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U.S. EDITION

J&J Chief To Receive \$143 Million Farewell

By Peter Loftus
698 words
15 March 2012
The Wall Street Journal
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English
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Johnson & Johnson Chairman and Chief Executive William Weldon stands to collect pension benefits and deferred compensation currently valued at \$143.5 million after his retirement, according to new details released by the health-care conglomerate.

The payouts won't begin when Mr. Weldon, 63 years old, steps down as CEO in April because he will continue to be the company's chairman. They will start when he is no longer a J&J employee, and the value of his retirement package could change.

Mr. Weldon, who started at the company in 1971, earned his retirement benefits over "a very long career at J&J, 10 of those years as CEO," said J&J spokesman Al Wasilewski.

J&J has been navigating a rough patch, working to resolve quality problems and regain consumer loyalty after a series of recalls of Tylenol, Benadryl, Motrin and Zyrtec medicines due to problems that included metal shavings in some bottles, incorrect levels of an active ingredient and bad odors. The problems grew so intense that the company struck an agreement with U.S. health regulators about tighter oversight of some of its manufacturing.

In a regulatory filing Wednesday, the board said Mr. Weldon "successfully managed our company through a challenging economic environment in 2011," with solid financial results and advances in J&J's pharmaceutical pipeline.

The board added that while J&J made progress in addressing manufacturing-quality issues in 2011, "continued focus is needed to address critical product supply and quality issues that impact our responsibility of being able to deliver products to patients and customers who need them."

Mr. Weldon, who will be succeeded as CEO by Vice Chairman Alex Gorsky, stands to collect benefits from two main sources. The present value of his accumulated pension benefits is \$48.4 million, portions of which are paid out as a monthly annuity for life, according to Wednesday's filing with the Securities and Exchange Commission.

His pension's value places Mr. Weldon well into the top 10% of CEOs of Standard & Poor's 500 companies, said Paul Hodgson, chief communications officer and senior research associate at GMI Ratings, which tracks corporate-governance information.

Mr. Weldon also has amassed \$95.1 million in nonqualified deferred-compensation plans. This represents parts of his salary and bonus that had been deferred in prior years, as well as company contributions to savings plans. Portions of Mr. Weldon's deferred compensation have been recorded each year as part of his total annual pay.

Of the \$95.1 million, more than \$70 million represents Mr. Weldon's accumulated balance from a cash-incentive plan that J&J discontinued and replaced with a new executive-compensation plan. This sum would be paid to Mr. Weldon at retirement, J&J said. All deferred compensation is subject to taxes.

J&J, which is based in New Brunswick, N.J., also disclosed Wednesday that Mr. Weldon's overall compensation in 2011 declined nearly 7% from 2010 to \$26.8 million, largely because of a smaller increase in Mr. Weldon's pension value and non-qualified deferred compensation earnings compared with 2010.

Performance-based components of his compensation increased, however. As J&J disclosed last month, Mr. Weldon's annual performance bonus rose 55% for 2011, partially reversing a cut he received for 2010 because of the string of product recalls and a revenue decline.

The board said it was "deeply disappointed" in the continued challenges facing it to restore a reliable supply of the company's Doxil cancer drug. A Doxil shortage emerged last year after a contract producer experienced manufacturing-quality problems. J&J said it is trying to restore supply as quickly as possible.

Mr. Weldon's total compensation last year included \$1.9 million in salary, \$2.6 million in stock awards, \$4.2 million in option awards, \$14.3 million in nonequity incentive-plan compensation, a \$3.4 million change in pension value and nonqualified deferred compensation earnings, and \$321,000 in other compensation.

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Management J&J Chief To Receive \$143 Million Farewell

By Peter Loftus 1,098 words 15 March 2012 09:44 The Wall Street Journal Online WSJO English

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Performance-based components of his compensation increased, however. As J&J disclosed last month, Mr. Weldon's annual performance bonus rose 55% for 2011, partially reversing a cut he received for 2010 because of the string of product recalls and a revenue decline.

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But the stated rationale for the bonus increase wasn't known until J&J filed its proxy statement Wednesday. The board said it was "deeply disappointed" in the continued challenges facing it to restore a reliable supply of the company's Doxil cancer drug. A Doxil shortage emerged last year after a contract producer experienced manufacturing-quality problems. J&J said it is trying to restore supply as quickly as possible.

Mr. Weldon's total compensation last year included \$1.9 million in salary, \$2.6 million in stock awards, \$4.2 million in option awards, \$14.3 million in nonequity incentive-plan compensation, a \$3.4 million change in pension value and nonqualified deferred compensation earnings, and \$321,000 in other compensation.

Though he will remain chairman after he steps down as CEO, Mr. Weldon will no longer be a member of J&J's executive committee, the company said. The incoming CEO, Mr. Gorsky, will become a director and will lead the executive committee. All day-to-day management and operational responsibilities will be transferred to Mr. Gorsky.

Because Mr. Weldon isn't considered an independent chairman, board member James Cullen will continue to serve as presiding director for 2012, the company said.

The total 2011 compensation for the incoming CEO, the 51-year-old Mr. Gorsky, was valued at \$6.8 million. J&J hasn't released his compensation for 2010. The board said Mr. Gorsky performed very well during 2011, including his oversight of the company's medical-device and diagnostics unit.

J&J Vice Chairman Sherilyn McCoy, who had vied with Gorsky for the top spot, had total 2011 compensation valued at \$8.7 million, up from \$7.5 million for 2010. The board said Ms. McCoy performed very well in 2011, including her leadership of the pharmaceutical and consumer-products units.

J&J disclosed in its proxy that it has made changes in its overall executive-compensation policy after a sizeable minority of shareholders voted against the company's practices at last year's annual meeting. Some 61% of shares voted were cast in favor of J&J's executive compensation, but J&J's board was disappointed in the result.

After the vote, the board's compensation committee reviewed pay practices, including by gathering feedback from shareholders and employees. Last year, some shareholders said Mr. Weldon's pay was excessive in light of the string of product recalls and other challenges.

The changes include a new structure for long-term incentives for executives, the discontinuation of the cash-based incentives that had been place for more than 60 years, and the introduction of performance share units, with payouts contingent upon meeting goals for profits and total shareholder return. The underlying value of the share units is tied to J&J's share price.

In 4 p.m. trading on the New York Stock Exchange, J&J shares were down 25 cents at \$65.08.

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Corporate Watch

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EL PASO

Pipeline Company to

Sell Production Business

El Paso Corp. said it would sell its oil-and-natural-gas exploration-and-production unit for approximately \$7.15 billion to a group led by private-equity firm Apollo Global Management LLC.

Last year, Kinder Morgan Inc. agreed to buy El Paso for \$21 billion, and said it would sell the company's exploration-and-production unit to help finance its bid. Kinder Morgan's deal to purchase El Paso is expected to close by the second quarter of this year.

The sale of the unit -- EP Energy Corp. -- also is expected to close about the same time as the Kinder Morgan-El Paso merger.

"We are pleased that this pending sale will allow the El Paso exploration and production assets to be kept intact as a single entity," said Kinder Morgan Chairman and Chief Executive Richard D. Kinder.

-- Nathalie Tadena

EXXON

Record-Level Spending

Is Planned at Oil Giant

Exxon Mobil Corp. said Friday it plans to spend a record \$37 billion annually in capital projects for the foreseeable future, becoming the latest oil giant to unveil a significant capital budget aimed at boosting production and reserves.

"The corporation anticipates an investment profile of about \$37 billion per year for the next several years," Exxon said in an annual report filed with the Securities and Exchange Commission. "The corporation's financial strength enables it to make large, long-term capital expenditures." The figure is slightly higher than the record \$36.8 billion the Texas-based oil major invested in 2011 and a jump from the \$32.2 billion it spent in 2010.

The announcement marks the rebirth of a trend toward bigger spending by the major oil companies that was interrupted by the global financial crisis, which caused oil prices to tumble in 2008.

A recovery in crude prices has led the big oil companies to shrug off the uncertainty and keep boosting spending as they seek to fund the projects that will drive production growth and replenish reserves.

-- Isabel Ordonez

J.C. PENNEY

Retailer Swings to Loss

Amid Changes in Pricing

J.C. Penney Co. swung to a loss in its fiscal fourth quarter, as the retailer shouldered heavy costs tied to its revamped pricing strategy.

The company said sales in February, the first month of the new fiscal quarter, are trending below a year ago, especially as they go up against days when there was a major promotional event.

Led by new Chief Executive Ron Johnson, a former Apple Inc. executive, the department-store operator this month launched a new pricing approach that aims to cut through the clutter of department-store promotions.

Mr. Johnson said that while this month's sales are falling short of those a year earlier, he is confident the "simplified business model" will more than offset the shortfall, so the company can meet or exceed its 2012 earnings guidance.

For the quarter ended Jan. 28, J.C. Penney reported a loss of \$87 million, or 41 cents a share, compared with a year-earlier profit of \$271 million, or \$1.13 a share. The latest period included restructuring and management-transition charges that affected results by 56 cents a share as well as a 59-cent-per-share impact from the company's new pricing and promotional strategy. Minus charges from its restructuring and price changes, its earnings per share of 74 cents beat a forecast for 65 cents to 70 cents, based on the company's lowered target from last month after lackluster sales for the critical holiday selling season.

Total sales declined 4.9% to \$5.43 billion, coming in shy of the \$5.5 billion expected by analysts. Same-store sales were down 1.8%.

-- Karen Talley and Mia Lamar

JOHNSON & JOHNSON

CEO Gets 55% Increase

In Performance Bonus

Johnson & Johnson's outgoing chief executive received a 55% increase in his annual performance bonus for 2011, partially restoring the cut he was dealt for 2010 because of the company's string of product recalls.

J&J's board last month approved an annual bonus of \$3.1 million to CEO William Weldon for his performance in 2011, according to J&J's annual report filed Thursday with the U.S. Securities and Exchange Commission. The bonus is paid in the form of 85% cash and 15% J&J shares.

Mr. Weldon, 63 years old, will step down in April and be succeeded by J&J Vice Chairman Alex Gorsky, J&J said. Mr. Weldon will remain chairman of the board.

Last year, Mr. Weldon received a \$1.98 million bonus for his performance in 2010, a decrease of 45% from \$3.6 million the prior year, which J&J chalked up to such disappointments as the recalls of over-the-counter medicines and an overall sales decline in 2010. J&J has recalled Tylenol and other OTC drugs over the past two years due to manufacturing-quality lapses.

-- Peter Loftus

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Business
J&J CEO Gets 55% Increase in Performance Bonus

By Peter Loftus
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24 February 2012
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Mr. Weldon, 63 years old, will step down in April after 10 years as CEO and be succeeded by J&J vice chairman Alex Gorsky, J&J said this week. Mr. Weldon will remain chairman of the board.

Last year, Mr. Weldon received a \$1.98 million bonus for his performance in 2010, a decrease of 45% from \$3.6 million the prior year, which J&J chalked up to such disappointments as the recalls of over-the-counter medicines and an overall sales decline in 2010. J&J has recalled Tylenol and other OTC drugs over the past two years due to manufacturing-quality lapses.

The New Brunswick, N.J., company didn't explain in Thursday's regulatory filing why it raised Mr. Weldon's performance bonus for 2011. J&J's sales rebounded and the company won regulatory approval of several new products in 2011. But product recalls continued, and the company also experienced a shortage of its cancer drug Doxil.

The compensation and benefits committee of J&J's board "evaluates Mr. Weldon and all the executive officers against a set of both financial and strategic objectives," said J&J spokesman Al Wasilewski. "These objectives and the committee's assessments will be discussed in the company's upcoming proxy statement, and are consistent with our long-standing pay-for-performance philosophy."

J&J in recent years has filed its proxy statement with the SEC in March.

The company's board and its compensation committee approved new compensation levels for Mr. Weldon and certain other executives on Jan. 17, a month before the board's Feb. 14 decision to name Mr. Gorsky as Weldon's successor.

The board approved a 3% raise in Weldon's base salary for 2012, to \$1.97 million from \$1.92 million.

Mr. Wasilewski said the board will consider the appropriate compensation for Mr. Weldon in his continuing role as chairman, and the company will make the required disclosures after any decisions are made.

J&J also granted Mr. Weldon 628,911 stock options, each with an exercise price of \$65.37, and additional equity-based compensation. J&J shares fell seven cents to \$64.46 in 4 p.m. composite trading Friday on the New York Stock Exchange.

Mr. Weldon's overall compensation also appeared to get a recent boost from his exercise of stock options and sale of J&J shares. On Feb. 1, he exercised options for and sold 448,085 shares at prices resulting in a gain of about \$6.18 million, based on figures provided in an SEC filing.

Last year, J&J disclosed that Mr. Weldon's overall compensation—which includes additional elements such as changes in pension value—was valued at \$28.7 million for 2010, down from \$30.8 million for 2009. J&J

shareholders approved the company's executive compensation policy last year despite opposition by some critics who said Mr. Weldon's pay was too high in light of the company's setbacks.

Mr. Gorsky's annual base salary will rise to \$1.2 million when he becomes CEO in April, versus the \$880,600 approved by the compensation committee last month, J&J said in the regulatory filing.

Mr. Gorsky was approved for an annual performance bonus of \$1.28 million for his work in 2011, J&J said. His prior-year compensation wasn't disclosed.

Sherilyn McCoy, the J&J vice chairman who lost the CEO succession race to Mr. Gorsky, was also approved for a \$1.28 million annual performance bonus for 2011, up 13% from her bonus for 2010.

The committee approved a 3.6% increase in Ms. McCoy's base salary to \$932,400 for 2012, from \$900,000 for 2011.

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Business New J&J Chief to Face Repair Jobs

By Jonathan D. Rockoff And Joann S. Lublin 1,020 words 23 February 2012 The Wall Street Journal Online WSJO English Copyright 2012 Dow Jones & Company, Inc. All Rights Reserved.

Johnson & Johnson's next chief executive earned his spurs at the health-products giant by selling

Johnson & Johnson's next chief executive earned his spurs at the health-products giant by selling pharmaceuticals and medical devices. Yet Alex Gorsky's biggest order of business as the new CEO may involve repairing another and altogether different J&J business: consumer products.

In April, Mr. Gorsky will succeed William Weldon, J&J's CEO for the last 10 years. He will face a number of tasks, from navigating the pricing pressures weighing on health care to creating a management team—including determining a role for his main competition for chief executive, fellow J&J Vice Chairman Sheri McCoy.

For those tasks, Mr. Gorsky, 51 years old, can draw from the experiences that factored into his appointment, such as his recent efforts to fix manufacturing woes, according to a person familiar with J&J. Those who know Mr. Gorsky laud his skills diagnosing problems by reviewing reams of data and visiting the company's front lines, motivating experts on staff to fix the issues and then holding the staffers responsible.

"He has an incredible ability to connect with people and get the best out of people," said David Norton, a former senior J&J official who supervised Mr. Gorsky. Mr. Gorsky still emails back and forth with sales representatives he met at a product-launch conference 15 years ago, said Mr. Norton, interim CEO of Savient Pharmaceuticals Inc.

Another person close to the company says Mr. Gorsky takes great pains to remember people's names. At J&J, the person said, Mr. Gorsky is admired at all levels for his rise from pharmaceutical-sales representative. At the University of Pennsylvania's Wharton School, where he earned his M.B.A., he hands out his email address to students during guest lectures at a first-year class on managing people, said Prof. Michael Useem.

Neither Messrs. Gorsky and Weldon nor Ms. McCoy were available to comment, the company said.

Sales at J&J's consumer businesses, which sell well-known brands like Listerine mouth wash, Band-Aid bandages and Johnson's baby shampoo, have dropped because of a string of recalls of popular over-the-counter medicines including Tylenol. Last year, the group reported \$14.9 billion of J&J's \$65 billion sales, down more than 7% from revenue in 2008, the year before the recalls began.

Mr. Weldon, 63, had told J&J insiders that he didn't want to leave before fixing the quality problems. And J&J had begun reintroducing some recalled medicines, such as grape-flavored infants' Tylenol last November. But a recall last week of that medicine's entire U.S. supply, some 574,000 bottles, because of a design flaw suggests problems remain.

Although not among J&J's most profitable divisions, consumer products play an important role at the company. They furnish a steady supply of cash, offer ballast against the shifting fortunes of riskier medical devices and prescription drugs and have been central to J&J's historic high standing among doctors, nurses and parents, a plus for all its businesses.

Yet surveys show J&J's reputation retreating. For the first time in the 13 years of the Harris Poll Reputation Quotient study, J&J isn't ranked first or second among companies—it is seventh. Private-label medicines and rival brands like Pfizer Inc.'s Advil have gained share. Customers such as Mike Watts, a 35-year-old father in New York City, are rethinking their loyalties.

"Every time I'm turning around or turning on the news it seems that J&J is recalling something," said Mr. Watts, who had been giving his teething 22-month-old daughter infants' Tylenol but just threw out the bottle due to the

recall last week. "It doesn't give me a whole lot of confidence in them. I'm going to look for alternatives, especially now."

Regaining the confidence of such customers will be crucial to J&J's ability to hold on to its reputation, marketing experts say.

"A lot of where J&J's brand equity comes from is this umbrella they have from cradle to grave, from baby shampoo to hip-replacement devices," said Rex Briggs, CEO of Marketing Evolution, which has consulted for J&J. "They've got to protect their core value."

Recapturing consumer confidence will require a different skill set than the ones that catapulted Mr. Gorsky to roles heading J&J's pharmaceutical businesses in Europe, the Middle East and Africa, and later all of J&J's medical devices and diagnostics businesses.

Selling prescription medicines and medical devices relies on building relationships with individual doctors, not managing a brand's image among millions of people, said David Vinjamuri, a J&J consumer-brand manager in the 1990s who now heads ThirdWay Brand Trainers, which trains corporate marketers.

Mr. Gorsky will have to do more than set sales goals—he will also have to encourage subtle steps, like updating Johnson's baby shampoo's formulation, to appeal to customers, Mr. Vinjamuri said. "They have to systematically invest in all the brands."

To accomplish the job, Mr. Gorsky might tap an outsider to run the consumer group. One industry recruiter speculated Mr. Gorsky could pick a former colleague at Swiss health-products giant Novartis AG, where he worked from 2004 until returning to J&J in 2008

Mr. Gorsky may try to keep Ms. McCoy, 53, with J&J by offering her a job such as chief operating officer, though she will likely be sought after by other companies. But the pair enjoy a close bond and "sort of had an understanding between them that 'if you win, I will work for you'—and vice versa," a veteran drug-industry recruiter said.

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Corporate News: For New CEO, J&J Picks From Within --- Health-Products Company Makes Change as It Grapples With Quality Problems, Slowing Medical-Device Sales

By Jonathan D. Rockoff and Joann S. Lublin 1,277 words 23 February 2012 The Wall Street Journal Asia AWSJ 23 English

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Johnson & Johnson picked company veteran Alex Gorsky as its next chief executive, giving him the reins to a health-products giant that makes some of the world's most well-regarded medicines but whose reputation has been battered by quality problems at such iconic brands as Tylenol.

The 51-year-old Mr. Gorsky will take the helm of J&J this April as it struggles to overcome the quality problems that have cost it more than \$1 billion in lost sales and forced the shutdown of a production plant.

The problems grew so intense that the company struck an agreement with U.S. health regulators about tighter oversight of some of its manufacturing.

The New Brunswick, N.J., company is also trying to reshape a medical-device business whose sales have been hurt by the economic downturn and pricing pressures, especially in the U.S. and Europe.

These changes come as J&J's prescription-medicines business is grappling with stronger generic competition. The company lost about \$5.75 billion in world-wide sales after its antipsychotic drug Risperdal and epilepsy treatment Topamax went off patent two years ago.

William Weldon, 63, J&J's chief executive since 2002, will remain as board chairman for a transition period, but won't continue in that role for very long, according to a person familiar with the matter.

Mr. Gorsky will receive a base salary of \$1.2 million, effective April 26, when he becomes CEO.

Mr. Gorsky edged out fellow Vice Chairman Sheri McCoy, 53, for the top spot. Both inside and outside the company, Ms. McCoy was thought to have an edge over Mr. Gorsky in the horse race to become the 126-year-old company's ninth leader.

Mr. Gorsky said in a statement that he was honored by the appointment, "and I am also aware of the serious responsibilities that come with this office." Mr. Weldon called Mr. Gorsky an "experienced, visionary and disciplined leader." Neither was available for comment, a J&J spokesman said.

J&J booked \$65 billion in sales in 2011, up 5.6% from the year before. But it has work to do to resolve quality problems and regain consumer loyalty after a series of recalls of Tylenol, Benadryl, Motrin and Zyrtec medicines due to problems that included metal shavings in some bottles, incorrect levels of an active ingredient and bad odors.

The recalls have hurt consumer confidence in J&J, though it remains generally well regarded. J&J has dropped below Apple Inc. and Google Inc. to No. 7 among the country's most-respected companies, down from No. 2 a year ago, according to an annual survey by Harris Interactive of more than 17,000 people in the U.S.

