to initiate the withdrawal, Ms. Bobo said. "This all happened quite quickly," she added.

Bonnie Jacobs, a spokeswoman for J&J's McNeil Consumer Healthcare unit, said the company had begun an internal "assessment" before the FDA conducted its investigation and told the agency before receiving its letter that it would issue a recall. Ms. Jacobs said the recall was disclosed late in the day because it took time to work out the details of the announcement with the FDA.

J&J had long been held up as a model of corporate responsiveness, harking back to the deadly Tylenol poisonings in the early 1980s, when the company reacted swiftly to recall the product and inform the public.

But more recently U.S. regulators have criticized J&J's handling of product-quality issues, due to an ever-widening series of recalls of over-the-counter medicines that picked up steam late last year. In November, the company recalled a limited number of certain bottles of Tylenol arthritis-pain caplets after

identifying an uncharacteristic smell or taste associated with the products, which the company said led to a small number of consumers reporting nausea and related symptoms. At the time, the company said the recall affected only certain lots of the arthritis-pain caplets, and no other lots or other Tylenol products were recalled.

But in December, J&J expanded the recall to include all lots of the Tylenol arthritis-pain product. The company identified the cause of the odors as a chemical used to treat wooden pallets that transported and stored the packaging materials.

A month later, in January, J&J widened the recall again to include other brands such as Motrin and Benadryl. This time, the FDA sent J&J a warning letter saying the company had violated good-manufacturing rules at its Las Piedras, Puerto Rico, plant, which caused the product problems. The FDA said the contamination was first noted in 2008 and recurred in 2009, and accused J&J of not conducting a timely, comprehensive investigation.

The recalls hurt sales of J&J's over-the-counter medicines for the first quarter, the company disclosed in April. Sales of OTC and nutritional products--which J&J reports on a combined basis--dropped 25% in the U.S. to $542 million. World-wide sales were off 10.5% at $1.2 billion for the quarter.

Peter Loftus contributed to this article

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THE WALL STREET JOURNAL.

FDA Sees Increasing Number Of Insulin Pump Problems

By Jennifer Corbett Dooren
453 words
3 March 2010
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WSJO
English

WASHINGTON—The Food and Drug Administration said Wednesday it has seen an increasing number of hardware and software problems with insulin pumps, tiny devices worn by thousands of diabetics to deliver insulin.

"Device problems critical to insulin pumps exist across manufacturers," the agency said, noting there have been 18 recalls of devices over a five-year period, including recalls by a Roche Holding AG unit and Medtronic Inc.

The FDA is convening an advisory panel of outside medical experts on Friday to discuss what actions might be taken to "minimize risks associated with the devices in these recall situations." Background materials for the meeting were posted on the FDA's Web site Wednesday.

The agency didn't single out specific manufacturers, which also include a Johnson & Johnson unit.

Insulin pumps are primarily used by people with Type I diabetes, a condition in which the pancreas produces little or no insulin, a hormone needed to help the body properly use sugars from foods. People with Type 1 diabetes need to administer insulin daily whether through a pump or other methods like shots.

The more common form of diabetes, Type 2, which is often associated with obesity and typically develops later in life, is managed with oral medications designed to help the body properly use insulin, although some cases do require insulin.

The FDA said the number of Type I diabetics using insulin pumps has increased, with about 375,000 U.S. users in 2007, up from about 130,000 in 2002.

Manufacturers are required to report problems potentially associated with devices to the FDA. The FDA conducted a review of insulin pump-related adverse-event reports and found nearly 17,000 reports from Oct. 1, 2006, through Sept. 30, 2009. The reports don't necessarily mean a device caused a problem but serve as a signal for more investigation. Even if a device is functioning properly patients can inadvertently misuse the device. Of the reports, about 12,000 reported a patient injury (such as problems with blood glucose levels) and 310 deaths.

The agency said the information provided by manufacturers involving deaths "was typically incomplete." The agency said in 225 of the deaths reported the device problem was listed as "unknown," although in many cases the device was never returned to the manufacturer for additional follow-up.

However, in 41 death reports, a device problem wasn't identified but the circumstances involving the death involved diabetic coma and problems associated with blood-sugar levels being too high or too low, suggesting the device may not have been working properly.

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THE WALL STREET JOURNAL.

Advertising
Toyota Pulls Ads, Hires P.R. Firm

By Suzanne Vranica
914 words
27 January 2010
22:40
The Wall Street Journal Online
WSJO
English

In the wake of its massive recall, Toyota Motor Corp. is adjusting it advertising strategy.

The world's largest carmaker is pulling its national "Portfolio" campaign that promotes its cars' "dependability," "safety" and "reliability," according to Erin Poole, a spokeswoman for Publicis Groupe's Saatchi & Saatchi LA, one of the ad firms responsible for Toyota's advertising.