In recent months, J&J executives had begun saying it had finally turned a corner addressing the manufacturing problems.

Yet just last week, the company was forced to recall its entire U.S. supply of infants' Tylenol, some 574,000 bottles, because of a design flaw in a new cap that the company hoped would help it recapture the trust of customers.

Mr. Gorsky is a former U.S. Army Ranger who began his J&J career as a pharmaceutical sales representative in 1988 and has held leadership positions in J&J's pharmaceuticals and medical-device businesses.

J&J executives thought enough of him that they took the unusual step of bringing him back in 2008, four years after he had departed to head the U.S. pharmaceuticals business for rival Swiss health-care giant Novartis SA.

J&J's pharmaceuticals may now be in the strongest position among the company's businesses, despite generic competition for previously top-selling products. The prescription drugs group received approval of six new medicines in 2011, including Incivo for hepatitis C and Zytiga for prostate cancer.

The company's medical-devices and diagnostics businesses, meantime, are in the middle of a shake-up to find new sales growth.

Last year, J&J said it was exiting the \$5 billion world-wide market for tiny metal devices that prop open clogged arteries, called stents, that it had created but lost grip of amid fierce competition.

J&J's medical-devices side is now banking on growth from its pending \$21.3 billion acquisition of Synthes Inc., the dominant maker of plates and screws used to mend bones broken in traumatic accidents.

J&J has said this trauma segment is one of the fastest-growing categories in the industry, expanding at a 7% yearly clip world-wide.

The business is also insulated from the forces that have diminished sales of artificial hips, knees and other products that are more sensitive to the economy's ups and downs.

J&J's internal succession race narrowed to the two internal finalists in December 2010, when J&J promoted the heads of its two largest businesses to the highest executive suite. Ms. McCoy and Mr. Gorsky were named vice chairmen in an expanded Office of the Chairman, an arrangement that J&J followed before Mr. Weldon's ascension to CEO in 2002.

Upon his appointment as a vice chairman, Mr. Gorsky took control of a new manufacturing and supply group created to make sure all plants meet quality standards. Ms. McCoy gained oversight of the consumer business that includes the McNeil Consumer Healthcare unit responsible for the bulk of the recalls.

Ms. McCoy began her J&J career 30 years ago, as a research scientist and rose to oversee its pharmaceuticals business. As recently as last week, many J&J staff and industry recruiters described Ms. McCoy as the favorite to take J&J's helm.

And on Saturday, Ms. McCoy seemed unaware that she had lost the succession race. "She was happy as a clam" during a phone call that day, a former J&J official recalled.

By that time, the board had decided to elevate Mr. Gorsky, according to a person familiar with the matter. The board had voted in favor of Mr. Gorsky at a regular meeting on Feb. 14, the person said.

Ms. McCoy wasn't available for comment Tuesday.

Mr. Gorsky "has more of an operations background," and his supply-chain expertise "was part of that," the informed individual explained.

Ms. McCoy has a strong R&D background, and J&J's board "will do everything it can to retain" her, this person continued. She is expected to be attractive to a number of companies seeking new CEOs, such as medical-device maker Stryker Corp. and consumer giant Avon Products Inc. Both Stryker and Avon declined to comment.

The board used David Dotlich, a leadership and succession coach, to conduct 360-degree feedback assessments of both contenders -- in which peers, bosses and subordinates evaluated the executives. The evaluations "were so close that you could barely slide a sheet of paper [between] the ratings of the two of them," this person said.

Mr. Dotlich, chairman of Pivot Leadership LLC in Portland, Ore., said he thinks the board chose Mr. Gorsky partly because "he has been responsible for the largest acquisition in the history of J&J," the Synthes deal.

Christopher Weaver and Emily Glazer contributed to this article.

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EUROPE EDITION

J&J Taps Vice Chairman as CEO --- Alex Gorsky Steps Up as Health-Care Giant Works to Resolve Quality Issues After Recalls

By Joann S. Lublin 540 words 22 February 2012 The Wall Street Journal Europe WSJE UK18 English (Copyright (c) 2012, Dow Jones & Company, Inc.)

Johnson & Johnson picked Vice Chairman Alex Gorsky to be the next chief executive of the health-care giant, slating him to take over from longtime CEO William Weldon at its late-April annual meeting.

The New Brunswick, N.J., company announced Mr. Gorsky's selection Tuesday afternoon. Mr. Weldon will remain as chairman for a transition period but won't continue in that role for very long, a person familiar with the matter said.

Mr. Gorsky, 51 years old, will take over a company that booked \$65 billion in sales in 2011, but which still has work to do to resolve quality problems and regain consumer loyalty after a series of recalls in its consumer unit. Problems making Tylenol and other popular over-the-counter medicines have cost J&J more than \$1 billion in lost sales, hurting the company's financial performance as well as its once-sterling reputation for quality.

Mr. Gorsky edged out fellow Vice Chairman Sheri McCoy for the top spot. Ms. McCoy appeared to have been in the lead to succeed Mr. Weldon, people familiar with the matter said recently.

Both Mr. Gorsky and Ms. McCoy, 53, were highly qualified to be chief executive, and J&J hopes to retain Ms. McCoy, the person familiar with the matter said.

The internal succession race narrowed to two finalists in December 2010, when J&J promoted the heads of its two largest businesses to the highest executive suite. Ms. McCoy and Mr. Gorsky were named vice chairmen in an expanded Office of the Chairman, an arrangement that J&J followed before Mr. Weldon's ascension to chief executive in 2002.

Under the changes, the pair split the company's various duties. Ms. McCoy took charge of businesses generating a majority of J&J's revenue, while Mr. Gorsky managed more employees. Each also assumed certain responsibilities for fixing quality problems in the consumer unit that led to extensive recalls.

Upon his appointment as a vice chairman, Mr. Gorsky took control of a new manufacturing and supply group created to make sure that all plants met quality standards.

Ms. McCoy gained oversight of the consumer business that includes the McNeil Consumer Healthcare unit responsible for the bulk of the product recalls.

Continued problems with that consumer unit didn't influence J&J directors' selection of Mr. Gorsky, according to the person familiar with the matter. Board members "picked the better of two extraordinarily strong candidates,"" the person said

Mr. Gorsky began his J&J career as a pharmaceutical sales representative in 1988. J&J executives thought so highly of him that they rehired him in 2008, a veteran drug-industry recruiter said, four years after he had departed to work for rival Novartis AG.

Mr. Gorsky is seen as "a strong operator," the recruiter said.

J&J shares were nearly unchanged in after-hours trading Tuesday, after gaining five cents to \$65.04 in 4 p.m. New York Stock Exchange composite trading.

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Document WSJE000020120222e82m0001i

Business
J&J Recalls Infants' Tylenol

By Jonathan D. Rockoff 706 words 18 February 2012 The Wall Street Journal Online WSJO English

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Johnson & Johnson recalled its entire U.S. supply of infants' Tylenol—about 574,000 bottles—due to a design flaw that hasn't caused harm but sets back the health-products giant's efforts to regain sales following a string of earlier recalls.

The move Friday involved bottles of grape-flavored infants' Tylenol, which had only just returned to shelves in November, one of the few recalled consumer products J&J had put back on the market.

Since 2009, J&J has recalled millions of bottles of Tylenol, Benadryl, Motrin and Zyrtec as a result of such problems as metal shavings found in medicines, incorrect levels of an active ingredient and bad odors. The recalls prompted J&J to shut down a factory and have cost it more than \$1 billion in lost sales.

With this new recall, J&J's McNeil Consumer Healthcare unit said the popular over-the-counter cold and pain remedy was safe and that it hadn't received any side-effect reports, but it acted after receiving a "small number of complaints" about a new bottle cap and dose syringe.

The cap is meant to help parents draw the right dose for babies to 2-year-olds by inserting a syringe through the cap and into the bottle. J&J introduced the cap last year, as part of a broader effort to recapture the confidence of parents.

In some instances, a part of the cap intended to restrict the flow of liquid can fall into the bottle, McNeil said in a message to parents posted on the Tylenol.com website. Parents shouldn't use the medicine if that happens, the company said.

The recall, in the wake of a management shake-up in J&J's consumer group, of which the McNeil unit is a part, suggests J&J still has a ways to go to resolve its quality problems and regain consumer loyalty.

U.S. sales at McNeil were \$1.4 billion last year, 55% off the peak in 2008, the year before the recalls, according to Wells Fargo Securities. The recalls also damaged the company's reputation. Among over the counter pain medicines, Tylenol ranks eighth in loyalty, after trailing only Advil in 2009, according to the most recent survey of 49,000 adults by marketing consultant Brand Keys Inc.

J&J executives have expressed confidence recently that the worst is over. "We feel positive about where our consumer business is headed in 2012," Chief Executive William Weldon said during an earnings call last month.

In a statement on Friday, Mr. Weldon called the latest Tylenol recall "clearly disappointing after all the progress that McNeil has been making to ensure its products meet the highest level of quality and consumer satisfaction."

Mr. Weldon also said that the company issued the voluntary recall "to preserve and reinforce our commitment to patients and customers."

One mother who purchased the infants' Tylenol said her package didn't have a defective syringe—it had no syringe at all. Aruna Sokol, of Forest Hills, N.Y., said she had to pry off the Tylenol cap with scissors late last month when she needed to give the medicine to her son.

Ms. Sokol said she finds products that require specific parts, like a special syringe, "frustrating" and she prefers to buy generic medicines.

McNeil investigates seriously any reports it receives, but it hasn't received any reports of dosing syringes missing from infants' Tylenol packages, a spokeswoman said.

Maintaining or regaining consumer confidence is always a tricky proposition for drug makers, notes Bill Trombetta, a pharmaceutical marketing professor at Saint Joseph's University in Philadelphia. This recall will make that more difficult for J&J, he said. "Now, they have another uphill battle."

New designs for delivering medicines, aimed at improving the experience of users, have backfired at times as well. In 2007, Pfizer Inc. pulled out of a partnership to sell an insulin inhaler called Exubera, taking a \$2.8 billion charge, because of poor sales partly due to its unwieldy size.

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

Document WSJO000020120218e82i000jj

M J&J Recall Watch: McNeil Pulls Liquid Infant Tylenol on Dosing System Concerns

WSJ Blogs, 09:07, 17 February 2012, 1038 words, By Katherine Hobson, (English)
Johnson & Johnson's McNeil Consumer Healthcare division is recalling about 574,000
one-ounce bottles of grape-flavored liquid infant Tylenol after receiving a small
number of complaints that the dosing system was difficult to use.

Document WCWSJB0020120217e82h005v5

Business
Sanofi Unit Recalls One Lot of Leukemia Drug

By Peter Loftus
372 words
15 February 2012
15:50
The Wall Street Journal Online
WSJO
English

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Sanofi SA's Genzyme unit has recalled one batch of leukemia drug Fludara due to concerns about its sterility—the latest in a series of supply and quality issues arising from troubles at a contract manufacturer.

Fludara was being manufactured for Genzyme at a Ben Venue Laboratories plant in Ohio where U.S. and European health regulators have identified contamination-related deficiencies. Ben Venue, a unit of Boehringer Ingelheim GmbH, has suspended production at the plant to fix the problems.

According to a notice posted online Wednesday by the Food and Drug Administration, Genzyme sent letters to customers Jan. 31 and Feb. 1, alerting them that one lot of Fludara, comprising 9,380 vials, was being recalled. Fludara is a chemotherapy approved to treat B-cell chronic lymphocytic leukemia.

The FDA said the reason for the recall was "lack of assurance of sterility," based on a joint inspection of Ben Venue's Bedford, Ohio, plant conducted in November by the FDA and the European Medicines Agency.

In a statement, Paris-based Sanofi said the recall was a precautionary measure following the regulatory citations of Ben Venue, and that no issue has been identified with the drug itself. However, the deficiencies identified at Ben Venue raise the possibility of "hypersensitivity reactions" in recipients of drugs made there, Sanofi said.

Sanofi said no Fludara lots have been manufactured by Ben Venue for U.S. distribution since June 2010. Later batches of the drug aren't affected by the recall.

Inspectors cited a range of quality lapses at the Ben Venue plant last year, including the discovery of a container suspected to hold urine, the presence of metal particles in certain products and bacterial contamination in some medications, according to FDA documents.

Ben Venue's woes caused a shortage of Johnson & Johnson's cancer drug Doxil—for which no new supplies are expected until late 2012—as well as recalls of other drugs. In addition, European regulators have recommended doctors visually inspect certain Ben Venue-manufactured drugs for the presence of particulate matter.

A Ben Venue spokesman couldn't immediately be reached.

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

Document WSJO000020120215e82f009ki

U.S. EDITION

Health

J&J Shakes Up McNeil Unit Again --- Consumer-Drug Division Gets New Leadership Less Than a Year After Recall-Related Changes

By Jonathan D. Rockoff and Joann S. Lublin 556 words 31 January 2012 The Wall Street Journal J B9

English

(Copyright (c) 2012, Dow Jones & Company, Inc.)

Johnson & Johnson is shaking up oversight of the troubled unit that makes Tylenol and other over-the-counter medicines once again, naming new leadership less than a year after manufacturing problems sparked a revamp.

The New Brunswick, N.J., health-products giant is replacing two company group chairmen who held key roles trying to turn around a consumer business racked by recalls and more than \$1 billion in lost sales of popular cold, pain and allergy medicines.

Patrick Mutchler, who was put in charge of overseeing the McNeil Consumer Healthcare unit last April, is retiring after 35 years at the company, according to people familiar with the departures and an internal company announcement reviewed by The Wall Street Journal.

Mr. Mutchler's duties will be taken over by Roberto Marques, who heads J&J's consumer businesses in North America.

Also leaving by the end of March, the people said, will be Pericles Stamatiades.

He is a 28-year veteran at J&J who has served as chief strategist for J&J's consumer businesses since last spring's revamp and had previously headed the beauty-care business, which makes such products as Aveeno lotions and shampoos.

The duties of Mr. Stamatiades will be assigned to other company officials, according to a J&J spokeswoman, who confirmed the departures.

J&J's over-the-counter business in the U.S. "will continue to be operated as a separate, integrated business in order to maintain its focus on quality and compliance, and on the successful reintroduction of OTC medicines in the U.S. market," the spokeswoman said. She said neither Mr. Mutchler nor Mr. Stamatiades were available for comment.

J&J's consumer business has been in turmoil since late 2009, when it began recalling Tylenol, Benadryl, Motrin and Zyrtec -- many for children and infants -- due to bad odors, possible presence of metal shavings and other manufacturing issues.

The quality issues damaged the company's reputation with consumers, drew scrutiny from Congress and prompted the company to agree to a consent decree giving regulators tight oversight of three manufacturing plants.

Only a limited number of the recalled products have returned to store shelves so far.

Meanwhile, the company is undergoing an expensive upgrade of an important manufacturing plant outside Philadelphia while shifting production to various other facilities.

U.S. sales at the McNeil unit plunged to \$1.4 billion last year, from a peak of \$3.1 billion in 2008, the year before the recalls, according to Wells Fargo Securities.

Meantime, morale among employees has suffered amid cost-cutting, including layoffs of more than 100 people in the U.S. in recent weeks.

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The reasons for the management departures are unclear.

According to a former J&J official, J&J Vice Chairman Sheri McCoy encouraged the two officials to leave "to bring in some fresh thinking and direction" and fix the unit.

Day-to-day operations at McNeil Consumer Healthcare will continue to be led by Denice Torres, who took the role as part of the April 2011 overhaul.

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Document J000000020120131e81v0002m

WSJ Blogs, 14:54, 24 January 2012, 368 words, (English)

By Katherine Hobson and Peter Loftus Johnson & Johnson avoided a third consecutive year of sales declines in 2011 -- sales rose 5.6%, to \$65 billion, last year, according to the company's latest financial report, out today.

Document WCWSJB0020120124e81o006v9

U.S. EDITION

Corporate News: Corporate Watch

795 words
20 January 2012
The Wall Street Journal
J
B5
English
(Copyright (c) 2012, Dow Jones & Company, Inc.)
AMERICAN AIRLINES

Carrier Falls Short

On Pension Payment

American Airlines' parent company made only a small fraction of the roughly \$100 million payment it was scheduled to contribute to the company's employee pension plans, according to a federal agency.

AMR Corp. instead contributed just \$6.5 million by the Jan. 15 deadline. The shortfall threatens to further undermine funding at pension funds that cover 130,000 American Airlines workers and retirees, a Pension Benefit Guaranty Corp. spokesman said Thursday.

"The company has determined this is the appropriate course of action," an AMR spokesman said. "This action allows the company to preserve cash."

AMR filed for Chapter 11 bankruptcy protection in late November, saying it needed to cut costs to stay competitive. Since then, the company has warned that it may reduce its pension commitments as part of the restructuring.

Such statements have drawn a rebuke from the pension agency, which would inherit the pension funds' obligations if the airline was to terminate its employee retirement plans.

-- Michael Corkery

DRUG INDUSTRY

Bristol, Astra Hit Setback

For Diabetes Medication

The Food and Drug Administration declined to approve an experimental diabetes drug codeveloped by Bristol-Myers Squibb Co. and AstraZeneca PLC, asking for more clinical data to assess its safety and efficacy.

Expectations for the drug, dapagliflozin, were already reduced because an FDA advisory committee last year recommended against its approval, citing concerns about potential safety risks. More recently, however, Bristol executives had spoken optimistically about securing regulatory approval.

"The commercial potential of the product has always seemed in doubt," Sanford C. Bernstein analyst Tim Anderson wrote in a research note. "The drug has had little support from diabetes experts, and the diabetes field is already crowded with a host of different therapeutic options."

The companies said they remain committed to the drug's development, and "will work closely with the FDA to determine the appropriate next steps."

-- Peter Loftus and Sten Stovall

SABMILLER

Increased Lager Volumes

Give Brewer a Boost

SABMiller PLC posted a rise in lager volumes in its fiscal third quarter boosted by emerging markets, but European volumes fell due to fragile economic conditions underscoring the challenges in mature markets.

Lager volumes for the quarter ended Dec. 31 rose 3% on an organic basis, which excludes acquisitions and disposals, a rate that was unchanged on the year and compared with the first half of its current fiscal year.

Group revenue on an organic basis and at constant currencies, rose 7% in the quarter, while group revenue per hectoliter increased 3%, boosted by price increases.

The maker of Grolsch and Peroni Nastro Azzuro said the financial performance was in line with its expectations. The latest figures don't include a contribution from Foster's, the Australian brewer that SABMiller snapped up last year in a deal valued at \$10.47 billion.

-- Simon Zekaria

JOHNSON & JOHNSON

Drug Maker to Settle

Risperdal Suit in Texas

Johnson & Johnson agreed to pay \$158 million to settle a Texas lawsuit alleging the company's improper marketing of the antipsychotic Risperdal caused the state's Medicaid program to overpay for the drug.

It is the latest legal setback related to Risperdal, which was once J&J's top-selling drug. Would-be whistleblowers and government prosecutors have alleged in suits that J&J promoted Risperdal for unauthorized uses and misrepresented its risks.

Last year, a South Carolina judge ordered J&J to pay \$327.1 million after a jury found J&J's Janssen unit violated the state's unfair trade-practice law in the marketing of Risperdal. In Louisiana in 2010, a jury ordered J&J to pay \$257.7 million in a Risperdal case. J&J has appealed the cases.

J&J also has an agreement in principle to plead guilty to a misdemeanor violation of a federal law in connection with a Justice Department investigation of its Risperdal marketing practices. It is in talks to settle civil allegations in connection with the federal case, which could result in additional payouts.

J&J spokeswoman Teresa Mueller said the company wasn't admitting any liability or fault in settling the allegations.

-- Peter Loftus

WINN-DIXIE

Grocery Chain Recalls

Some Leasa Brand Sprouts

Winn-Dixie Stores Inc. said it is voluntarily recalling some Leasa brand sprouts due to potential exposure to salmonella.

Winn-Dixie, which operates about 480 retail grocery stores in the Southeast, said as a precautionary measure it will recall Leasa's broccoli sprouts, gourmet sprouts, spicy sprouts and onion sprouts from all of its stores. Recalled sprouts were sold from Jan. 7 to Jan. 18 with expiration dates between Feb. 1 and March 15.

-- Tess Stynes

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Document J000000020120120e81k0002z

Business FDA Warns of Mix-Up in Pills by Novartis

By Jennifer Corbett Dooren
716 words
10 January 2012
The Wall Street Journal Online
WSJO
English
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The Food and Drug Administration warned of potential mix-ups involving certain prescription pain pills and over-the-counter medicines that were made at a Novartis AG manufacturing plant in Nebraska.

Novartis is recalling 1,645 lots of its Excedrin, NoDoz, Bufferin and Gas-X medicines because the products could contain stray capsules or caplets from other products, or "contain broken or chipped tablets."

The plant in Lincoln, Neb., where the products are manufactured was shut down last month. The plant also makes some opioid prescription painkillers for Endo Pharmaceuticals Holdings Inc., including Opana, Percocet and an extended-release version of morphine tablets.

Both Novartis and the FDA said they weren't aware of any adverse events in patients from any mix-ups. Novartis said it was offering customers a refund.

The company said Gas X Prevention is the only Novartis product manufactured on the same line as the Endo products and that it doesn't have any reports of any mix-ups of those medicines.

Novartis is the most recent company to suffer from production problems. Just last month Johnson & Johnson's McNeil Consumer Healthcare unit recalled 12 million bottles of Motrin, saying some pills may not dissolve as quickly as intended. That company has been plagued by manufacturing quality problems since 2009 and has dozens of product recalls including Tylenol and Benadryl.

However, "given existing inventories, the expected restart of Novartis production and our ability to shift production to other facilities we believe the supply constraints of our products should be limited," said Julie McHugh, the company's chief operating officer.

Novartis said it would take a charge estimated at \$120 million in the fourth quarter of 2011 related to the recalls and the work needed to fix the Lincoln facility.

"We are committed to a single quality standard for the entire Novartis Group and we are making the necessary investments and committing the right resources to ensure these are implemented across our entire network," Joseph Jimenez, the Swiss company's chief executive, said.

Edward Cox, a director in FDA's office of new drugs, said there's a potential for tablets to be retained in a machine involved in the product packaging process but said the FDA couldn't comment further on the ongoing investigation into the plant's problems.

Mr. Cox said the agency opted against asking for a recall of Endo's prescription pain products because the potential for drug mix ups appeared to be low and pharmacists can screen for any problems before the pain pills reach consumers. He said there's been three reports of mix-ups since 2009 that were caught by pharmacists. Endo on Monday said there may be a short-term disruption in the supply of some of its pain products and recommended that doctors refrain from starting new patients on the extended-release version of Opana to preserve supply for existing patients.

A July inspection report released by the FDA cited several consumer complaints of certain formulations of Excedrin being mixed up. For example some consumers said they found Excedrin Migraine Tablets being mixed with Excedrin Migraine caplets or geltabs. The agency said Novartis failed to adequately investigate 166 complaints related to "foreign tablets in your drug products since 2009."

Specifically Novartis is recalling three types of Bufferin, an aspirin product, and Gas-X Prevention, a food-enzyme supplement, with expiration dates of Dec. 20, 2013 or earlier. The company is recalling certain bottle sizes of its pain medicine Excedrin and NoDoz products with expiration dates of Dec. 20, 2014 or earlier. NoDoz contains caffeine and is marketed as an alertness product.

Detailed information about the recalled products can be found at www.novartisOTC.com.

Corrections & Amplifications

An earlier version of this article said the FDA warned of potential mix-ups of prescription pain pills and over-the-counter medicines like Excedrin and NoDoz made at a Novartis AG manufacturing plant in Nebraska, Late Monday, the company said that only Gas-X is produced on the same manufacturing line as the prescription drugs and that it doesn't have any reports of mix-ups in those medicines.

Write to Jennifer Corbett Dooren at jennifer.corbett-dooren@dowjones.com

Document WSJO000020120110e81a0006s

CFO Report, 13:55, 28 December 2011, 353 words, By Vipal Monga, (English) While Johnson & Johnson may be facing bad publicity from its recall of metal hip replacement parts, as detailed in the New York Times today, the liabilities associated with the recall and litigation have so far had minimal impact on the ...

Document WCCFO00020111228e7cs000dx

WSJ Blogs, 10:13, 22 December 2011, 998 words, By Katherine Hobson, (English)
Johnson & Johnson said it recalled about 12 million bottles of Motrin brand
painkillers because some pills may not dissolve quickly, delaying pain relief.

Document WCWSJB0020111222e7cm004ph



U.S. EDITION

Corporate News: New Lapses at J&J's Doxil Supplier --- Container of Suspected Urine Among Problems Cited at Ben Venue's Ohio Plant

By Peter Loftus
901 words
9 December 2011
The Wall Street Journal
J
B4
English
(Copyright (c) 2011, Dow Jones & Company, Inc.)

New quality and sterility lapses cited by regulators at a troubled drug manufacturer's Ohio plant are highlighting challenges posed by the increasing reliance of big drug makers on contractors for manufacturing.

The lapses, including the discovery of a container suspected to hold urine, were uncovered during a recent inspection of a supplier, Ben Venue Laboratories Inc., of Johnson & Johnson's cancer drug Doxil. Problems at Ben Venue have caused a number of disruptions in medicines the company manufactures. There have been severe shortages of Doxil, which treats ovarian and other cancers, leaving 2,700 patients on a waiting list.

European regulators recently recommended the recall of three other cancer drugs manufactured by Ben Venue, citing contamination risks. And other drugs made at the plant have been in short supply or recalled.

Ben Venue spokesman Jason Kurtz said the company, which shut down manufacturing at its Bedford, Ohio, plant last month, is working on "appropriate corrective actions to address the observations" of regulators and to bring products back to patients as soon as possible.

The ongoing challenges for Ben Venue shine light on a little-known aspect of the pharmaceutical industry -- big drug companies don't directly make all their own products, and they increasingly farm out work to contractors like Ben Venue.

As drug companies cut back on their own manufacturing, these contractors have played a growing role. In biologic manufacturing alone, contractor work is worth about \$2.1 billion and is expected to grow 5% to 10% annually over the next five years, according to research firm HighTech Business Decisions. Other players in the industry include Patheon Inc. and Vetter Pharma International Inc., and some big drug makers including Abbott Laboratories operate contract businesses.

"A lot of drugs are made on contract without any problems," said Stephen Byrn, professor of medicinal chemistry in Purdue University's department of industrial and physical pharmacy. "The quantities made safely are in large numbers."

But while pharmaceutical companies and U.S. regulators maintain oversight of contractors, supply and quality setbacks can still arise. If a contractor makes drugs for many companies, quality problems can have far-reaching ripple effects. And if a contractor is the sole supplier for a drug, as is the case with Doxil, the problem is exacerbated.

"The trend is more outsourcing," said Prabir Basu, executive director of the National Institute for Pharmaceutical Technology and Education, a not-for-profit organization that conducts research on drug development and manufacturing. Large drug companies, he said, try to keep tabs on contractors to "bring them to the standard they want. Sometimes they're successful and sometimes they're not."

Ben Venue, a unit of Boehringer Ingelheim GmbH, makes sterile, injectable drugs on behalf of multiple drug companies, including J&J, Celgene Corp. and certain European drug makers.

New findings about Ben Venue, which has been cited in previous inspections, were included in a report by the U.S. Food and Drug Administration regarding an inspection from Nov. 7 to Dec. 2. According to the report, Ben Venue in September began investigating a 10-gallon can in a storage area of its plant that contained an unknown liquid. An independent laboratory test found substances consistent with urine, the report said.

The FDA said Ben Venue failed to follow established procedures during its investigation and that the probe was past due.

Ben Venue's Mr. Kurtz said the company immediately began an investigation of the container, which he called an "isolated incident," and reported the incident to the police.

Problems at the plant have hit Doxil especially hard. J&J says U.S. Doxil sales plunged 87% to \$10 million for the third quarter.

J&J has created an allocation program requiring doctors to sign up patients to receive the drug. About 2,000 patients received supplies but about 2,700 remain on a waiting list. A spokeswoman said J&J has identified a potential alternative supplier, but the transition will likely take time.

Maggie Heim, an attorney in Los Angeles, had a recurrence of ovarian cancer in the summer and her oncologist told her Doxil would be a good option. But she wasn't able to get it, and instead began another chemotherapy regimen. She responded well, but she is uncertain whether the absence of Doxil will affect her long-term prognosis.

"It makes me angry and frustrated that in a country like ours people can't get the medication that our scientists have been so good about formulating," she said.

The shortage has also interrupted or delayed clinical trials of cancer drugs being tested with or against Doxil. Patient studies of drugs from Amgen Inc., Celgene Corp. and Eli Lilly & Co. are among those affected.

Manufacturing Issues

Some of the drugs produced at Ben Venue's Ohio facility that have been affected by the contractor's recent manufacturing problems:

- -- Lantheus Medical Imaging's Definity, Neurolite and Cardiolite -- injectable agents for medical-imaging procedures
- -- The Medicines Co.'s Angiomax -- anticoagulant
- -- Bedford Laboratories' Indomethacin -- arthritis pain reliever
- -- J&J's Velcade -- for multiple myeloma and mantle cell lymphoma
- -- J&J's Doxil -- injectable drug for ovarian and other cancers

WSJ research

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Business Briefs

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Forestry

Sino-Forest's Investigation Won't Include Tree Valuation

A special investigation into claims of fraud at Sino-Forest Corp. won't include an independent valuation of the trees the Chinese forestry company says it owns, leaving open a key question raised by a short seller whose report sent the company's shares plunging 65%.

Last week, the company said a special committee of Sino-Forest's board of directors had found no fraud at the company. The committee said in its report that it intended to complete its probe by the end of the year, and that one of its remaining pieces of business was to "engage an independent valuator."

A company spokesman said Wednesday, however, that the valuation of Sino-Forest's assets won't be finished by the time the investigation wraps up at year-end. It is expected to take until early in 2012.

Sino-Forest's shares collapsed earlier this year after a report by short-selling research firm Muddy Waters LLC said the company was a "near total fraud." Its Toronto-listed stock has been suspended since August, its founder and chief executive has resigned, and it is under investigation by the Ontario Securities Commission and the Royal Canadian Mounted Police.

The special panel has spent five months and \$35 million on its inquiry, using more than 100 auditors and three law firms. Last week it emphatically rejected Muddy Waters' allegations and affirmed the company's ownership of the timber and of the cash recorded on its books.

One of the last major concerns to investors and investigators is what the trees are worth. Despite earlier statements that implied that the committee would hire an independent consultant to determine whether the valuations were accurate, the company spokesman said the committee's final report won't include that information.

The report said the investigators had hired a firm to do the valuation but the effort was abandoned after concerns arose about the firm's independence from Sino-Forest.

The true value of Sino-Forest's timber is at the heart of some of the accusations made by Muddy Waters.

It alleges that Sino-Forest manipulated the results of a third-party timber valuation. The short seller also claims that the value of the trees in company accounts was inflated because Sino-Forest purchased them from related parties and paid more than it should have.

Duncan Mavin

Manufacturing

Deere's Net Profit Rises 46%

Deere & Co. posted a 46% rise in fiscal-fourth-quarter earnings as the agricultural- and construction-equipment maker benefited from stronger volume and pricing, as well as currency fluctuations.

Deere also projected profit of \$3.2 billion for the new fiscal year, above the \$2.92 billion forecast of analysts polled by Thomson Reuters. The world's largest manufacturer of farm machinery expects equipment sales to rise 15% for the year.

The company's profit growth has been driven recently by strong demand for agricultural equipment as commodities prices have remained high. However, recent economic uncertainty has led some analysts to worry that high commodities prices may not be enough to sustain the sector in the coming year. Heavy machinery equipment demand continues to face challenges from weak construction markets.

Like other manufacturers, Deere also has been grappling with rising costs for materials such as steel, copper, tires and components.

For the quarter ended Oct. 31, Deere reported a profit of \$669.6 million, or \$1.62 a share, up from \$457.2 million, or \$1.07 a share, a year earlier. Revenue increased 20% to \$8.61 billion. Analysts polled by Thomson Reuters most recently forecast earnings of \$1.43 a share on revenue of \$7.87 billion.

Equipment sales climbed 20% to \$7.9 billion, with foreign exchange contributing two percentage points of growth. Sales jumped 14% in the U.S. and Canada. They increased 31% elsewhere, with foreign-exchange fluctuations providing a four-percentage-point boost.

Farm machinery sales rose 18% on higher volume and prices. At Deere's smaller construction and forestry-equipment segment, sales were up 34% mainly on increased volume.

Tess Stynes

Pharmaceuticals

EU Regulators Recommend Recall of Three Cancer Drugs

European health regulators recommended a precautionary recall of certain batches of three cancer drugs and restricted use of a fourth, after inspectors found potential contamination risks at the Ohio contract-manufacturing plant where they were made.

Johnson & Johnson's Velcade, Celgene Corp.'s Vidaza and Pierre Fabre Médicament's Busilvex were recommended for recall, according to a statement from the European Medicines Agency.

The recalls affect only batches of these drugs made by Ben Venue Laboratories at its Bedford, Ohio, plant. Batches from alternative suppliers aren't being recalled.

The recalls mark the latest fallout from problems at Ben Venue's contract-manufacturing plant. Equipment failures earlier this year led to a shortage of J&J's cancer drug Doxil, which has cut off treatment for many patients and left 2,700 people on a waiting list because Ben Venue has been the sole supplier of Doxil. Regulators also identified deficiencies at the site earlier this year.

Peter Loftus

Technology

HTC Lowers Revenue Forecast On Weakening Global Demand

Smartphone maker HTC Corp. said it has lowered its forecast for fourth-quarter revenue due to weakening global demand and intensifying competition.

HTC, which built market share in the U.S. and Europe through its early adoption of the Android platform for mobile phones, now expects its revenue for the period to be "largely similar" to the year-earlier level. That compares with its forecast on Oct. 31, when it said it expected revenue growth of between 20% and 30% from a year earlier to a range of 125 billion-135 New Taiwan dollars (US\$4.1 billion-US\$4.4 billion). The company's revenue in the fourth quarter of 2010 was NT\$104 billion.

HTC said it expects growth momentum to resume in the first half of next year, but the downward revision comes as a blow as HTC's previous fourth-quarter guidance had already disappointed analysts.

It also follows news that S3 Graphics, a subsidiary HTC recently bought for US\$300 million, lost a suit in the U.S. International Trade Commission that said Apple Inc. didn't violate two of HTC's patents. The Taipei-based smartphone maker has defended its decision to purchase S3, but investors have since questioned the move.

Though demand for smartphones is likely to continue to be strong as consumers switch from traditional cellphones, HTC's revenue revision reflects the challenges it faces as demand in mature markets like Europe and the U.S. continue to slip and markets elsewhere continue to become more competitive with companies like Apple, Samsung Electronics Co., Nokia Corp. and Motorola Mobility Holdings Inc. all releasing premium smartphones.

Analysts had worried, in particular, that the release of the iPhone 4S along with the Samsung's Galaxy Nexus would hurt HTC's ability to sell its products in the run-up to the Christmas holiday season. There has also been general concern about how well HTC can differentiate itself from the growing number of smartphone makers releasing phones that also run on Google Inc.'s Android and Microsoft Corp.'s Windows platforms.

During an investor call Oct. 31, the company said it expected to ship between 12 million and 13 million phones in the fourth quarter, slightly down from the 13.2 million it shipped in the third quarter, marking its first quarter-to-quarter drop in shipments since the first quarter of 2010.

Paul Mozur

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-- Paul Mozur

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Business
J&J Profit Falls 6.3% on Deal Costs

By Peter Loftus 660 words 19 October 2011 The Wall Street Journal Online WSJO English

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Johnson & Johnson reported a 6.3% decline in third-quarter profit on costs related to a planned medical-device acquisition, while favorable currency-exchange rates helped lift sales amid sluggish U.S. market conditions.

The health-care giant, which makes products ranging from Band-Aids to anti-inflammatory drug Remicade, also adjusted its forecast of full-year 2011 earnings, slightly lifting the bottom end of the estimate range.

J&J, New Brunswick, N.J., has been grappling with both internal and external challenges. The sluggish economy and pricing pressure from health payers have damped sales growth for certain businesses, while manufacturing-quality lapses have led to a series of product recalls, mostly in J&J's over-the-counter medicine business.

J&J is trying to overcome these challenges partly by fixing its manufacturing facilities, launching new products including prostate-cancer drug Zytiga, and expanding its medical-device unit through the planned acquisition of Synthes Inc. for about \$21 billion.

"In the current period, we continue to see challenging macro-economic conditions," J&J Chief Financial Officer Dominic Caruso said on a conference call with analysts Tuesday. "Despite these near-term head winds, I'm encouraged by the business outlook for our company."

For the third quarter, J&J said it earned \$3.2 billion, or \$1.15 a share, compared with \$3.4 billion, or \$1.23 a share, a year earlier. The latest quarter included a mark-to-market adjustment associated with a currency option and deal costs related to the planned acquisition of Synthes. Excluding these, earnings would have been \$1.24 a share, ahead of the \$1.21-per-share mean estimate of analysts surveyed by Thomson Reuters.

Expenses were also on the rise. Cost of goods sold rose 10%, which Mr. Caruso attributed to ongoing remediation efforts for the McNeil Consumer Healthcare business. Selling, marketing and administrative expenses rose 11%, partly due to spending on new product launches like Zytiga, Mr. Caruso said.

Edward Jones analyst Linda Bannister said that although such expenses were higher than expected, the spending on new products should help J&J in the long run. "The new products are off to a solid start," she said.

Sales rose 6.8% to \$16 billion, just short of the Thomson estimate of \$16.02 billion. Favorable currency rates contributed 4.2 percentage points of the growth. U.S. sales dropped 3.7%, while non-U.S. sales rose 16.4%.

J&J's biggest unit, medical devices and diagnostics, had sales of \$6.3 billion, up 6% from a year earlier. Sales growth was helped by products for diabetes care, joint-replacement parts and surgical products. The cardiovascular care division continued to post sales decline due to diminished sales of drug-coated stent devices, a business J&J has decided to exit.

J&J expects to close its planned acquisition of Synthes in the first half of 2012, Mr. Caruso said.

J&J's pharmaceutical unit sales increased 9% to \$5.98 billion, with Remicade gaining 15%, HIV drug Prezista up 37% and cancer drug Velcade up 20%.

Sales of antibiotic Levaquin plunged 91% due to generic competition. U.S. sales of cancer drug Doxil dropped 87% due to a shortage caused by production problems at a contract manufacturer.

J&J's consumer unit sales rose 5% to \$3.74 billion, helped by baby-care, skin-care and oral-care products. Combined sales of over-the-counter medicines and nutritional products in the U.S. dropped 24% due to a series of recalls of OTC medicines stemming from manufacturing-quality lapses.

J&J said it expects to ship a limited supply of certain recalled OTC products later this year, and to reintroduce products throughout 2012.

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

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U.S. EDITION

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ALIBABA.COM

HiChina Unit Is Seeking

A Separate Listing in U.S.

Chinese e-commerce portal Alibaba.com Ltd. said Monday its non-wholly-owned unit, HiChina Group Ltd., is seeking a separate listing of its shares in the U.S.

Hong Kong-listed Alibaba, which operates websites connecting buyers and suppliers, said it has submitted a proposal to the Hong Kong Stock Exchange related to a proposed spinoff of HiChina Group.

The proposed offering is currently under review by the relevant securities regulatory authority, Alibaba said, adding that details of the offering, including its size and price, haven't yet been finalized.

HiChina is a provider of Internet infrastructure services including those related to domain names, traditional hosting, cloud-based services and website construction for small- and medium-size enterprises in China, it said.

-- Joanne Chiu

AUTOS

Sales Keep Strong Pace

As Inventories Recover

U.S. auto sales are running at the strongest pace since April as vehicle inventories recover for Toyota Motor Corp. and Honda Motor Co., said Ford Motor Co. sales analyst George Pipas.

The annualized rate of sales in September is tracking at about 12.5 million cars and light trucks on a seasonally adjusted rate, the highest since April.

Inventories have been below normal for months for Toyota and Honda because of production slowdowns caused by parts shortages stemming from Japan's natural disaster in March.

With Honda and Toyota restocked, by the end of October there "will be no excuses" for the strength of auto sales, Mr. Pipas said Friday.

-- Mike Ramsey

JOHNSON & JOHNSON

Syringes of Anemia Drug

Are Recalled in 17 Countries

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Johnson & Johnson has recalled about 200,000 syringes of its Eprex anemia drug in 17 countries, including Canada and the U.K., after internal testing revealed some batches of the drug were less potent than necessary.

J&J believes most of the product from the affected lots already has been consumed, and that fewer than 6,300 syringes remain on the market, said spokesman Stefan Gijssels.

J&J, based in New Brunswick, N.J., has issued a series of product recalls across its diversified businesses over the past two years due to manufacturing-quality problems, ranging from over-the-counter medicines to contact lenses to joint-replacement parts. The biggest concentration of recalls has been among over-the-counter medicines such as Tylenol, and J&J is gradually reintroducing such brands to the market.

"We have made this decision after standard internal quality testing of samples identified a potency issue," Mr. Gijssels said. "No related adverse events have been reported with these batches."

The two batches subject to recall had expiration dates of January 2012. In addition to the U.K. and Canada, the affected countries were: Albania, Australia, Belgium, Egypt, France, Germany, Ireland, Israel, Italy, New Zealand, Portugal, Russia, Spain, Sweden and Taiwan.

-- Peter Loftus

AMAZON

Online Retailer Wins

California Tax Reprieve

California Gov. Jerry Brown on Friday signed compromise legislation granting Amazon.com Inc. a reprieve from collecting state sales tax after the company offered the promise of thousands of jobs, a development that comes as the online retail giant takes up a broader sales-tax fight on multiple fronts.

The bill pushes back by a year the time when Amazon and other Internet retailers would have to start collecting sales tax in California. It now says they have to start collecting the tax there by September 2012, but only if Congress fails to act on a federal measure.