Toyota also has hired Robinson Lerer & Montgomery, a public relations outfit, to handle the crisis, according to a person familiar with the matter.

One commercial in the "Portfolio" ad effort, which has been running since September, features a man named Kenny, who drives a Toyota Rav4, coming home to find his house falling apart, from the doorknob that comes off to the leak that springs up in his front yard. Kenny is greeted by construction workers who are scrambling to fix it. "Toyota has won more Total Quality Awards than any other automaker and we can all use little more quality these days," says the voiceover.

The "Portfolio" push is the first time Toyota has done an over-arching corporate campaign that ties many of its vehicles to the same attributes. Toyota, at that time, said the campaign was created because of the "economy" and the state of the car industry.

Toyota will use the media time that was supposed to support the "Portfolio" ad push to pitch its Prius brand. "Prius is one of the models unaffected by the recent gas pedal recall," adds Ms. Poole.

The agency will resurrect a previous ad campaign for the Prius brand that officially stopped running nationally Sept 20. Colorful TV spots shows a utopian landscape made entirely of people; the sun, clouds and ocean are depicted by humans moving in unison. It carries the ad slogan "Harmony between man, nature and machine." Prius ads will begin appearing on TV on Thursday.

Toyota, which long has been viewed as the leader in automotive quality, has been scrambling to trying to figure out how best to handle the public-relations crisis stemming from the recall and the related halt in sales. This week Toyota halted sale of its most popular vehicles models in response to worries over car accelerators that can get stuck.

Over the years, companies such as Ford Motor Co. and Johnson & Johnson have learned that corporate crisis have to be handled delicately and quickly.

Toyota has a lot riding on its response. Over the past few years the company has become one of the top brands in the world thanks to its quality ratings as well as its massive ad budget. Its cars often top J.D. Power's quality ranking. And Toyota spent over $1 billion on U.S. ads in 2008 and $755.6 million for the first nine months of 20009, according to a WPP research company.

In 2009, Toyota was ranked the eight-most-valuable brand in the world, according to Interbrand, a branding firm owned by Omnicom Group Inc.

It's an "astonishing" and "painful development for a brand that stands for quality," says Allen Adamson, managing director of the New York office of Landor, a branding firm owned by WPP PLC. "It raises eyebrows because people assumed they are beyond these types of problems."

Experts say Toyota must move quickly. "Today companies have to be Johnny-on-the spot as soon as something hits," says Chris Gidez, director of risk management and crisis communications at Hill & Knowlton, a public relations firm owned by WPP. "We live in a Facebook world and you have to move fast to keep consumers informed."

Shortly after it recalled 2.3 million vehicles on Jan. 21 Toyota pulled back on corporate ads that tout about Toyota's "environmental mission" and product specific ads in some markets, according to two people familiar with the matter.

Toyota's marketing team and executives from its ad firm Saatchi met early Wednesday to decide what steps its advertising and marketing needs to take, according to a person familiar with the matter. The company was working on new print and online ads since the weekend, the person says.

Branding and corporate communications experts expect Toyota to take aggressive action when it comes to communicating with consumers. "There has to be an ongoing narrative of voices from top management" says Harlan Loeb, director of crisis and issue management at P.R. giant Edelman.

In the past companies in crisis often called on their leaders to take center stage. Both Lee A. Iacocca to Bill Gates have been used by their respective companies to calm fears or deliver bad news.

During the Ford and Firestone tire recall involving Ford Explorers In 1999, both companies involved enlisted their top brass - Masatoshi Ono of Bridgestone/Firestone Inc. and Jacques Nasser of Ford-to pitch. Ford ran a newspaper ad just two days after the recall and it also ran two different commercials that showed Mr. Nasser updating viewers on the recall. TV ads showed Mr. Nasser telling consumers that "over one million tires have been replaced" and he offered a personal guarantee that Ford was working hard to remedy the situation.

Johnson & Johnson's handling of the 1982 Tylenol tampering scare is often sited one of the most effective cases on handling crisis management. The company was credited with moving quickly with its rollout of a nationwide warning campaign and its decision to remove of all Tylenol from store shelves.

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THE WALL STREET JOURNAL.

FDA Chastises J&J Over Tylenol Recall

By Jared A. Favole And Jennifer Corbett Dooren
558 words
16 January 2010
The Wall Street Journal Online
WSJO
English

WASHINGTON—A Johnson & Johnson unit said Friday it is expanding a recall of Tylenol products to include a broad array of medicines, drawing fire from U.S. regulators who said the company should have acted more quickly after reports of a moldy smell.

The company and the Food and Drug Administration said the smell reported by consumers was caused by trace amounts of a chemical that is sometimes applied to wood pallets used to store and transport Tylenol, Rolaids and other products. Some people reported nausea and stomach problems, which the FDA described as temporary, but no serious events were recorded.