In exchange, Amazon has agreed to create at least 10,000 full-time jobs in the state and hire 25,000 seasonal employees by the end of 2015.

Seattle-based Amazon has said it wants a federal law to cover the issue, rather than a state-by-state system.

-- John Letzing

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WSJ Blogs, 09:34, 23 September 2011, 1022 words, By Katherine Hobson, (English)
Johnson & Johnson has recalled about 200,000 syringes of its Eprex anemia drug at the wholesale and pharmacy level because some batches of the drug may not be sufficiently potent.

Document WCWSJB0020110923e79n005ei

Business
J&J Recalls Syringes of Anemia Drug

By Peter Loftus 313 words 23 September 2011 08:22 The Wall Street Journal Online WSJO English

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Johnson & Johnson has recalled about 200,000 syringes of its Eprex anemia drug in 17 countries, including Canada and the U.K., after internal testing revealed some batches of the drug were less potent than necessary.

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"We have made this decision after standard internal quality testing of samples identified a potency issue," Mr. Gijssels said. "No related adverse events have been reported with these batches."

He said J&J issued the recall as a safety precaution at the pharmacy and wholesale level. The company has sufficient stock to replace the recalled products.

The two batches subject to recall had expiration dates of January 2012. In addition to the U.K. and Canada, the affected countries were: Albania, Australia, Belgium, Egypt, France, Germany, Ireland, Israel, Italy, New Zealand, Portugal, Russia, Spain, Sweden and Taiwan.

Eprex, which is injected or infused intravenously, is approved to boost certain blood components and help avoid blood transfusions in people with conditions such as chronic kidney failure. It is similar to J&J's Procrit, which is marketed in the U.S.

Combined Eprex and Procrit sales were \$1.9 billion for 2010.

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

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Business

J&J Resumes Shipments of Tylenol Flu Caplets

By Jonathan D. Rockoff
451 words
22 September 2011
The Wall Street Journal Online
WSJO
English
Copyright 2011 Dow Jones & Company, Inc. All Rights Reserved.

Johnson & Johnson began shipping Tylenol Cold & Flu Severe caplets this week, in a step toward recovery from lengthy recalls of popular over-the-counter medicines that have cost the company more than a billion dollars in lost sales.

The health-products giant announced the resumption of shipments in an internal message to employees reviewed by The Wall Street Journal. J&J is making the caplets at a pharmaceuticals plant in Latina, Italy, and they will reappear on store shelves "within weeks," the announcement said.

A spokeswoman for J&J's McNeil Consumer Healthcare unit confirmed that the company is resuming shipments.

The Tylenol flu caplets will be among the first medicines to go back on sale since manufacturing problems and recalls beginning in late 2009 prompted J&J to shuffle management and shut down a key manufacturing plant for an upgrade. Among the issues that J&J and regulators found were metal shavings floating in some children's medicine bottles, as well as a musty smell associated with other liquid medicines. The problems dented J&J's image and led to a congressional investigation.

The company has said the problems cost \$900 million in lost sales last year. J&J will lose more than \$1 billion in sales this year, according to Wells Fargo estimates. Market shares of rival products, including private-label brands, have risen in the absence of J&J's popular brands.

The Tylenol flu caplets return in time for the cold-and-flu season, a period of intense demand.

J&J executives say they have now turned a corner on the consumer division's manufacturing problems. "Products are coming back on the market," J&J Chief Financial Officer Dominic Caruso told investors at a conference last week. "The business is recovering."

First to resume manufacturing, late last year, was a grape-flavored version of children's Tylenol. Tablets of ulcer remedy Pepcid Complete, whose availability was interrupted due to manufacturing improvements, should begin shipping to stores later this year, the company said.

Most Tylenol products remain off the market still. Tuesday's internal announcement said certain Tylenol Sinus, Sudafed and Benadryl medicines will be back in stores early next year.

One reason for the delays is J&J needed to find new places to manufacture the recalled medicines and equip the plants. And under terms of a consent decree with the U.S. Food and Drug Administration, an independent expert must certify before any products can go back on sale.

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

Document WSJO000020110922e79m001ur

MA. M. Vitals: Johnson & Johnson's Flu Caplets to Return to Shelves

WSJ Blogs, 06:47, 22 September 2011, 333 words, By Katherine Hobson, (English)
Flu Caplets Are Back: Johnson & Johnson has begun shipping Tylenol Cold & Flu Severe caplets to stores once again after the medication -- like many other Tylenol products -- was recalled due to production problems, the WSJ reports. ...

Document WCWSJB0020110922e79m002bg

Business
Tylenol Supplies Low for Flu Season

By Kristen Gerencher
898 words
18 September 2011
The Wall Street Journal Online
WSJO
English
Copyright 2011 Dow Jones & Company, Inc. All Rights Reserved.

A staple of the American medicine cabinet may be hard to come by this fall because of a slew of recalls -- but that's all the more reason to take a closer look at the cold and flu medications you stock at home.

Many kinds of Tylenol, the popular over-the-counter pain reliever and fever reducer, have been recalled in the last few years due to a moldy, musty smell and other quality concerns. That's led to Tylenol shortages in some areas as cold and flu season ramps up.

But experts say consumers can take advantage of unintended side effects that could be good for their health and pocketbook. They can talk with pharmacists about which over-the-counter remedies are safe and appropriate for them in light of new concerns about liver damage from accidental overdoses of acetaminophen, the active ingredient in Tylenol.

Consumers accustomed to buying Tylenol also can choose a generic alternative that's less expensive. Many drugstore chains offer their own store brands of acetaminophen, and they're typically at least a dollar cheaper than Tylenol for the same quantity of identical-dosage drugs.

"Generics may use a different type of salt or sugar to compose it, but it has the same active ingredient, which is acetaminophen," says Kristen Binaso, senior director of corporate alliances for the American Pharmacists Association and a pharmacist in Clifton, N.J.

Consumers should look for an asterisk or highlighted portion of the package that compares the generic drug with a known brand, she says. And they shouldn't be shy about asking a pharmacist if they get stumped when trying to figure out which drug or combination of drugs is right for them.

"It's a great opportunity to talk to their pharmacist... and maybe we [pharmacists] can find a better match for what they're trying to treat." she says.

Tylenol products have been reappearing in parts of New Jersey, Ms. Binaso says. But people seeking Tylenol would be wise to tap an online resource from its manufacturer before heading out the door.

The manufacturer, McNeil Consumer Healthcare, a unit of Johnson & Johnson, offers a locator at Tylenol.com that allows people to type in their ZIP Code and find the nearest stores that have a variety of Tylenol products in stock. The company updates the information weekly, says McNeil spokeswoman Bonnie Jacobs. Still, the website lists the stores' phone numbers and advises consumers to call to make sure their desired product is indeed on the shelves. The locator doesn't include Wal-Mart stores.

Earlier this year, three McNeil-operated manufacturing facilities in Pennsylvania and Puerto Rico came under tighter scrutiny from the U.S. Food and Drug Administration. The FDA now requires independent reviews before certain products can be released, causing shipping delays.

Tylenol's manufacturer has issued numerous recalls of product lots, including Children's Tylenol, since 2009. The recalls extended to their other medicines available without prescription, such as Benadryl, Sudafed and Motrin, causing some shortages of those drugs as well. The company maintains that health risks associated with taking recalled products are remote. Consumers can call McNeil's recall help line at 888-222-6036 or visit mcneilproductrecall.com.

Meanwhile, it's a good time for consumers to check their pain-relief habits and assumptions. Acetaminophen can be found in more than 600 over-the-counter and prescription medications, according to McNeil. It's in many Page 50 of 164 © 2021 Factiva, Inc. All rights reserved.

combined cough and cold remedies in addition to stand-alone products, and consumers have to guard against harming themselves by unintentionally doubling doses when they take multiple medicines at the same time.

Taking more acetaminophen than advised can set people up for severe liver damage that might result in death or the need for a liver transplant in extreme cases, says Michael Carome, deputy director of Public Citizen's Health Research Group in Washington.

"Limiting the dose, in terms of total amount in a particular dose and the total amount per day, and avoiding alcohol are critical things to do when taking this medicine," he says.

In January, the FDA lowered the per-dose limit of acetaminophen in prescription painkillers that contain it, such as Vicodin and Percocet, to no more than 325 milligrams per tablet. It didn't change the standards for over-the-counter acetaminophen products.

But McNeil recently announced it would lower the maximum daily dose of its Extra Strength Tylenol to six pills a day, or 3,000 milligrams, down from eight pills a day, or 4,000 milligrams, in its dosing instructions. It's also putting more space between doses -- recommending two pills every six hours, instead of every four to six hours. The company said: "The change is designed to help encourage appropriate acetaminophen use and reduce the risk of accidental overdose."

Dr. Carome calls the lower maximums a step forward but says they don't go far enough to prevent accidental overdoses from popular products such as Extra Strength Tylenol.

"We believe the FDA should require that the over-the-counter 500-milligram tablets of acetaminophen be removed from the market," he says. "For most people, regular-strength acetaminophen, whether you take it for pain or fever, should be more than sufficient."

Write to Kristen Gerencher at kgerencher@dowjones.com

Read more at marketwatch.com.

Document WSJO000020110917e79i004mp

WSJ Blogs, 15:21, 15 August 2011, 973 words, By Katherine Hobson, (English)
Johnson & Johnson is recalling from wholesalers and stores almost 2.5 million packages
of Tylenol Cold Multi-Symptom Nighttime Rapid Release Gelcaps.

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Business J&J's Tight Staffing Contributed to Recalls, Report Says

By Peter Loftus 756 words 22 July 2011 14:19 The Wall Street Journal Online WSJO English

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Johnson & Johnson's recent efforts to cut costs by laying off employees and avoiding new hires may have contributed to the manufacturing-quality problems behind a damaging series of medicine recalls over the past two years, a company report said.

A report of an internal investigation led by J&J's independent directors cites "periodic headcount freezes" and "a virtual hiring freeze" at J&J's McNeil Consumer Healthcare unit among the factors behind the recalls. The report also cites staff reductions in certain J&J corporate departments that were supposed to oversee global quality and regulatory compliance.

The McNeil Consumer Healthcare unit has recalled millions of bottles of popular medicines such as Tylenol and Motrin since 2009 for defects ranging from musty odors to floating particles in liquid formulations. J&J says the defects didn't pose serious health risks. J&J's financial results and reputation have been damaged as a result of the recalls, which have continued into this summer.

The independent directors investigated the McNeil recalls and other problems at J&J in response to shareholder demands and lawsuits alleging that certain J&J officers and directors breached their fiduciary duties by allowing improper activities to occur across the company.

J&J's board on Monday adopted recommendations made in the report—to create a regulatory and compliance committee of the board, and not to pursue litigation against the officers and directors accused by shareholders of breaching their fiduciary duties. The report concludes that senior J&J management and the board largely acted properly in their handling of the recalls and other lapses.

J&J has laid off thousands of employees since 2007 in response to drug-patent expirations and economic pressures. The job cuts have been aimed at reducing J&J's annual expenses by hundreds of millions of dollars.

The directors' report doesn't explicitly cite the broad scope of the layoffs, but it does show that under-staffing in certain areas played a role in the McNeil quality problems.

In 2007, J&J cut its world-wide quality-and-compliance staff by 35% to 28 from 43 workers, and reduced its worldwide health-care compliance staff by 25% to 12 from 16 workers. Some of these staffs' functions were transferred to individual J&J divisions.

The report said the restructuring of J&J's corporate quality and compliance staffs in 2007 was a "potential contributing factor to the apparent failure of the checks and balances" when it came to overseeing McNeil.

At McNeil's manufacturing plants, "there seemed to be a lack of attention to product quality" by certain non-quality control workers, such as engineering and operations, which produced tension between quality control and operations, the report said.

"Periodic head-count freezes and an emphasis on production volume may have contributed to this situation," the report said.

As J&J tried to integrate its December 2006 purchase of Pfizer Inc.'s consumer-health unit, McNeil had trouble transferring the acquired products to its own plants. Quality and compliance staffing "may not have increased sufficiently to adjust to this added complexity," the report said.

Some of the over-the-counter medicines acquired from Pfizer, such as Benadryl and Sudafed, were later recalled by J&J.

Also, "a virtual hiring freeze in 2008-2009 made it difficult to hire additional McNeil Quality personnel," the report said

A quality site leader position at McNeil's Las Piedras, Puerto Rico, plant went unfilled for more than four months during 2009, the report said. A committee overseeing J&J's consumer operations didn't have a chief compliance officer until June 2008, the report said.

"With reduced central oversight and tasked with implementing the Pfizer Healthcare acquisition, some McNeil employees may have lost focus and commitment to maintain quality standards," the report said.

The McNeil recalls reached critical mass last year, and in response McNeil shut down its Fort Washington, Pa., plant. Some 300 workers were laid off in the process.

But in the summer of 2010, after much of the damage was done, McNeil was placing help-wanted ads for a key area: quality control workers.

A J&J spokeswoman said the report speaks for itself and the company can't comment further because of the ongoing litigation.

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

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EUROPE EDITION

J&J Profit Falls 20% On Charges

By Peter Loftus
527 words
20 July 2011
The Wall Street Journal Europe
WSJE
19
English
(Copyright (c) 2011, Dow Jones & Company, Inc.)

Johnson & Johnson on Tuesday posted a 20% drop in second-quarter profit on costs tied to the exit of a heart-device business, and expressed concern about pressures on health-care markets in a sluggish U.S. economy.

Executives at the health-care giant said lower rates of elective surgical procedures and patient visits to doctors' offices, together with pricing pressures, were keeping a lid on sales growth for certain businesses, including medical devices and diagnostics.

"I think it's fair to say that these head winds are proving to be stronger and more persistent than we would have hoped, and we're feeling their effects," Alex Gorsky, vice chairman of J&J's executive committee, said on a conference call with analysts.

Nevertheless, J&J's second-quarter results exceeded Wall Street expectations, including an 8% revenue gain. Sales were helped by favorable currency-exchange rates and a return to growth for its consumer-products unit, despite a series of recalls of over-the-counter medicines including Tylenol.

The New Brunswick, N.J., maker of products ranging from Band-Aids to the anti-inflammatory drug Remicade flexed its diversification muscles. Sales growth of pharmaceutical and medical-device products helped offset the sales decline for the OTC drugs that have been subject to a series of product recalls since 2009 due to manufacturing-quality lapses.

J&J, which in recent months has secured regulatory approval for three new prescription drugs, including a prostate-cancer treatment, also reiterated its full-year profit outlook. The company said planned higher investment spending and uncertainty about the economy factored into its decision to leave its forecast unchanged.

J&J said earnings for the second quarter declined to \$2.78 billion, or \$1 a share, from \$3.45 billion, or \$1.23 a share, a year earlier. The latest quarter included a restructuring charge of \$549 million tied to its June announcement it would exit the market for drug-coated stents, which are tiny devices that prop open clogged arteries. J&J is leaving the business following slumping sales and research setbacks.

The quarter also included a net charge of \$223 million for litigation-related expenses; additional costs for the recall of hip-replacement parts; and a gain associated with J&J's planned acquisition of medical-device maker Synthes.

Excluding the items, earnings were \$1.28 a share, above the mean estimate of \$1.24 a share by analysts surveyed by Thomson Reuters.

Sales rose 8% to \$16.6 billion, ahead of the Thomson estimate of \$16.2 billion. Favorable currency-exchange rates contributed 5.7 percentage points of growth.

J&J's biggest unit -- medical devices and diagnostics -- posted sales of \$6.6 billion, up 7% from a year earlier. Pharmaceutical sales rose 12% to \$6.2 billion. J&J's consumer unit sales rose 4% to \$3.8 billion, marking the first year-over-year gain for the unit since the first quarter of 2010.

Tess Stynes contributed to this article.

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Business
J&J Profit Falls 20% on Charges

By Peter Loftus 807 words 19 July 2011 10:21 The Wall Street Journal Online WSJO English

Copyright 2011 Dow Jones & Company, Inc. All Rights Reserved.

Health-care giant Johnson & Johnson on Tuesday reported a second-quarter profit decline of 20% on costs related to the exit of a heart-device business, and expressed concern about persistent pressures on health-care markets as a result of the sluggish economy.

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"I think it's fair to say that these head winds are proving to be stronger and more persistent than we would have hoped, and we're feeling their effects," Alex Gorsky, vice chairman of J&J's executive committee, said on a conference call with analysts.

J&J shares fell 82 cents, or 1.2%, to \$66.27 in late morning trading Tuesday on the New York Stock Exchange.

Nevertheless, J&J's second-quarter results exceeded Wall Street expectations, including an 8% revenue gain. Sales were helped by favorable currency-exchange rates and a return to sales growth for its consumer-products unit, despite the drag from a series of recalls of over-the-counter medicines including Tylenol.

The New Brunswick, N.J., maker of products ranging from Band-Aids to the anti-inflammatory drug Remicade flexed its diversification muscles, with sales growth of pharmaceutical and medical-device products helping to offset the sales decline for the OTC drugs that have been subject to a series of product recalls since 2009 due to manufacturing-quality lapses.

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Excluding the items, earnings were \$1.28 a share, above the mean estimate of \$1.24 a share by analysts surveyed by Thomson Reuters.

A lower-than-expected effective tax rate also boosted earnings, said Wells Fargo analyst Larry Biegelsen.

Sales rose 8% to \$16.6 billion, ahead of the Thomson estimate of \$16.2 billion. Favorable currency-exchange rates contributed 5.7 percentage points of growth, accelerating a benefit that surfaced earlier this year. A weakening of the U.S. dollar against certain foreign currencies this year is providing a boost to U.S.-based multinational drug makers.

J&J's biggest unit—medical devices and diagnostics—posted sales of \$6.6 billion, up 7% from a year earlier. Sales increases for diabetes-care and surgical products helped offset continued declines in its heart-stent business.

Pharmaceutical sales rose 12% to \$6.2 billion. Its top-selling drug, Remicade, had sales of \$1.37 billion, up 21%. HIV drug Prezista and Velcade posted gains, while antianemia drugs Procrit and Eprex and antibiotic Levaquin had sales declines.

J&J's consumer unit sales rose 4% to \$3.8 billion, marking the first year-over-year gain for the unit since the first quarter of 2010. Combined sales of over-the-counter medicines and nutritionals dropped 33% in the U.S., due largely to the impact of recalls, as well as J&J's shutdown of a Pennsylvania plant to help fix the manufacturing-quality problems.

J&J has recalled OTC medicines for various problems, including musty odors. The recalls also have extended to other areas of J&J, including prescription drugs and devices, though J&J has insisted there is no company-wide breakdown in quality control.

To further address the recalls and various legal challenges, J&J's board Monday agreed to create a new regulatory and compliance committee, though it declined to pursue litigation against certain officers and directors who were accused in shareholder lawsuits of allowing various improper activities to occur.

Improved sales of skin-care and baby-care products helped the consumer unit.

Tess Stynes contributed to this article.

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

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U.S. EDITION

J&J Board Creates Panel In Response To Lawsuits

By Peter Loftus
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19 July 2011
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(Copyright (c) 2011, Dow Jones & Company, Inc.)

Johnson & Johnson's board of directors agreed Monday to create a new regulatory and compliance committee but decided against pursuing litigation against certain company officials in connection with recent manufacturing and legal challenges at the health-care giant.

The board's decisions follow the recommendations of a special committee of four independent directors, formed last year, to investigate allegations made by certain shareholders in so-called derivative lawsuits, which were brought on behalf of J&J against certain officers and directors, including Chairman and Chief Executive William Weldon.

Separately, a federal judge dismissed a lawsuit seeking monetary damages from J&J for consumers who bought the company's over-the-counter medicines including Tylenol, which have been subject to a series of recalls for quality problems since 2009.

The developments follow a series of setbacks that have tarnished J&J's reputation -- and hurt its financial performance -- since 2009. J&J has recalled products ranging from over-the-counter medicines to hip-replacement parts and resolved government probes of allegations of payments to foreign doctors, as well as improper drug marketing.

The shareholder lawsuits accused certain officers and directors of allowing improper activities to occur across J&J's businesses, allegedly in breach of their fiduciary duties to the company.

In a report filed in federal court in Trenton, N.J., on Monday, the special committee recommended the creation of a compliance committee to monitor oversight of compliance and quality issues, including J&J's obligations under various settlements of government investigations of improper conduct.

An attorney for the shareholders couldn't be reached.

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Business

J&J Board Creates Panel In Response to Lawsuits

By Peter Loftus
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19 July 2011
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Johnson & Johnson's board of directors agreed Monday to create a new regulatory and compliance committee but decided against pursuing litigation against certain company officials in connection with recent manufacturing and legal challenges at the health-care giant.

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Separately, a federal judge dismissed a lawsuit seeking monetary damages from J&J for consumers who bought the company's over-the-counter medicines including Tylenol, which have been subject to a series of recalls for quality problems since 2009.

The developments stem a series of setbacks that have tarnished J&J's reputation—and hurt its financial performance—since 2009. J&J has recalled products ranging from over-the-counter medicines to hip-replacement parts, and resolved government probes of allegations of payments to foreign doctors, as well as improper drug marketing.

The shareholder lawsuits accused certain officers and directors of allowing the improper activities to occur across J&J's businesses, allegedly in breach of their fiduciary duties to the company.

In a 127-page report filed in federal court in Trenton, N.J., on Monday, the special committee concluded that "it is not in the best interests of the company to pursue the derivative litigation currently pending or to initiate litigation based upon the demands made upon the board by the demand shareholders."

The committee said J&J's quality and compliance systems have been enhanced over the past several years.

The committee did, however, recommend the creation of a regulatory and compliance committee to monitor oversight of compliance and quality issues, including J&J's obligations under various settlements of government investigations of improper conduct.

In April, J&J agreed to pay nearly \$80 million to settle U.S. and U.K. allegations that it paid bribes to doctors in three European countries, as well as kickbacks to Iraq to illegally obtain business under former leader Saddam Hussein.

In March, the company signed a consent decree with the government which requires J&J to fix manufacturing-quality problems at three plants operated by its McNeil Consumer Healthcare unit.

Also, the company last year agreed to pay more than \$81 million to resolve a U.S. probe of its promotion of epilepsy drug Topamax for unauthorized uses.

J&J's board, with the exception of CEO Mr. Weldon, who didn't participate, unanimously adopted the committee's recommendations at a meeting earlier Monday, the company said in a court filing.

"The company's management takes the shareholder concerns and criticisms very seriously and appreciates that the independent Special Committee has given these matters careful consideration," said J&J spokeswoman Carol Goodrich.

An attorney for the shareholders couldn't immediately be reached.

The consumer lawsuit—a consolidation of several cases brought against the company beginning last year—alleged consumers paid inflated prices for substandard medicines, and weren't fully compensated by J&J's refund program.

But U.S. Judge Mary McLaughlin in federal court in Philadelphia dismissed the consumer lawsuit, ruling that the 27 people named as plaintiffs had no legal standing because they failed to demonstrate they suffered any economic injury as a result of J&J's alleged actions.

In a July 14 memo issued with her dismissal order, the judge said the lawsuit lacked important details, such as pinpointing which products were purchased by individual plaintiffs.

"The allegations of specific economic injury pertaining to the named plaintiffs ... are sparse," Judge McLaughlin wrote. She also said the lawsuit's allegations "are difficult to distill into a coherent summary."

Judge McLaughlin will permit the plaintiffs to file a new lawsuit within 30 days against J&J and some of its executives and directors.

However, the plaintiffs are barred from filing a new suit against J&J contractors who were defendants in the prior suit because the judge found no basis they had a substantial role in the alleged harm to the plaintiffs.

A McNeil spokesman declined to comment on the consumer lawsuit.

Donald Haviland, attorney for the plaintiffs, said he intends to file a new lawsuit addressing the judge's concerns. "I think the case will proceed as it should and get to the merits of the products not being fit for the purposes they were sold," he said.

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

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U.S. EDITION

Hip Joints Set Off New Rush to Court

By Jonathan D. Rockoff and Dionne Searcey
1,125 words
8 July 2011
The Wall Street Journal
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English
(Copyright (c) 2011, Dow Jones & Company, Inc.)

First came a flood of lawsuits blaming Toyota Motor Corp. cars for unintended acceleration, then a wave of litigation over BP PLC's massive oil spill. Now, artificial hip joints made by Johnson & Johnson have plaintiffs' attorneys flocking to the courthouse.

"Everybody is looking for the next big tort," says California attorney Dana Taschner, who is representing clients in numerous lawsuits against J&J, as well as the other two companies.

About 1,000 lawsuits have been filed in federal and state courts accusing the drug and medical-device maker of knowing about problems with some of its metal-on-metal hip joints before its DePuy Orthopaedics Inc. unit stopped making them in 2009. J&J, which later recalled the joints world-wide, denies the allegations and is fighting back.

The number of hip-joint lawsuits against J&J pales beside the tens of thousands filed against Merck & Co. over the painkiller Vioxx, withdrawn from the market in 2004. But the litigation could expose the New Brunswick, N.J., health-care company to \$1 billion-plus in potential liability and other costs, according to a Wells Fargo analyst.

A spokeswoman for DePuy declined to comment on the liability issue, except to say that J&J boosted its reserves for product-liability costs, for products including the recalled hip joints, by \$570 million last year. In addition, J&J, which had 2010 sales of \$61.6 billion, has put aside about \$280 million to cover surgeries and other medical care for patients with those joints.

A panel of federal judges has consolidated many of the hip-joint lawsuits in federal court in Ohio. Some plaintiff's lawyers are pushing for the court to certify the plaintiffs in the case as a class, whose complaints can be combined into a single lawsuit.

Florida attorney Ben Gordon, one of the leaders of the plaintiffs committee in the federal litigation, said J&J has turned over more than 200,000 of the nearly 18 million pages of internal documents it is expected to submit.

Such mass litigation is a big business, often producing multimillion-dollar settlements and sometimes similarly large jury verdicts for plaintiffs. Defense attorneys, meanwhile, can rack up huge bills for their services during the long-running cases.

But these battles also can be a gamble. Plaintiff's attorneys in the Toyota case have spent millions of dollars hiring experts and translating Japanese documents. But a recent government report that blamed driver error -- and not Toyota -- for incidents in which the company's vehicles appeared to speed out of control could end up undermining their case.

J&J recalled its metal-on-metal hip joints last year after British data showed them wearing down or otherwise requiring replacement at unusually high rates. That was the first indication the company had of any flaws in the product, the DePuy spokeswoman said.

Some patients had to undergo risky and expensive surgery to remove and replace the recalled implant -- a metal ball and socket designed to replicate a natural hip joint.

J&J estimates that about 37,000 patients in the U.S. and about 93,000 world-wide have received the recalled device. The DePuy spokeswoman said the company will cover the cost of all medical care associated with the device, including replacement surgery. She wouldn't say how many replacement surgeries it has paid for but said

that, as of mid-June, DePuy had helped nearly 27,000 callers, many of whose calls led to claims for reimbursement.

Some patients who received the recalled hip joint, the so-called articular surface replacement, or ASR, system, say in their lawsuits that medical tests showed chromium and cobalt in their bloodstreams and allege the potentially toxic metals came from parts of the joint wearing down and leaching into their system.

Many of the plaintiffs also complain of pain and infections or inflammation, among the most common reasons that doctors removed and replaced the devices. "I had a lot of weird problems -- urinary tract infections, fevers -- they'd come back every time I stopped taking antibiotics," said 59-year-old Lavonne Gordon, of Brea, Calif. Ms. Gordon says medical tests also revealed she had high levels of chromium and cobalt in her blood. She sued J&J claiming her problems were tied to the two DePuy devices she had implanted in August 2006.

Ms. Gordon's lawsuit was filed in state court in California.

Though the DePuy spokeswoman said the recalled joints contain cobalt and chromium, she said it wasn't clear whether the devices contributed to elevated levels of those metals in patients' blood or how many patients might have this problem.

In May, the FDA said particles from the metal-on-metal hip joints, such as cobalt and chromium, might wear off and make their way into a patient's blood. The agency said this could contribute to heavy concentrations of cobalt and chromium in the body but it wasn't clear if that would cause symptoms -- such as trouble seeing and diseased heart muscle -- that had been reported by a "small number" of those who received the joints. To better understand potential health effects, the FDA ordered J&J and other makers of the metal-on-metal joints to monitor the devices for possible health risks.

Most replacement hips are metal on plastic, but these joints also can wear down, potentially leaving plastic debris in the body, according to Mary O'Connor, chair of the orthopedic department at the Mayo Clinic Florida.

To attract new clients to the litigation, plaintiffs' lawyers have launched websites, such as depuyhipreplacementlawsuit.com, and even YouTube videos to encourage patients who received the device to sue.

The outcome of the ASR lawsuits may hinge on when DePuy learned the devices were faulty. Most of the plaintiffs' attorneys contend that officials from an Australian medical-device registry, a database that tracks patient complaints, first warned DePuy about high rates of failure and complications from the ASR devices in 2007. After analyzing the data, Australia's medical-device regulator took action to curb the use of DePuy's ASR hip joint, an agency spokeswoman says.

The spokeswoman for DePuy said the Australian database was among a variety of sources that the company monitored to keep track of the safety of its hip joints, but it was subsequent information from a British registry that prompted last year's decision to recall the parts.

The spokeswoman said the ASR devices appeared to have low replacement rates until the British data came out.

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Business Hip Joints Set Off New Rush to Court

By Jonathan D. Rockoff And Dionne Searcey 1,475 words 8 July 2011 The Wall Street Journal Online WSJO English

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First came a flood of lawsuits blaming Toyota Motor Corp. cars for unintended acceleration, then a wave of litigation over BP PLC's massive oil spill. Now, artificial hip joints made by Johnson & Johnson have plaintiffs' attorneys flocking to the courthouse.

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The number of hip-joint lawsuits against J&J pales beside the tens of thousands filed against Merck & Co. over the painkiller Vioxx, withdrawn from the market in 2004, and the myriad suits filed over the years against asbestos makers. But the litigation could expose the New Brunswick, N.J., health-care company to \$1 billion-plus in potential liability and other costs, according to a Wells Fargo analyst.

A spokeswoman for DePuy declined to comment on the liability issue, except to say that J&J boosted its reserves for product-liability costs, for products including the recalled hip joints, by \$570 million last year. In addition, J&J, which had 2010 sales of \$61.6 billion, has put aside about \$280 million to cover surgeries and other medical care for patients with those joints.

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Many of the plaintiffs also complain of pain and infections or inflammation, among the most common reasons that doctors removed and replaced the devices. "I had a lot of weird problems—urinary tract infections, fevers—they'd come back every time I stopped taking antibiotics," said 59-year-old Lavonne Gordon, of Brea, Calif. Ms. Gordon says medical tests also revealed she had high levels of chromium and cobalt in her blood. She sued J&J claiming her problems were tied to the two DePuy devices she had implanted in August 2006. She is slated to have the second of the two recalled hip joints replaced this August.

Ms. Gordon's lawsuit was filed in state court in California and has been consolidated with similar complaints there. A hearing on those suits is set for July 26.

Though the DePuy spokeswoman said the recalled joints contain cobalt and chromium, she said it wasn't clear whether the devices contributed to elevated levels of those metals in patients' blood or how many patients might have this problem.

In May, the FDA said particles from the metal-on-metal hip joints, such as cobalt and chromium, might wear off and make their way into a patient's blood. The agency said this could contribute to heavy concentrations of cobalt and chromium in the body but it wasn't clear if that would cause symptoms—such as trouble seeing and diseased heart muscle—that had been reported by a "small number" of those who received the joints. To better understand potential health effects, the FDA ordered J&J and other makers of the metal-on-metal joints to monitor the devices for possible health risks.

Most replacement hips are metal on plastic, but these joints also can wear down, potentially leaving plastic debris in the body, according to Mary O'Connor, chair of the orthopedic department at the Mayo Clinic Florida.

To attract new clients to the litigation, plaintiffs' lawyers have launched websites, such as depuyhipreplacementlawsuit.com, and even YouTube videos to encourage patients who received the device to sue. They also have filed suits—several dozen, so far—alleging similar defects in another metal-on-metal DePuy hip device called Pinnacle, which remains on the market.

The DePuy spokeswoman said the company stands by Pinnacle. She called the product "one of the most widely used and clinically successful" hip-replacement devices on the market, and said it is "backed by more than a decade's worth of clinical data consistently showing that it is a safe and effective option."

The outcome of the ASR lawsuits may hinge on when DePuy learned the devices were faulty. A suit Mr. Taschner filed on behalf of hip-replacement patient Maurice Brigham accuses DePuy and J&J of knowing two years before the recall that the devices failed "early in a high percentage of patients."

Most of the plaintiffs' attorneys contend that officials from an Australian medical-device registry, a database that tracks patient complaints, first warned DePuy about high rates of failure and complications from the ASR devices in 2007. After analyzing the data, Australia's medical-device regulator took action to curb the use of DePuy's ASR hip joint, and achieved a "marked reduction" in implants of the device, an agency spokeswoman says.

"If you knew about the problem and didn't recall the product for a year more, that tends to justify a higher award of punitive damages," said Columbia University law professor John Coffee. But, he added, the defendant can seek to block the cases from being certified as class actions by arguing that injuries in each patient are different. That move could limit its liability, though individual cases could still rack up big awards or settlements if patients suffered significantly, Mr. Coffee said.

The spokeswoman for DePuy said the Australian database was among a variety of sources that the company monitored to keep track of the safety of its hip joints, but it was subsequent information from a British registry that prompted last year's decision to recall the parts.

DePuy voluntarily recalled the devices last fall"in the best interest of patients," after new data from the British database showed five-year rates for replacing the hip parts were 12% and 13%, higher than previously reported, the company spokeswoman said. Under generally accepted standards, DuPuy has said, no more than 5% of patients should require a repeat hip replacement surgery within five years.

The spokeswoman said DePuy monitors the performance of all its products, and the ASR devices appeared to have low replacement rates until the British data came out.

Write to Jonathan D. Rockoff at <u>jonathan.rockoff@wsj.com</u> and Dionne Searcey at <u>dionne.searcey@wsj.com</u>

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$\hbox{$\,{}^{\underline{M}}$ J\&J Recall Watch: Extra-Strength Tylenol Pulled Due to Smell}$

WSJ Blogs, 14:57, 28 June 2011, 964 words, By Katherine Hobson, (English)
Johnson & Johnson can't seem to shake the "musty, moldy odor" that has prompted a series of product recalls. Today it was Extra-Strength Tylenol caplets. J&J's McNeil Consumer Healthcare division is pulling one ...

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U.S. EDITION

U.S. News: FDA Leaves Silicone Implants on Market Despite Risks

By Jennifer Corbett Dooren and Thomas M. Burton 583 words 23 June 2011 The Wall Street Journal J A5 English

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Women receiving silicone-gel breast implants have frequent complications like scarring or hardening breasts, and 20% or more of patients required implant removal within 10 years, the Food and Drug Administration said Wednesday.

But the federal safety agency's analysis didn't show any unexpected or new safety concerns, and the implants will stay on the market. The conclusions were drawn in large part from studies done by the implants' manufacturers, Allergan Inc. and Johnson & Johnson's Mentor Worldwide unit.

Silicone breast implants were allowed back onto the U.S. market for cosmetic purposes in 2006, after their sale was sharply curtailed by the FDA in 1992 over perceived safety issues.

"Despite frequent local complications and adverse outcomes, the benefits and risks of breast implants are sufficiently well understood for women to make well informed decisions about their use," the FDA said in its analysis of medical data.

It is imperative for women with implants to get routine medical images to screen for implant ruptures and other complications, said Jeffrey E. Shuren, director of the FDA's device division. Women should notify doctors if they experience pain, swelling or other changes, he said.

Silicone gel-filled breast implants are safe and effective when used as intended, said Allergan and Mentor. "We concur with FDA that women should fully understand there are potential risks associated with breast implants, and they should discuss risks and benefits with their plastic surgeon prior to breast augmentation or reconstruction," Mentor said in a statement.

According to the data released Wednesday, 20% to 40% of women receiving implants for augmentation had a reoperation in the first eight to 10 years after getting the implants. The figure was 40% to 70% for women who got implants for reconstruction, including after cancer surgery.

The FDA said one of the most common side effects was a hardening of the breast around the implant. Other side effects include rupture and gradual seeping out of silicone as well as scarring, pain and infection.

During the 1990s, litigation by thousands of women alleged that systemic illnesses including lupus, rheumatoid arthritis and scleroderma had been caused by silicone seeping through the body. While those contentions led to multibillion-dollar settlements with Dow Corning Corp. and other manufacturers, the allegations were never proved.

In Wednesday's statement, the FDA said there was no apparent association between silicone implants and such "connective tissue" diseases, nor with breast cancer or reproductive problems.

In January, the agency warned there may be a small but increased risk of a rare type of cancer in women with silicone- or saline-filled implants. It didn't release any new information on that risk Wednesday.

Allergan and Mentor enrolled about 40,000 women each with implants in studies, but the companies have lost contact with many of the participants since the studies, intended to last about 10 years, began several years ago. The FDA said Allergan had followed about 60.5% of the women for two years, while Mentor has followed 21% over three years. Both companies said they were trying to improve follow-up.

William Maisel, deputy director for science of the FDA's device center, said the agency's overall conclusions weren't dependent on just those studies. He said the FDA also looked at studies that began before 2006 and followed fewer women.

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U.S. EDITION

Health & Wellness -- Aches & Claims: Contacts Let In Sun, But Block UV Rays

By Laura Johannes
761 words
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The Wall Street Journal
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(Copyright (c) 2011, Dow Jones & Company, Inc.)

Most people know that the sun's rays are bad for the skin. Far fewer know that it can be harmful to the eyes. To lessen the risk, companies are selling contact lenses with a special ultraviolet-blocking ingredient that they say can keep out as much as 90% to 99% of ultraviolet rays.

Two types of ultraviolet radiation from the sun reach the eyes -- A and B. The most known negative effects are from ultraviolet B radiation, which causes small damage that builds over time, says Gregory Good, assistant dean at Ohio State University College of Optometry. The cumulative damage can contribute to the formation of cataracts and pterigia, raised wedge-shaped growths on the eye that can cause irritation and even obstructed vision

While the sun feels hottest at midday, the exposure to the eyes is often worst during early morning and late afternoon, according to a published study. The reason is most likely that eyebrows shield the eyes when the sun is high in the sky, scientists say. Wearing a hat can help, but it doesn't block all rays. Sunglasses with UV block also help, but ultraviolet rays still slip in over the rims and through the sides.

UV-blocking contact lenses protect the inner structures of the eye -- including the cornea, the iris, the lens and the retina. "All other things being equal, I would want the best UV protection in a lens," says Jeffrey L. Weaver, executive director of the American Board of Optometry in St. Louis, Mo., which certifies optometrists.

Contact lenses with UV blocking are completely clear, and there are no downsides -- except limited choice, says Stephen M. Cohen, past president of the Arizona Optometric Association.

UV-blocking contact lenses have been around for more than a decade, but have gained in popularity in recent years. Only a limited number meet Food and Drug Administration standards for "Class 1" protection, in which 90% of UV-A radiation is blocked and 99% of UV-B radiation is blocked. The American Optometric Association (AOA), a doctors' group, offers a "seal of acceptance" for Class I lenses, and so far only six products -- all from Johnson & Johnson's Vistakon unit's Acuvue line -- have gotten the seal. To get the seal, a company must pay for testing by an independent AOA-chosen lab and also pay a licensing fee for use of the seal. Due to costs of the seal-of-acceptance program and concerns about possible legal liability, the AOA says it has stopped accepting new applications. Consumers who are unsure about UV blocking in lenses can ask the optometrist for the FDA-approved package insert.

A number of other lenses on the market -- including Cooper Companies Inc.'s Avaira and ClearSight product lines -- meet Class 2 standards, in which 70% of UV-A and 95% of UV-B is blocked. Some Class 2 lenses beat the standard: Avaira, for example, block at least 75% of UV-A radiation and 99% of UV-B radiation, according to the package insert. J&J says all of its contact lenses meet at least the Class 2 standard. Bausch & Lomb Inc., a contact-lens maker that doesn't sell ultraviolet-blocking lenses, declined to comment.

Studies so far suggest the UV-blocking lenses can work. A January study of a dozen rabbits found that J&J's Class 1 lenses protected the cornea and lens of the eye from ultraviolet-related damage, such as protein damage that could in the long term result in cataracts, according to the study, published in Investigative Ophthalmology & Visual Science. The rabbits were subjected to radiation equivalent to about 16 hours of sunlight exposure, condensed into a half-hour period, says Cristina Schnider, Vistakon's senior director of medical affairs.

Lacking so far is direct scientific proof that wearing ultraviolet-blocking contact lenses will prevent long-term eye issues. To do so, a long-term study would be needed which compared people wearing the lenses and people who

didn't, optometrists say. Despite direct proof of efficacy, it is logical to think UV-blocking contacts will help keep the eyes healthy, optometrists say.

But they warn against overdependence on contacts. "I recommend a triad," says Dr. Cohen. "A hat with a brim, blocking rays from above, sunglasses with a wraparound and, for those who wear contacts, UV blocking."

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U.S. EDITION

Corporate News: J&J Issues Recall for HIV Drug --- Chemical With Musty Odor Is Detected in Bottles of Prezista in Europe, Canada

By Peter Loftus
504 words
12 May 2011
The Wall Street Journal
J
B2
English
(Copyright (c) 2011, Dow Jones & Company, Inc.)

Johnson & Johnson's manufacturing-quality lapses continued as the company recalled at least 11,700 bottles of the HIV/AIDS drug Prezista in several countries after it discovered trace amounts of a chemical emitting offensive odors.

J&J said Wednesday it had received four consumer reports of musty or moldy odors, and it found the chemical in five batches of products sold in the U.K., Ireland, Germany, Austria and Canada.