FDA officials said Friday that the company first became aware of a possible odor-contamination problem with Tylenol in 2008, but didn't conduct a full investigation and report the problem to the agency until a year later. The company also didn't begin recalling products until November 2009, while FDA investigators were inspecting one of the firm's plants in Puerto Rico.

"When something smells bad, literally or figuratively, companies must aggressively investigate," said Deborah Autor, the director of FDA's Office of Compliance. The FDA has sent a warning letter to the company detailing manufacturing violations and quality problems.

A J&J spokeswoman declined to comment on the FDA's criticism and said the company is working with the agency to address concerns.

J&J's McNeil Consumer Healthcare, which makes over-the-counter Tylenol products, said it is recalling an array of medicines. It was the third recall in response to the odor problems, following smaller steps in November and December that targeted a limited number of Tylenol products.

The new recall affects 500 lots, or about 50 million bottles, from the Americas, Fiji and the United Arab Emirates. Brand names involved include Tylenol, Motrin, Benadryl, Rolaids, Simply Sleep and St. Joseph. (A full list of the product lots affected is at www.mcneilproductrecall.com.)

McNeil said it is stopping shipment of products on the wood pallets. The chemical on the pallets had leached into the product bottles. McNeil said consumers should stop using the products and contact the company for instructions on a refund or replacement.

J&J said it will record costs connected to the recall in its 2009 financial results, but it doesn't expect the loss to be material. The company's chief financial officer said last year that adult Tylenol products have about $1 billion in sales in the U.S. annually.

The FDA's allegation that J&J was slow to address a potential safety problem with Tylenol contrasts with how the company was praised in 1982 for responding to a Tylenol crisis. At the time, seven people died from taking Extra-Strength Tylenol that someone had laced with cyanide and placed on store shelves. The company was quick to alert the public to the deaths and immediately recalled millions of Tylenol bottles. Sales quickly recovered.

The tampering later spawned new FDA package guidelines that required over-the-counter products to be tamper-resistant.

The FDA's Ms. Autor said the agency is trying to determine whether other companies use pallets that contain the chemical.

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THE WALL STREET JOURNAL.
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Corporate News: FDA Chastises J&J Over Tylenol Recall

By Jared A. Favole and Jennifer Corbett Dooren
556 words
16 January 2010
The Wall Street Journal
J
B6
English

WASHINGTON -- A Johnson &Johnson unit said Friday that it is expanding a recall of Tylenol products to include a broad array of medicines, drawing fire from U.S. regulators who said the company should have acted more quickly after reports of a moldy smell.

The company and the Food and Drug Administration said the smell reported by consumers was caused by trace amounts of a chemical that is sometimes applied to wood pallets used to store and transport Tylenol and other over-the-counter products.

Some people reported nausea and stomach problems, which the FDA described as temporary, but no serious events were recorded.

FDA officials said Friday that the company, based in New Brunswick, N.J., first became aware of a possible odor-contamination problem with Tylenol in 2008 but didn't conduct a full investigation and report the problem to the agency until a year later.

The company also didn't begin recalling products until November 2009, while FDA investigators were inspecting a plant.

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THE WALL STREET JOURNAL.

Recall Widened for Tylenol Arthritis Caplets

By Associated Press
255 words
30 December 2009
The Wall Street Journal Online
WSJO
English

Johnson & Johnson is expanding a voluntary recall of Tylenol Arthritis Pain Caplets due to consumer reports of a moldy smell that can cause nausea and sickness.

According to a statement posted to the Food and Drug Administration Web site late Monday, the New Brunswick, N.J., company is now recalling all product lots of Arthritis Pain Caplet 100-count bottles with the red, easy-open cap.

Johnson & Johnson had recalled five lots of the product last month after consumers complained of a musty, mildew-like odor that triggered nausea, stomach pain, vomiting and diarrhea.

The health-care company said the odor results from trace amounts of a chemical called 2,4,6-tribromoanisole. The chemical is believed to result from the breakdown of another chemical used to treat wooden pallets that transport and store packaging materials.

To date, the side effects have been "temporary and non-serious," although the compound's health effects haven't been studied.

The recall affects only the specific lots cited. All other Tylenol Arthritis Pain products remain available.

Consumers seeking a refund or replacement can call J&J at 1-888-222-6036. The company plans to reintroduce Tylenol Arthritis Pain Caplets 100 count by January, after moving production to a new facility.

J&J's McNeil consumer health-care division, which also sells over-the-counter medicines such as Sudafed and Mylanta, posted 2008 sales of $16 billion, according to J&J's annual report.

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Home &Family: Recall Widened For Tylenol Arthritis Caplets

Associated Press
265 words
30 December 2009
The Wall Street Journal
J
D6
English

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