The chemical is 2,4,6 tribromoanisole, also known as TBA, which is a byproduct of a chemical preservative sometimes applied to wood used for pallets to transport and store products.

J&J has initiated recalls at the wholesale and retail levels in the affected European countries, including about 9,000 bottles of 400-milligram tablets, and about 2,700 bottles of 600mg tablets, said spokesman Mark Wolfe. J&J estimates fewer than 2,000 bottles remain in countries where recalls have been initiated. In the U.K., only the 400mg tablets were affected.

In Canada, one lot of 600mg Prezista was found to contain bottles with TBA, and J&J estimates fewer than 300 affected bottles remain on the Canadian market from this lot. J&J is in discussions with Canadian regulatory authorities to determine the appropriate course of action, Mr. Wolfe said.

Patients shouldn't stop taking Prezista, he added.

J&J, of New Brunswick, N.J., has been grappling with a series of product recalls that span its diversified businesses, from over-the-counter medicines to hip-replacement parts to surgical sutures. The actions have hurt sales and tarnished J&J's once-sterling reputation for quality. In response, the company has shuffled management, shuttered a plant outside Philadelphia and taken other steps to try to recover from the quality lapses.

J&J previously blamed TBA and a related chemical for reports of uncharacteristic odors that led to recalls of various over-the-counter medicines including Tylenol since 2009. Pfizer Inc. also cited TBA in recalls of its cholesterol-lowering drug Lipitor last year.

J&J said Wednesday TBA isn't toxic but can generate musty or moldy odors that cause some patients to have temporary gastrointestinal symptoms.

J&J said there have been no reported serious adverse events caused by the presence of TBA in Prezista.

The affected products were manufactured at a J&J plant in Puerto Rico, Mr. Wolfe said. The company had previously taken steps to reduce the potential for TBA contamination, including requiring suppliers to verify they don't use pallets made from chemically treated wood. J&J said it is conducting an internal investigation with suppliers to identify potential sources of TBA.

J&J recorded \$857 million in Prezista sales for 2010, up 45% from 2009.

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WSJ Blogs, 10:55, 11 May 2011, 915 words, By Katherine Hobson, (English)
Johnson & Johnson is recalling another product because it stinks -- literally. The
company said it will pull an estimated 2,000 bottles of HIV/AIDS drug Prezista in four
European countries due to a handful of reports of musty or moldy ...

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Business J&J, Others to Revamp Pain Drug

By Jonathan D. Rockoff 542 words 5 May 2011 The Wall Street Journal Online WSJO English

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In a move to curb overdoses of the pain and fever medicine acetaminophen, Johnson & Johnson and other drug makers will switch to a single concentration in their over-the-counter remedies for infants and children, according to three of the companies.

The medicines, including J&J's Tylenol, now come in different concentrations depending on whether they are for infants or older children. That has made it confusing for parents to figure out how much to give, causing overdoses and, in rare cases, deaths.

In 2009, there were 14 hospitalizations caused by pediatric versions of medicines containing acetaminophen, but no deaths, according to the most recent data from the American Association of Poison Control Centers.

Under the move expected to be announced Thursday, drug makers will voluntarily discontinue the more concentrated infant drops and sell just a single concentration of infants' and children's medicines containing acetaminophen. The appropriate dose will still vary by age of the child.

Perrigo Co., which makes 95% of the kids' acetaminophen medicines sold under private labels, says its products should be switched over to the single 160 milligrams per 5 milliliter concentration by the summer.

J&J's McNeil Consumer Healthcare unit plans to roll out the single concentration as its infants' Tylenol bottles return to the market later this year and the beginning of next, following a lengthy recall.

Novartis AG, maker of Triaminic, confirmed that the company would follow suit.

Acetaminophen is the most commonly used medicine for relieving pain and fevers in children, according to the Consumer Healthcare Products Association, which will be announcing the switch. According to a 2008 study, 23% of caregivers had given infants under 2 years of age a single-ingredient acetaminophen medicine during the previous week. Companies sold \$153 million in kids' acetaminophen medicines in the year leading up to April 10, Perrigo said.

Manufacturers of acetaminophen products have been under pressure from the U.S. Food and Drug Administration to help minimize medication errors. A 2009 meeting of experts convened by the agency prompted drug makers to revise the labels on medicine bottles and provide specific dosing instructions for children under 2.

Another meeting is scheduled for later this month to discuss further steps, such as adding to the labels to include dosing instructions based on children's weight.

Switching to a single concentration will help prevent medication errors, "but I still think there could be better things done with the labeling," said Allen Vaida, executive vice president of the Institute for Safe Medication Practices, who participated in the FDA's 2009 meeting and serves on its Drug Safety and Risk Management Advisory Committee.

At the 2009 meeting, companies including J&J resisted moving to a single pediatric concentration. Now, J&J is seeking to regain the confidence of parents after more than a year of recalls of Tylenol and other popular brands. Last week, the company said it would give its medicine bottles a new cap, called a flow restrictor or dose-limiting cap, that allows parents to insert a syringe to draw out the correct dose.

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U.S. EDITION

J&J CEO Works on Legacy

By Peter Loftus and Jon Kamp 535 words 4 May 2011 The Wall Street Journal J English (Copyright (c) 2011, Dow Jones & Company, Inc.)

William Weldon's 40-year career at Johnson & Johnson may be nearing an end, but the chief executive hasn't shied away from trying to reshape the health-care company during challenging times.

Even as Mr. Weldon is under pressure to fix manufacturing-quality lapses that spurred a series of product recalls, mostly of over-the-counter medicines like Tylenol, he has signed off on what would be the biggest acquisition in J&J's history, a \$21.3 billion purchase of medical device maker Synthes Inc.

"I don't look at it as positive or negative for me; I look at it as positive for" the company, Mr. Weldon said in a recent interview. The deal, expected to close next year, will significantly expand J&J's medical-device and diagnostics business, though J&J remains committed to its strategy of also having large pharmaceutical and consumer health-care operations.

If the Synthes deal helps J&J rebound from consecutive years of overall sales declines in 2009 and 2010, and if the manufacturing problems are fixed, Mr. Weldon may be able to depart J&J on a high note.

"He'll probably want to clean up the consumer business and get the company growing again before he leaves," said Les Funtleyder, health-care portfolio manager at Miller Tabak.

Mr. Weldon hasn't said publicly when he plans to leave the company. But the recent elevation of Alex Gorsky and Sheri McCoy to an expanded "Office of the Chairman" signal that a two-person succession race is under way and Mr. Weldon's departure likely won't be too far away.

Mr. Weldon himself isn't talking about a personal legacy. "I think people that know me really would tell you my legacy for me is not as important as the legacy for Johnson," he said.

Mr. Weldon, a Brooklyn, N.Y., native and graduate of Quinnipiac University, started in 1971 in a sales and marketing position with J&J's McNeil Pharmaceutical unit, and a decade later began working in managerial posts with the company in Asia.

During the 1980s and '90s, Mr. Weldon ascended through various leadership posts in J&J's medical device and pharmaceutical operations in the U.K. and at home before assuming his current responsibilities as chairman and CEO in April 2002.

Under Mr. Weldon, J&J has made some large acquisitions. In 2004, J&J launched a \$24 billion bid for medical device maker Guidant but walked away after Boston Scientific Corp. came in with a higher offer. Many investors later viewed J&J's loss as a win when problems emerged for the Guidant business.

In 2006, J&J acquired Pfizer Inc.'s consumer health care unit for \$16.6 billion.

The product recalls since 2009, however, have hurt J&J's financial performance as well as its once sterling reputation for quality. Mr. Weldon has said he is disappointed with the setbacks and is taking steps to remedy the situation.

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U.S. EDITION

Corporate News: Device-Firm Deal Poses Test for J&J

By Jonathan D. Rockoff and Jon Kamp 617 words 28 April 2011 The Wall Street Journal J B3 English (Copyright (c) 2011, Dow Jones & Company, Inc.)

The \$21.3 billion deal for medical-equipment maker Synthes Inc. positions Johnson & Johnson to capitalize on a rapidly growing market for bone-repair devices, but it will test leadership already grappling with manufacturing problems and investor concerns about mismanagement.

The two companies said Wednesday that J&J would use a combination of cash and stock to buy Synthes, the dominant seller of plates and screws used to mend bones broken in traumatic auto accidents. Under the terms, Synthes shares would be valued at 159 Swiss francs, or \$181.50, apiece. If completed -- likely in the first half of next year -- it would be J&J's biggest deal ever.

Chief Executive William Weldon said Wednesday that J&J had long viewed Synthes's trauma business as a "great opportunity" in the broader \$37 billion world-wide market for devices repairing diseased and broken bones, where sales have been hurt by pricing pressures.

"Trauma is one of the fastest-growing segments, and it's an area where we're a small player and they're a large player," Mr. Weldon said in an interview. The segment is growing 7% a year world-wide, Mr. Weldon said, and demand for the trauma parts is insulated from the economic challenges afflicting sales of more discretionary medical devices.

News of the deal gives J&J a positive note heading into a shareholder's meeting Thursday that is shaping to be unusually contentious. The company expects to face questions about its handling of manufacturing problems that have led to more than a dozen recalls of popular pain medicine Tylenol and other products, temporary shutdown of a key manufacturing plant and \$900 million in lost sales last year.

Earlier this month, Institutional Shareholder Services Inc. said Mr. Weldon and J&J's board hadn't done enough to address the issues. The advisory firm recommended that shareholders vote against ratifying the compensation of J&J's executive officers.

Mr. Weldon noted that most of his compensation is tied to J&J's long-term performance, but his shorter-term compensation was affected "dramatically" last year, "as it should be." His total compensation was valued at \$28.7 million for 2010 versus \$30.8 million for 2009, and his performance bonus for 2010 was cut 45% to \$1.98 million, J&J reported last month in a filing with the U.S. Securities and Exchange Commission.

The 2010 recalls were "a tremendous disappointment for us," said Mr. Weldon, who said he has personally assumed accountability for fixing these issues, launching a companywide review of all of its manufacturing and revamping the operations.

But Mr. Weldon and his team face challenges in digesting Synthes, which has had its own recall issues. Synthes, which also makes spine and bone-replacement products, withdrew some spine devices in 2009 that had potential safety issues. Last year, Synthes agreed to pay more than \$23 million to settle U.S. criminal and civil charges over the actions by the company's Norian unit that encouraged unapproved uses of another spine product.

Combining the operations of Synthes and J&J's DePuy orthopedics unit will pose some organizational challenges. Synthes and DePuy take different approaches to marketing, for instance, with Synthes using its own employees as sales representatives while DePuy hires independent contractors.

Mr. Weldon said the integration of the two companies will be "much simpler than you would think in a deal of this size" because they're largely complementary, rather than overlapping.

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Business
J&J Shareholders Approve Executive-Compensation Policy

By Peter Loftus 687 words 28 April 2011 14:23 The Wall Street Journal Online WSJO English

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NEW BRUNSWICK, N.J.—A majority of Johnson & Johnson shareholders approved the company's executive-compensation policy, despite opposition by critics concerned about a series of product recalls by the health-care giant.

J&J Chief Executive William Weldon told shareholders gathered at a hotel near company headquarters that he was personally overseeing measures to improve the quality manufacturing of over-the-counter medicines such as Tylenol. He detailed steps J&J was taking, including the renovation of a manufacturing plant outside Philadelphia and a plan for "dose-limiting" packaging for medicines for children and infants.

"I'm confident we are addressing these matters in ways that will see us coming back stronger than ever," he said.

J&J's board also boosted the company's quarterly dividend by 5.7%.

Shareholders elected J&J's director nominees, and more than 95% rejected several shareholder proposals, including one to adopt a policy of price restraint for pharmaceutical products.

The advisory vote on J&J's executive compensation—the first held at J&J since a new U.S. law mandated such votes—was closer than the shareholder proposals. J&J said a preliminary tally showed that about 61% of all shares voted were in favor of J&J's pay policies.

Institutional Shareholder Services Inc. had advised shareholders to vote against that measure, while another proxy advisory firm, Glass Lewis, recommended approval of the policy.

A representative of public-employee union AFSCME told Mr. Weldon that shareholders were disappointed that his total compensation package was worth nearly \$29 million for 2010, a year when J&J shares declined about 4%.

J&J defended its pay practices, noting the performance bonus for Mr. Weldon was cut by 45% for 2010 to reflect business setbacks. His overall compensation was valued at \$28.7 million for 2010, down from \$30.8 million for 2009.

Mr. Weldon told shareholders that J&J's board would take the advisory vote under consideration.

One J&J board member, James Cullen, retired head of Bell Atlantic, said that he and the board had confidence in J&J's management, and that he was comfortable with the steps management has taken to address the product recalls.

Shareholders arriving at the meeting were greeted by a small number of protesters, including one dressed in a pig costume to oppose J&J's use of live pigs to demonstrate certain medical devices. A shareholder proposal to curtail such practices was rejected by shareholders. J&J said it tries to use non-animal alternatives when possible, and when it does use animals it treats them humanely.

In the hotel lobby before the meeting started, shareholder Scott Croce said he was concerned about the product recalls.

"A company like this stresses quality, and when you get a recall, it's a reflection on their quality assurance program," said the East Brunswick, N.J., resident, who used to work in manufacturing.

Mr. Croce, who was happy with J&J's overall performance, said executive compensation at J&J was fair, but the company needed to do more to pre-empt product recalls in the future. He cited the complaints about musty and moldy odors in certain J&J products, asking "How basic is that?"

Mr. Weldon and other J&J executives spent about two hours conducting the business portion of the meeting and presenting advertisements and videos touting J&J's products, research and development and other programs. The general question-and-answer session lasted less than a half-hour.

The meeting comes a day after J&J agreed to buy medical-device maker Synthes Inc. for about \$21.3 billion, which would be the largest purchase in J&J history if it closes as planned. The deal will significantly expand J&J's presence in the market for trauma-related bone-repair devices.

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WSJ Blogs, 15:38, 27 April 2011, 401 words, By Jonathan D. Rockoff, (English) At its shareholders' meeting tomorrow, Johnson & Johnson is expected to roll out changes to the packaging of its over-the-counter medicines for children, making it easier to give kids the right dose -- and furnishing J&J a ...

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Business
J&J Profit Falls; Forecast Boosted

By Peter Loftus 836 words 20 April 2011 The Wall Street Journal Online WSJO English

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Johnson & Johnson's first-quarter earnings fell 23% from a year earlier, when results were helped by a litigation gain, while a weaker dollar and higher drug sales helped offset the drag on revenue from product recalls.

The health-care giant boosted its full-year earnings forecast, citing currency trends and improvements in J&J's underlying business.

J&J had said in recent quarters that overall health-care spending was slowing due to the sluggish economy, but on a conference call with analysts, Chief Financial Officer Dominic Caruso said it is "seeing some sequential improvements."

Investors pushed up J&J shares \$2.23, or 3.7%, to \$62.69 in 4 p.m. trading Tuesday on the New York Stock Exchange.

The New Brunswick, N.J.-based conglomerate could soon make a major move: It is in talks with Swiss medical-device maker Synthes Inc. about a potential merger that people familiar with the matter say could be valued at about \$20 billion, making it J&J's largest ever.

A Synthes takeover could re-energize J&J's device business, which has faced challenges on several fronts. The company's once high-flying Cordis division, which makes artery-opening stent devices, has lost market share and faces fresh regulatory complications.

J&J officials declined to discuss the Synthes negotiations.

Meanwhile, J&J reiterated Tuesday that shareholders should approve the company's compensation plans for Chief Executive William Weldon, and it defended its ability to tie the CEO's pay to J&J's performance.

The company's comments, included in a filing Tuesday with the Securities and Exchange Commission, follows a report last week by influential advisory firm Institutional Shareholder Services Inc. that recommended a vote against ratifying compensation for J&J's executive officers and said shareholders should be "concerned" about Mr. Weldon's pay.

For the first quarter, J&J said it earned \$3.48 billion, or \$1.25 a share, down from \$4.53 billion, or \$1.62 a share, a year earlier.

The latest quarter included charges of \$271 million for costs associated with litigation and a recall of hip-replacement parts, while the year-earlier period included a litigation gain of \$910 million. Excluding these items in both periods, earnings rose to \$1.35 a share from \$1.29 a share.

The maker of Band-Aids, baby shampoo and other products said sales rose 3.5% to \$16.17 billion, with currency-exchange trends contributing 1.7 percentage points of the growth. The recent weakening of the dollar against certain foreign currencies is giving a lift to first-quarter results for U.S.-based multinational drug makers.J&J's U.S. sales declined 0.6%, while sales outside the U.S. rose 7.3%.

The results exceeded the mean estimates of analysts surveyed by Thomson Reuters for earnings of \$1.26 a share on revenue of \$15.87 billion. J&J raised its full-year earnings forecast to a range of \$4.90 to \$5 a share, excluding certain items, from a prior range of \$4.80 to \$4.90 a share, citing "both currency exchange rate changes and recent developments in the business."

The company doubled its projection of full-year 2011 currency benefit to 16 cents a share from eight cents. Analysts expect J&J to earn \$4.84 a share on revenue of \$64.2 billion for 2011.

J&J's biggest unit, medical devices and diagnostics, had first-quarter sales of \$6.4 billion, up 3.3% from a year earlier. Sales of diabetes-care and vision-care products contributed to growth, while the Cordis unit continued to decline.

The company's pharmaceutical unit saw sales rise 7.5% to \$6.06 billion. Sales of anti-inflammatory drug Remicade rose 8.3% to \$1.29 billion.

J&J recently resolved a dispute with marketing partner Merck & Co. over the rights to Remicade and a follow-up drug, Simponi. Under the terms of the agreement, Merck will pay J&J \$500 million and cede to J&J rights to the drugs in certain countries.

Combined sales of anti-anemia drugs Procrit and Eprex dropped 24% to \$397 million, continuing a multi-year slide related to safety concerns.

J&J's consumer-healthcare unit had sales of \$3.68 billion, down 2.2% from a year earlier. The consumer medicine recalls continued to be a drag—combined over-the-counter and nutritional sales in the U.S. dropped 27%—though J&J's baby-care products posted sales growth of 6%. Also, J&J now expects costs and lost sales associated with its McNeil Consumer Healthcare recalls to reduce 2011 earnings by 12 cents a share, versus a prior forecast of six cents.

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

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U.S. EDITION

Earnings: J&J Profit Falls; Forecast Boosted

By Peter Loftus
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Business
Synthes Is Seen as a Fit for J&J

By Jonathan D. Rockoff 1,075 words 18 April 2011 The Wall Street Journal Online WSJO English

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If it pulls the trigger on a potential \$20 billion deal for Synthes Inc., Johnson & Johnson would acquire a dominant player in a major segment of the medical-device market.

Synthes accounts for nearly 50% of the sales of the plates and screws that doctors use to treat broken bones.

One person familiar with the matter said J&J is making headway on its due-diligence examination of Synthes's books. A factor in the talks, this person said, is that the AO Foundation, a nonprofit surgical-research group affiliated with the company may have a say in any sale.

The transaction would be the health-care giant's biggest-ever acquisition and reinvigorate its device business, which like those of its rivals has been struggling to recapture the heady growth it enjoyed before the economic downturn and pricing pressures began to weigh on sales.

The Wall Street Journal reported late Friday that J&J is in talks to acquire Synthes, which has headquarters in both Switzerland and the U.S. Synthes, based in West Chester, Pa., on Monday confirmed it was in talks with J&J over the potential takeover but declined to give further details. Synthes shares opened 12% higher in Europe.

People familiar with the talks described them as fragile, and it isn't clear whether or how soon a deal could be reached.

Synthes would give J&J immediate presence in one of the fastest-growing segments of the \$28.3 billion market for orthopedic devices. The \$5.5 billion trauma category grew 8% last year, according to Wells Fargo Securities.

"It's the gaping hole in [J&J's] orthopedic portfolio, so Synthes really is a good match for them," said a person familiar with the industry. Synthes "pretty much built the trauma market."

J&J's DePuy unit also sells the plates and screws, but it hasn't kept up with either Synthes, or rivals Stryker Corp. and Smith & Nephew PLC. Synthes reported \$2.69 billion in sales of trauma products last year, a 10% increase from 2009, said Wells Fargo analyst Larry Biegelsen in a note to investors. By contrast, DePuy had \$258 million in trauma sales in the same period.

Of course, prospects of capturing more than half of this market could prompt scrutiny by regulatory authorities.

For J&J, the transaction would also come as the company is grappling with quality lapses that have prompted more than a dozen recalls of popular over-the-counter medicines, contact lenses and hip-repair implants. The recalls cost the company \$900 million in sales last year, resulting in a sales decline and adding to pressure to find new sources of revenue and earnings growth.

A spokesman for J&J said the company doesn't comment on speculation.

A \$20 billion transaction would eclipse J&J's \$16.6 billion purchase of Pfizer Inc.'s consumer business in 2006 and mark a departure from its long-standing practice of building its myriad business units largely through acquisition of smaller companies.

For J&J, which sells health-care products ranging from Band-Aids to the anti-anemia drug Procrit, the transaction would be consistent with its strategy of acquiring businesses with leading positions in promising markets.

Synthes, which also makes spine and bone-replacement products, would expand J&J's presence in emerging markets, an area the New Brunswick, N.J., conglomerate is targeting for growth. Last year, Synthes had \$424.4 million in sales in the Asia Pacific region, up some 19%.

Alex Gorsky, the J&J executive who oversees the medical-device business, told investors last year that emerging markets "are growing right now at about two to three times the rate of our developed markets, but we think we have just started to scratch the surface of what the real opportunity is."

Despite its recent sales dip, J&J has amassed a hefty pile of cash, cash equivalents and marketable securities amounting to \$27.7 billion, according to a filing with the Securities and Exchange Commission earlier this year. J&J has been on the hunt for a medical-device maker for some time and last year took at look at Smith & Nephew, the U.K.-based orthopedics firm.

Synthes shares, which trade on the Swiss exchange, are up 17% since March 17, including a 6.2% rise Friday amid speculation over a potential sale. Its current market value is 16.5 million Swiss francs, or about \$18.4 billion. J&J's shares were up 0.2% at \$60.69 in after-hours trading Friday on the New York Stock Exchange.

Because Synthes is based in both the U.S. and Switzerland, J&J could use cash it has kept overseas to pay for Synthes in Swiss francs, the person familiar with the industry said. By doing so, J&J would avoid having to pay taxes on cash brought back to the U.S.

J&J's medical-device business could use a boost. The \$24.6 billion business grew 4.4% last year, down from loftier levels a few years earlier. Synthes sales rose 8.6% in 2010, to \$3.69 billion.

Medical-device makers generally have been hurt not only by the economic downturn but also longer-term factors like mounting efforts to restrain health-care spending. "Hospitals today are requiring us to provide clinical and economic justification for our products," Karen Licitra, who heads J&J's Ethicon Endo-Surgery medical device unit, told investors last year. Marketing such technology "is not just about going to the surgeon anymore."

Many of the devices Synthes sells are used in emergency procedures and may be less vulnerable to cost pressures affecting equipment used in elective operations.

A major acquisition could be a distraction to management focused on revamping manufacturing operations and repairing a corporate reputation damaged by quality problems. But J&J typically allows businesses it acquires to operate as independent units. Thus the huge management challenges of integrating businesses affected by a big acquisition may not be a big factor if the Synthes talks move to completion.

Anupreeta Das and Gina Chon contributed to this article.

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

Document WSJO000020110417e74i000mw

Business J&J Recalls Some Topamax After Odor Reports

By Jon Kamp 512 words 14 April 2011 10:15 The Wall Street Journal Online WSJO English

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A Johnson & Johnson unit is recalling two lots of its Topamax antiseizure drug after getting complaints about an unusual odor potentially linked to chemically treated wooden pallets, and J&J is looking into whether other products also could be affected.

This marks the first time J&J has recalled a prescription drug because of this issue, following prior recalls of the over-the-counter products including Tylenol. Topamax adds to a series of J&J recalls since 2009 related to quality lapses and other problems.

Though J&J has a policy of eliminating problem pallets used to ship and store products, some apparently slipped through the cracks, raising questions about a possible impact for other prescription drugs and products. J&J said Thursday these pallets were mislabeled and it is investigating to see if there are broader implications.

"The entire supply chain organization is looking at this," J&J spokeswoman Carol Goodrich said.

J&J's Ortho-McNeil-Janssen unit said the recall affects about 57,000 Topamax bottles shipped in late 2010 in the U.S. and Puerto Rico, although the company believes fewer than 6,000 bottles remain in the marketplace. Specifically, the issue involves 100-milligram tablets.

There were four consumer reports of an "uncharacteristic odor," but no reports of serious adverse events with this product, the J&J unit said. The odor can cause temporary gastrointestinal symptoms.

The company believes the smell is caused by trace amounts of 2,4,6-tribromoanisole, or TBA, which is a byproduct of a chemical preservative sometimes used to treat wooden pallets. J&J launched efforts in January 2010 to reduce the potential for TBA contamination, including requiring suppliers to verify they don't use this chemically treated wood.

"An internal investigation is under way with our suppliers to evaluate the potential source of this TBA issue," Ortho-McNeil-Janssen said. "In addition, we are working with peer companies to better understand how and where TBA is entering and impacting our supply chains and what we can do to further mitigate this exposure."

Elsewhere in the drug sector, Pfizer Inc. has launched multiple recalls for bottles of its blockbuster cholesterol-lowering drug Lipitor because of odor reports.

Late last month, J&J's McNeil Consumer Healthcare unit recalled about 34,000 bottles of Tylenol 8-Hour Extended Release caplets after receiving a small number of odor complaints, adding to previous Tylenol recalls. The over-the-counter recalls at J&J linked to problem pallets have also covered Motrin and Benadryl products, among others.

Topamax was once a big-selling drug for J&J, but sales have plummeted in recent years because it no longer has market exclusivity. Last year the drug posted sales of \$538 million, less than half the 2009 tally. It represented a small fraction of J&J's overall sales of \$61.6 billion last year.

Drew FitzGerald contributed to this article.

Document WSJO000020110414e74e005k1

WSJ Blogs, 09:15, 14 April 2011, 871 words, By Katherine Hobson, (English) Johnson & Johnson is recalling about 57,000 bottles of the anti-epilepsy drug Topamax because four customers reported a bad odor, the company says. J&J says it believes only about 6,000 bottles are still on the market. Here's ...

Document WCWSJB0020110414e74e0053d

Business

J&J Names Torres President at McNeil Unit

By Jonathan D. Rockoff 313 words 7 April 2011 17:53 The Wall Street Journal Online WSJO English

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Johnson & Johnson named a new president at its troubled McNeil Consumer Healthcare unit Thursday, the latest step in the company's ongoing effort to fix manufacturing problems that led to Tylenol recalls.

Denice Torres, who takes the post on April 25, had led the J&J business selling Concerta, a drug used to treat attention deficit/hyperactivity disorder, and other neurological drugs. Ms. Torres is a lawyer by training who joined J&J from Eli Lilly & Co. in 2005.

She will bring "business acumen and high integrity to the job of leading businesses that are facing significant challenges," said the company's message to employees announcing the move.

A J&J spokeswoman confirmed the appointment.

McNeil has issued more than a dozen recalls of Tylenol and other popular over-the-counter drugs since late 2009 as a result of manufacturing problems that led to metal shavings floating in some children's medicine bottles and other liquid medicines bearing a musty smell. The problems cost J&J \$900 million in sales last year, hurt its reputation for quality and prompted the temporary shutdown of a key manufacturing plant.

In addition, the Food and Drug Administration is now closely monitoring McNeil's manufacturing, under the terms of a recent consent decree.

To tackle the quality problems, J&J Chief Executive William Weldon has revamped manufacturing across the company. Most recently, McNeil was made into an independent unit in order to make sure its issues are addressed.

The company late last month named J&J veteran Patrick Mutchler as the company group chairman overseeing the unit. Ms. Torres will be running McNeil's day-to-day operations and will report to Mr. Mutchler.

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

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Business
J&J Revamps McNeil Unit After Recalls

By Jonathan D. Rockoff
687 words
31 March 2011
The Wall Street Journal Online
WSJO
English
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Johnson & Johnson is revamping the troubled unit that makes Tylenol and giving it new leadership in an effort to fix quality problems that have prompted multiple recalls, according to people familiar with the matter.

The changes are the latest in a series of efforts by the New Brunswick, N.J., health-care-products company to address manufacturing issues, which have damaged its reputation with consumers and invited scrutiny from Congress and regulators.

Through its McNeil Consumer Healthcare unit, J&J sells Tylenol as well as such other popular cold, pain and allergy medicines as Benadryl, Motrin and Zyrtec. Within the J&J organization, the McNeil unit had been lumped together with a wider group of consumer health-care businesses, selling products ranging from Listerine mouthwash to Visine eyedrops.

Starting on April 4, McNeil Consumer Healthcare in the U.S. will be its own organization, according to people familiar with the matter.

The unit will be overseen by Patrick Mutchler, a 35-year J&J veteran who has held a variety of assignments on the company's consumer side, most recently overseeing the sale of baby products such as Johnson's Baby Lotion, these people said.

Marc Robinson, who had overseen J&J's over-the-counter businesses world-wide, and Peter Luther, who had been president of McNeil Consumer Healthcare, have been given other roles. Neither was available for comment, a J&J spokeswoman said.

Jesse Wu, the J&J executive who manages all of its consumer businesses, told employees in a message reviewed by The Wall Street Journal that he is making McNeil separate "in order to give focused attention to quality and compliance, and the critical task of restoring" the reputation of its products.

A J&J spokesman confirmed the reorganization and declined further comment.

Since late 2009, McNeil has issued more than a dozen recalls due to manufacturing problems that have included the presence of metal shavings in some children's medicine bottles. The problems prompted the shutdown of one of McNeil's manufacturing facilities and dealt a notable blow to the company's once-sterling reputation for quality.

Some parents say they won't buy Tylenol for their children anymore. Congress has held two hearings probing the problems. The company says the recalls cost it \$900 million in sales last year.

Separating out McNeil is an unusual move for sprawling J&J.

In fact, the rest of the company's consumer businesses will be organized regionally, with different units for different parts of the globe, such as Latin America and Asia-Pacific. Keeping McNeil separate signals the company wants to focus on its operations and on fixing its problems.

Still, resolving them will depend on the ability of Mr. Mutchler and other officials to figure out what led to the lapses and establish stringent new systems to ensure raw materials are handled properly, machinery is maintained correctly, testing of finished products is done appropriately and complaints are investigated promptly, said one person familiar with the undertaking.

"Everybody will make a speech saying, 'We are going to clean this up.' The question is, are you going to put up or shut up, because these things are difficult to fix," this person said.

Chief Executive William Weldon, who has faced criticism for his handling of the quality issues, has reorganized manufacturing companywide, and a review of operations has resulted in recalls of some hip-repair parts, certain contact lenses and a variety other products that are made by units aside from McNeil.

In March, the McNeil unit signed a consent decree with the Food and Drug Administration that puts three key manufacturing plants under at least five years of close regulatory supervision. Among the plants is the one in Fort Washington, Pa., that made Benadryl, Motrin, Tylenol and Zyrtec. It was shut down in April 2010 and can't re-open until the FDA certifies a re-fitting has fixed its problems.

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EUROPE EDITION

J&J's McNeil unit gets revamp, new direction

By Jonathan D. Rockoff 554 words 31 March 2011 The Wall Street Journal Europe WSJE UK23 English (Copyright (c) 2011, Dow Jones & Company, Inc.)

Johnson & Johnson is revamping the troubled unit that makes Tylenol and giving it new leadership in an effort to fix quality problems that have prompted multiple recalls, according to people familiar with the matter.

The changes are the latest in a series of efforts by the U.S. health-care products giant to address the manufacturing issues, which have damaged its reputation with consumers and invited scrutiny from the U.S. Congress and regulators.

Through its McNeil Consumer Healthcare unit, J&J sells Tylenol as well as other popular cold, pain and allergy medicines such as Benadryl, Motrin and Zyrtec. Within J&J, the McNeil unit had been lumped together with a wider group of consumer health-care businesses.

Starting Monday, McNeil Consumer Healthcare will be its own organization, according to people familiar with the matter.

The unit will be overseen by Patrick Mutchler, a 35-year J&J veteran who has held a variety of assignments on the company's consumer side, these people said.

Marc Robinson, who had overseen J&J's consumer health-care businesses, and Peter Luther, who had been president of McNeil Consumer Healthcare, have been given other roles. Neither was available for comment, a J&J spokeswoman said.

Jesse Wu, the J&J executive who manages all of its consumer businesses, told employees in a message reviewed by The Wall Street Journal that he is making the change "in order to give focused attention to quality and compliance, and the critical task of restoring" the reputation of the company's products.

A J&J spokesman confirmed the reorganization but declined further comment.

Since late 2009, McNeil has issued more than a dozen recalls due to manufacturing problems that have included the presence of metal shavings in some children's medicine bottles. The problems prompted the shutdown of one of its manufacturing facilities and dealt a notable blow to the company's once-sterling reputation for quality.

Some parents say they won't buy Tylenol for their children anymore. Congress has held two hearings investigating the problems. The company says the recalls cost it \$900 million in sales last year.

Giving McNeil this breakout status is unusual for sprawling J&J. In fact, the rest of the company's consumer businesses will be organized regionally, with different units for different parts of the globe. Separating McNeil signals the company wants to focus on its operations and fixing its problems.

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MA. M. Vitals: Johnson and Johnson Revamps McNeil

WSJ Blogs, 07:59, 31 March 2011, 295 words, By Robert Lee Hotz, (English)
Headache Remedy: To fix its recurring Tyenol problems, Johnson & Johnson is revamping its McNeil Consumer Healthcare unit, which sells the pain medication, the WSJ reports.

Document WCWSJB0020110331e73v004mp

Business

J&J Issues Another Round Of Drug Recalls

By Peter Loftus
367 words
30 March 2011
The Wall Street Journal Online
WSJO
English

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Johnson & Johnson issued another round of recalls of over-the-counter medicines Tuesday, citing quality lapses similar to those implicated in a series of recalls since 2009.

The products that are subject to the latest recall were manufactured at J&J's McNeil Consumer Healthcare plant in Fort Washington, Pa., before production was suspended in April 2010 in connection with prior recalls, company officials said.

In one action, McNeil recalled about 34,000 bottles of Tylenol 8-Hour Extended Release caplets after receiving a small number of complaints of a musty or moldy odor. J&J advised consumers to stop using the product and contact the company about receiving a refund or product coupon.

J&J believes the odor was caused by the presence of trace amounts of chemicals called 2,4,6-tribromoanisole, or TBA, and 2,4,6-trichloroanisole, or TCA. TBA has been linked to complaints of odors that spurred previous recalls of J&J over-the-counter products. J&J has attributed its presence to a chemical applied to wood pallets that transport and store packaging materials.

The detection of TCA, however, hasn't been cited in previous recalls. J&J spokeswoman Bonnie Jacobs said that TCA can form on wood pallets as a result of cleaning processes.

Separately, J&J widened a wholesale-level recall first announced in January, adding 10 product lots comprising nearly 717,696 bottles of various Tylenol, Benadryl and Sudafed products.

This recall doesn't require any action by consumers or doctors, and wasn't undertaken on the basis of adverse events, J&J said.

J&J said the wholesale-level recall was a precautionary measure because a review of past manufacturing records found cases where equipment cleaning procedures were insufficient, or cleaning wasn't adequately documented.

J&J has said it is unlikely this affected the quality of the products.

J&J shares declined by 2 cents to \$59.22 in 4 p.m. trading Tuesday on the New York Stock Exchange.

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

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Business
J&J's Ethicon Unit Recalls Products

By Jon Kamp 299 words 24 March 2011 11:02 The Wall Street Journal Online WSJO English

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Johnson & Johnson's Ethicon unit is recalling about 360,000 units of products used to drain surgical wounds because it determined following customer complaints that the sterile barrier on packaging could be compromised.

Ethicon posted a letter to customers on its website and said the recall affects multiple lots of Blake Silicone Drains, Blake Silicone Drain Kits, Blake Cardio Connectors, J-VAC Reservoirs and J-VAC Drain Adapters. The company said it hasn't gotten any reports of adverse events.

Ethicon linked this issue to a contract manufacturer, but declined to name the company. "We take full accountability for our supply chain," Ethicon spokeswoman Barbara Montresor said Thursday.

The voluntary recall affects 341 product lots in the U.S., and the products in question were distributed between May 10 last year and Feb. 28 this year.

The packaging issue follows Ethicon's early February recall of a wound-sealing adhesive and its December recall of a hernia-repair product. The new recall also adds to a list of product challenges at J&J.

The health-care conglomerate has issued numerous recalls of over-the-counter medicines, including Tylenol and Motrin, due to manufacturing-quality problems. It has also issued separate recalls for certain contact lenses and hip-replacement parts. The recalls have hurt overall sales, and J&J has said it is taking steps to improve quality, including the renovation of an over-the-counter medicine manufacturing plant outside Philadelphia.

J&J doesn't make sales data available for the Ethicon products. Ethicon posted total sales of \$4.5 billion last year, while J&J posted overall sales of \$61.6 billion.

Write to Jon Kamp at jon.kamp@dowjones.com

Document WSJO000020110324e73o006em

Health J&J CEO's Total Pay Falls 7%

By Peter Loftus 654 words 17 March 2011 The Wall Street Journal Online WSJO English

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The value of Johnson & Johnson Chief Executive William Weldon's total compensation for 2010 dropped 7% from 2009, as his performance bonus was reduced to reflect the health-care company's series of product recalls and a second consecutive year of a decline in overall sales.

Mr. Weldon's total compensation was valued at \$28.7 million for 2010 versus \$30.8 million for 2009, according to J&J's proxy statement filed Wednesday with the Securities and Exchange Commission.

As reported in J&J's annual report last month, Mr. Weldon's performance bonus was reduced 45% for 2010 to \$1.98 million.

J&J, which is based in New Brunswick, N.J., detailed the reasons for Mr. Weldon's bonus decline in its proxy statement Wednesday.

The company said its board compensation committee lowered the annual performance bonuses for senior executives, including Mr. Weldon, to reflect disappointments the company experienced in 2010.

"Significant recalls during 2010, primarily at McNeil Consumer Healthcare, negatively impacted both the company's reputation and revenue," the proxy statement said. J&J also cited the sales decline.

J&J has recalled numerous over-the-counter medicines, including Tylenol, and various other products such as hip-replacement parts, citing manufacturing-quality lapses. The recalls have extended into this year as well.

J&J's McNeil unit last week signed a consent decree with U.S. authorities that requires the company to take certain steps to ensure its manufacturing facilities meet standards.

Although critics, including members of Congress, have questioned J&J's handling of the product recalls, J&J's board praised Mr. Weldon's handling of the aftermath of the recalls: "The company's reputation was challenged and revenue impacted during 2010 primarily due to a series of product recalls at McNeil Consumer Healthcare," the proxy statement said. "Mr. Weldon's leadership and engagement with employees, legislators, regulators, investors and the news media enabled the company to deal with the issues."

The proxy also states: "The board believes that Mr. Weldon generally met expectations during 2010, a year with many successes and very visible challenges."

J&J's list of successes for 2010 included adjusted earnings-per-share that met objectives, the implementation of a CEO succession plan and an improved product-research pipeline. The succession plan elevated two executives who are in the running to replace the 62-year-old Mr. Weldon when he departs. He hasn't publicly disclosed a retirement date yet.

The board granted Mr. Weldon a 3% merit raise, effective Feb. 21.

Mr. Weldon's 2010 compensation comprised \$1.85 million in base salary, \$2.8 million in stock awards, \$4.7 million in option awards, \$12 million in non-equity incentive-plan compensation, a \$7 million change in pension value and nonqualified deferred compensation earnings and other miscellaneous items.

In addition, Mr. Weldon gained \$1.8 million by exercising 240,00 options that had been acquired in previous years.

His perquisites and other benefits in 2010 included personal use of company aircraft, valued at \$89,796; a car and driver for commuting and other personal transportation valued at \$29,635; and a nominal amount of home security system monitoring fees.

The proxy also gave a hint of the large payout Mr. Weldon can expect when he ends a J&J career that started in 1971.

The present value of his accumulated pension benefit is listed as \$44.9 million, which would be paid out as an annuity and not as a lump sum. In addition, the aggregate balance of his non-qualified deferred compensation is \$90.7 million.

J&J shares fell 4% in 2010, ending the year at \$61.85. They closed at \$57.66 Wednesday.

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

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U.S. EDITION

Corporate News: J&J Chief's Total Pay Declines After Recalls

By Peter Loftus 654 words 17 March 2011 The Wall Street Journal J B2 English (Copyright (c) 2011, Dow Jones & Company, Inc.)

The value of Johnson & Johnson Chief Executive William Weldon's total compensation for 2010 dropped 7% from 2009, as his performance bonus was reduced to reflect the health-care company's series of product recalls and a second consecutive year of a decline in overall sales.

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U.S. EDITION

Corporate News: FDA Set To Oversee J&J Plants

By Jonathan D. Rockoff and Jennifer Corbett Dooren 445 words 11 March 2011 The Wall Street Journal J B3 English (Copyright (c) 2011, Dow Jones & Company, Inc.)

Johnson & Johnson signed a consent decree with the Food and Drug Administration on Thursday that puts three key manufacturing plants under years of tight regulatory scrutiny, but doesn't levy any fines or shut down two of the three plants that are still running.

Manufacturing problems at the New Brunswick, N.J.-based J&J have led to recalls since late 2009 of over-the-counter medicines, as well as certain contact lenses and hip-repair parts. Just this week, the company recalled leaky insulin cartridges, as it reviews the quality of its operations and finds more deficiencies.

The consent decree involves J&J's McNeil Consumer Healthcare unit, the home to many of the problems. It will subject the company to at least five years of regulatory oversight, a J&J spokeswoman said.

Under the decree, J&J must hire an outside expert to investigate the problems that prompted the FDA to formally warn the company about violations of good manufacturing practices and to develop a plan for fixing the issues. Moreover, the company will have to make sure it's complying with the detailed terms of the 29-page document, including orders for retraining employees and for investigating all returns and consumer complaints.

With the decree, the company can't make any products at its Fort Washington, Pa., plant until the FDA certifies its problems are fixed. The company doesn't expect to reopen the plant this year, a J&J spokeswoman said. J&J had closed the plant last April after recalling more than 135 million bottles of Tylenol and other popular over-the-counter medicines. Since then, the company has been refitting the plant.

"This is a strong, but necessary, step to ensure that the products manufactured by this company meet federal standards for quality, safety and purity," said Deborah Autor, director of the FDA's Office of Compliance, part of the agency's drug division.

Nevertheless, J&J avoided harsh terms required of other companies. The agency has required companies including Abbott Laboratories, Schering-Plough Inc., now owned by Merck & Co., and Wyeth, now part of Pfizer Inc., to pay tens of millions of dollars in fines. By contrast, J&J didn't have to pay a penalty, though it could face fines of up to \$15,000 per violation per day if it doesn't fully comply with plans or timetables for ensuring the plants adhere to all of FDA's manufacturing rules.

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New York Real Estate
FDA Set to Oversee J&J Plants

the three plants that are still running.

By Jonathan D. Rockoff and Jennifer Corbett Dooren 685 words 11 March 2011 The Wall Street Journal Online WSJO English Copyright 2011 Dow Jones & Company, Inc. All Rights Reserved.

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Manufacturing problems at the New Brunswick, N.J.-based J&J have led to recalls since late 2009 of over-the-counter medicines, as well as certain contact lenses and hip-repair parts. Just this week, the company recalled leaky insulin cartridges, as it reviews the quality of its operations and finds more deficiencies.

The consent decree involves J&J's McNeil Consumer Healthcare unit, the home to many of the problems. It will subject the company to at least five years of regulatory oversight, a J&J spokeswoman said.

Under the decree, J&J must hire an outside expert to investigate the problems that prompted the FDA to formally warn the company about violations of good manufacturing practices and to develop a plan for fixing the issues. Moreover, the company will have to make sure it's complying with the detailed terms of the 29-page document, including orders for retraining employees and for investigating all returns and consumer complaints.

With the decree, the company can't make any products at its Fort Washington, Pa., plant until the FDA certifies its problems are fixed. The company doesn't expect to reopen the plant this year, a J&J spokeswoman said. J&J had closed the plant last April after recalling more than 135 million bottles of Tylenol and other popular over-the-counter medicines. Since then, the company has been refitting the plant.

"This is a strong, but necessary, step to ensure that the products manufactured by this company meet federal standards for quality, safety and purity," said Deborah Autor, director of the FDA's Office of Compliance, part of the agency's drug division.

Nevertheless, J&J avoided harsh terms required of other companies. The agency has required companies including Abbott Laboratories, Schering-Plough Inc., now owned by Merck & Co., and Wyeth, now part of Pfizer Inc., to pay tens of millions of dollars in fines. By contrast, J&J didn't have to pay a penalty, though it could face fines of up to \$15,000 per violation per day if it doesn't fully comply with plans or timetables for ensuring the plants adhere to all of FDA's manufacturing rules.

Meantime, J&J's plants in Las Piedras, Puerto Rico, and Lancaster, Penn., can keep running. The Puerto Rico plant makes over-the-counter pain and cold medicines such as Benadryl and Motrin. The Lancaster plant, owned by a J&J and Merck joint venture, makes heartburn medicines Pepcid and Mylanta; Merck is not subject to the decree.

The manufacturing problems have affected some of J&J's best-known products like the allergy medicine Benadryl and hurt the company's reputation with many consumers, who, for instance, found metal particles in bottles of Tylenol children's medicines. Company sales plunged about \$900 million last year due to the recalls. The company has continued making withdrawals, as it reviews its operations.

In addition, CEO William Weldon has come in for criticism. Early this year, the Change to Win pension funds, which hold about 13.5 million J&J shares, chastised Mr. Weldon for not doing enough to protect the reputation of J&J products.

Mr. Weldon has reorganized manufacturing, establishing a companywide team to oversee the supply chain and upgrade standards and facilities. "The consent decree requires additional quality-assurance measures, and is a

reminder that important work remains to be done," Mr. Weldon said in a message to employees. The company declined to make him available for comment.

Write to Jonathan D. Rockoff at $\underline{jonathan.rockoff@wsj.com}$ and Jennifer Corbett Dooren at $\underline{jennifer.corbett-dooren@dowjones.com}$

Document WSJO000020110311e73b000e0

₪ J&J Recall Watch: More Than 384,000 Insulin-Pump Cartridges Pulled

WSJ Blogs, 08:13, 9 March 2011, 732 words, By Katherine Hobson, (English)
Johnson & Johnson's Animas unit has recalled more than 384,000 insulin-pump
cartridges in the U.S. and France, saying they have the potential to leak and give a
too-low dose, Dow Jones Newswires reports. So far J&J has ...

Document WCWSJB0020110309e739003ml

Health
President of J&J's DePuy Orthopaedics Unit to Leave

By Jon Kamp 283 words 7 March 2011 13:54 The Wall Street Journal Online WSJO English

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The president of DePuy Orthopaedics, a Johnson & Johnson unit that makes replacement hips and knees and is dealing with an expensive product recall, has resigned his position to pursue outside interests, a spokeswoman confirmed Monday.

David Floyd has been president of DePuy since 2007. He'll leave after a short transition period. A replacement hasn't been named yet, spokeswoman Mindy Tinsley said.

DePuy in August recalled certain hip-replacement systems due to a high rate of repeat surgeries. The company took a \$280 million reserve in the fourth quarter to cover reasonable and customary testing and treatment for people with the implants.

DePuy has the largest replacement hip business in a market where it competes with Zimmer Holdings Inc. and Stryker Corp., among other firms.

The J&J unit put up a multiyear streak in which its hip business grew faster than the market, but that changed recently. The unit had a slight decline in U.S. market share pegged to the recall of "ASR" hip parts and a decline in sales for so-called metal-on-metal hips, said Michael Mahoney, world-wide chairman for J&J's Medical Devices and Diagnostics business, at a recent RBC Capital Markets conference. The market for these all-metal hips has come under pressure due to worries about particles wearing off and causing medical problems.

Mr. Mahoney, who had been group chairman of J&J's DePuy—which itself includes a handful of companies including DePuy Orthopaedics—was promoted in December to his current job.

Write to Jon Kamp at jon.kamp@dowjones.com

Document WSJO000020110307e737008vi

U.S. EDITION

Health & Wellness: Drugstore Dangers

By Melinda Beck 360 words 1 March 2011 The Wall Street Journal J D2 English (Copyright (c) 2011, Dow Jones & Company, Inc.)

These days, navigating the world of children's pain relievers is almost as tricky as interpreting a child's temperature.

Johnson & Johnson's McNeil Consumer Healthcare unit recalled 136 million bottles of liquid Tylenol, Motrin, Zyrtec and Benadryl for infants and children last year after federal investigators found bacterial contamination and other problems at a plant in Pennsylvania. Subsequent recalls included Children's Tylenol Meltaway strips in bubblegum flavor, Junior Strength Motrin caplets and Children's Benadryl Allergy Fast Melt tablets in cherry and grape.

Problems ranged from moldy smells to floating metal particles to the possibility of excess concentrations of an ingredient. In a legal filing last week, Johnson & Johnson said alternative supplies are expected to be available in the second half of this year.

In their absence, many parents have turned to generics and drugstore brands, children's Advil or Triaminic, another liquid acetaminophen for children.

Experts are still concerned about combination cough-and-cold syrups. Manufacturers voluntarily withdrew those labeled for children under age 2 in 2007 after pediatricians complained that they didn't work well and posed a risk of accidental overdose. But this week's American Academy of Pediatrics report warns that parents should not give cough-and-cold products containing acetaminophen even to older children, given the risk that they might unknowingly take other products with acetaminophen, which can cause fatal liver damage at high doses.

Many liquid medications for children still on the market have confusing dosing information, according to a study in the Journal of the American Medical Association in December. For example: a label calling for a one-teaspoon dose packaged with a cup marked in milliliters. Since the study was conducted, the Food and Drug Administration issued voluntary guidelines for making children's medication labels easier to understand. The researchers, from New York University, plan to repeat the study to see if the guidelines have made a difference.

In the meantime, experts say, parents should pay very careful attention to dosing information since even small errors can have big consequences in children.

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Document J000000020110301e7310000n

Health
J&J CEO's Performance Bonus Cut 45%

By Peter Loftus
544 words
28 February 2011
The Wall Street Journal Online
WSJO
English
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Johnson & Johnson slashed Chief Executive William Weldon's performance bonus by 45% for 2010, a year in which the health-care giant issued a series of product recalls due to manufacturing-quality lapses.

The recalls are continuing, with the company saying this past week that certain packages of the decongestant Sudafed were being recalled because of a misprint on product directions.

In an annual report filed with the Securities and Exchange Commission Friday, J&J said Mr. Weldon's performance bonus for 2010 was \$1.98 million, down from \$3.6 million for 2009. The bonus, which was approved by the compensation committee of J&J's board in January, is paid out in the form of 85% cash and 15% in J&J shares.

In addition, the New Brunswick, N.J., company granted fewer stock options, restricted share units and nonequity incentive compensation units to Mr. Weldon this year than last year. He was granted 560,691 stock options in January, with an exercise price of \$62.20, versus 586,873 options last year with an exercise price of \$62.62.

J&J did, however, boost Mr. Weldon's base salary for 2011 by 3% to \$1.9 million, according to the SEC filing. The year-earlier figures were contained in last year's annual report.

J&J spokeswoman Carol Goodrich said the board's compensation committee evaluated Mr. Weldon and other senior executives against a set of financial and strategic objectives that will be disclosed in a proxy statement expected to be filed with the SEC in March. She said the objectives are based on a pay-for-performance philosophy, but declined to be more specific.

Ms. Goodrich declined to say whether the reduction in Mr. Weldon's performance bonus was related to the product recalls.

Mr. Weldon's total compensation was valued at \$30.8 million for 2009, the last full year for which total compensation was reported. The figure included salary, bonus, changes in pension value and other items.

Last year, quality problems spurred numerous recalls of over-the-counter medicines including Tylenol and Motrin, as well as contact lenses and hip-replacement parts, which hurt J&J's sales and tarnished its reputation for quality products. Mr. Weldon has vowed to fix the problems, including management changes and a renovation of a consumer health-care products manufacturing plant in Fort Washington, Pa. The recalls have continued in the new year, including a series this month.

Regarding the latest recall, J&J's McNeil Consumer Healthcare unit said it is recalling 667,632 packages of the decongestant Sudafed because of a misprint on the product directions. The company said in a website notice that the label repeats the word "not" in the sentence "do not not divide, crush, chew, or dissolve the tablet." McNeil said the recall is taking place on the wholesale level in the U.S. and affects nine product lots of Sudafed 24-hour extended release tablets. No action is required by consumers or health-care providers, the company said.

Jon Kamp contributed to this article.

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

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U.S. EDITION

J&J CEO's 2010 Bonus Cut by 45%

By Peter Loftus
407 words
28 February 2011
The Wall Street Journal
J
NPC
English
(Copyright (c) 2011, Dow Jones & Company, Inc.)

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Jon Kamp contributed to this article.

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Document J000000020110228e72s00014

WSJ Blogs, 08:34, 25 February 2011, 867 words, By Katherine Hobson, (English) Johnson & Johnson's latest recall was caused by a typo that inserted the bête noire of high-school English teachers -- a double negative -- into dosing instructions on more than 667,000 Sudafed packages. The incorrect wording ...

Document WCWSJB0020110225e72p003s8

Health
J&J Recalls Auto-Injection Products

By Peter Loftus
412 words
18 February 2011
12:59
The Wall Street Journal Online
WSJO
English

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Johnson & Johnson recalled at least 395 injection devices containing rheumatoid-arthritis drug Simponi in the U.S. and Germany, due to a potential defect that could result in an insufficient dose of the drug.

European health authorities warned Friday that the manufacturing snafu could cause a temporary shortage of the Simponi injector devices. As an alternative, patients are being advised to use prefilled syringes of Simponi.

The Simponi recall is the latest in a series of product recalls at J&J due to manufacturing-quality lapses, which have hurt sales and damaged the company's reputation. The biggest impact has been on J&J's over-the-counter medicine brands including Tylenol. But recalls also have been issued for other J&J products, including certain pharmaceutical and device products earlier this month.

Simponi, which went on sale in 2009, is approved to treat rheumatoid arthritis and other inflammatory conditions. It's typically injected monthly, either through prefilled syringes or pre-filled "pens," which are devices that allow patients to press a button to deliver the dose.

J&J recently identified a manufacturing problem at a plant in Switzerland that could result in an incomplete dose of the drug delivered by the pens, said spokesman Brian Kenney. The problem was discovered in routine quality testing.

J&J was able to quarantine the bulk of the affected lots, but some got past the wholesale level, and J&J is now recalling them. The recall affects about 230 Simponi pens in Germany and 165 pens in the U.S. that were distributed beyond the wholesale level.

The European Medicines Agency said Friday that only certain Simponi pens were being recalled, and that other pens currently on the market aren't affected and should continue to be used.

J&J will start to make new prefilled pens of Simponi available by the end of February, the EMA said, but not all European countries will have regular supplies until May. The EMA recommended no new patients should start treatment with the pens until the supply problems are resolved.

Although J&J manufacturers the Simponi pens in Europe, Merck & Co. markets the product in Europe under a partnership with J&J, while J&J handles U.S. marketing. A Merck spokesman wasn't immediately available.

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

Document WSJO000020110218e72i008vi

M J&J Recall Watch: Simponi Injection Pens Pulled in U.S. and Germany

WSJ Blogs, 13:32, 18 February 2011, 641 words, By Katherine Hobson, (English)
For the third time this week, we're reporting on a Johnson & Johnson recall. (See hereand herefor the other two.) This time the recall seems to involve only a few hundred units. As Dow Jones Newswires reports, J&J is pulling at ...

Document WCWSJB0020110218e72i006my

U.S. EDITION

Corporate News: J&J Recalls 70,000 Invega Syringes

206 words
16 February 2011
The Wall Street Journal
J
B2
English
(Copyright (c) 2011, Dow Jones & Company, Inc.)

Johnson & Johnson has recalled about 70,000 syringes of an injectable formulation of the antipsychotic Invega after discovering cracks in the syringes, which could potentially lead to infections or reduced efficacy in users.

J&J, which has issued a series of recalls of various products due to manufacturing-quality problems since 2009, sent notice of the recall of Invega Sustenna to distributors, pharmacists and health-care providers on Feb. 11, according to a company website. The recall affects products sold in the U.S., Australia, Canada and South Korea.

The recalled syringes contain 234-milligram dosages of Invega Sustenna, which were distributed beginning in March 2010. Other dosage strengths of the drug aren't being recalled.

J&J said some of the prefilled syringes had a crack in the syringe barrel, which isn't detectable by the user. The cracks may have been caused by stress during the label application process, said J&J spokesman Greg Panico. J&J discovered the flaw in routine testing, he said. "Our manufacturing team did resolve the issue and the production line is up," Mr. Panico said.

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Health
J&J Recalls 70,000 Invega Syringes

By Peter Loftus
423 words
16 February 2011
The Wall Street Journal Online
WSJO
English

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Johnson & Johnson has recalled about 70,000 syringes of an injectable formulation of the antipsychotic Invega after discovering cracks in the syringes, which could potentially lead to infections or reduced efficacy in users.

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"Our manufacturing team did resolve the issue and the production line is up," Mr. Panico said.

The New Brunswick, N.J., company said the cracks could theoretically compromise the sterility of the syringe contents and possibly result in local injection-site infections or systemic infections. Leakage of the drug through the crack could result in a lower-than-intended therapeutic dose if the product is administered.

J&J said the risk for infection or reduced efficacy is considered low. J&J has received one report of an adverse event in Australia that may be related to the cracks, Mr. Panico said. He didn't have further details on the nature of the adverse event.

Invega Sustenna is an injectable formulation of Invega that can be administered monthly for treatment of schizophrenia. The tablet formulation can be taken daily.

J&J reported global Invega sales of \$424 million for 2010.

J&J has issued numerous recalls of over-the-counter medicines, including Tylenol and Motrin, due to manufacturing-quality problems. It has also issued separate recalls for certain contact lenses and hip-replacement parts. The recalls have hurt overall sales, and J&J has said it is taking steps to improve quality, including the renovation of an over-the-counter medicine manufacturing plant outside Philadelphia.

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

Document WSJO000020110216e72g000m9

Health

Device Review Process Faulted; Most Recalled Medical Products Were Cleared in Abbreviated Manner, Study Says

By Alicia Mundy And Jon Kamp 800 words 15 February 2011 The Wall Street Journal Online WSJO English

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Most of the medical devices recalled in recent years because of serious or life-threatening hazards were initially cleared for market through an abbreviated approval system that doesn't require testing on patients, according to a study in the Archives of Internal Medicine.

The study by a Washington health-research group and the Cleveland Clinic's Steven Nissen comes after the Food and Drug Administration proposed changes to tighten the faster approval system, known as 510(k), but put off some of its toughest proposals for further study under pressure from device makers.

Of 113 medical devices that were subject to recalls between 2005 and 2009, 80 were allowed on the market through the 510(k) program, the study found. About a third of the recalled devices were cardiovascular products, including several brands of external defibrillators.

"These findings suggest that reform of the regulatory process is needed to ensure the safety of medical devices," said the authors. The lead author, Diana Zuckerman, heads the National Research Center for Women & Families, a group that has advocated stiffer approval standards for medical devices.

The 510(k) process is popular with the industry because it can save time and money in regulatory reviews, and industry lobbyists have been campaigning on Capitol Hill against radical revisions to the program.

The process requires that the proposed device be similar to a product already marketed, and is intended for low and moderate-risk devices.

The industry's lobbying group, the Advanced Medical Technology Association, or AdvaMed, said the study is flawed because it looks at the number of recalls without comparing that to the number of devices that didn't have problems. AdvaMed-supported studies say that more than 99% of the devices cleared through 510(k) don't face recalls.

Overall, the 510(k) program has a "remarkable safety record with extremely low recall rates," AdvaMed said.

"Adoption of the paper's recommendations would actually harm American patients by further delaying access to safe and effective treatments," said AdvaMed's president Stephen Ubl. The group represents top device makers such as Johnson & Johnson and Medtronic Inc.

In an interview, Dr. Nissen dismissed the criticism, saying the withdrawn products are used on millions of Americans. "We are looking at the recalls that the FDA deemed serious, potentially life-threatening ... We found—to my surprise—that more than 70% of them got through the FDA on the fast-track 510(k)," he said.

The study, using FDA data, said that nearly 20% of the one million external defibrillators in use have been recalled, and "hundreds of deaths" are attributed to their malfunctions. The FDA has proposed tougher rules that would require the external defibrillators to undergo the same kind of review that implanted defibrillators get.

Makers of external defibrillators defended their safety record and said the devices can save lives of people who suffer sudden heart attacks in public places. A spokesman for Medtronic, which makes some of the devices cited in Dr. Nissen's article, said a study looking at 1,600 of the devices found no device failures or clinical harm.

Jonathan Rennert, president of Zoll Medical Corp., said the problem with his company's external defibrillator, involving the batteries, didn't manifest itself until several years after it went into use. "I don't believe a more stringent approval path would have made a difference," he said.

A 510(k) costs the FDA an average of about \$20,000 per application compared to more than \$800,000 for a full device review by the agency, according to the report. A full review includes evaluation of safety-and-efficacy clinical trials.

Companies pay user fees that cover about a quarter of those review costs, but the real expense comes from conducting trials that may cost millions of dollars.

The FDA began reconsidering the 510(k) process in 2009 after articles in The Wall Street Journal about a knee implant that got 510(k) approval in 2008 over repeated objections from FDA scientists and managers. A government report in 2009 said that the abbreviated clearance process was being overused.

The changes proposed by the FDA last month to the 510(k) would leave the general contours of the program intact and won praise from the industry.

FDA spokeswoman Karen Riley said Monday that while "even one recall is too many," the 80 recalls cited in the new study "represent a small number of the devices cleared via this program and don't reflect the thousands of people who have benefited from these devices."

Write to Alicia Mundy at alicia.mundy@wsj.com and Jon Kamp at jon.kamp@dowjones.com

Document WSJO000020110215e72f0008h

WSJ Blogs, 16:43, 15 February 2011, 504 words, By Katherine Hobson, (English) Johnson & Johnson is recalling 70,000 syringes preloaded with its Invega injectable anti-psychotic drug, the WSJ reports. Cracks have been found in the syringes that could theoretically lead to infections or under-dosing in users of ...

Document WCWSJB0020110215e72f007c0

Management PR Experts' Advice for Toyota

By Joann S. Lublin
415 words
26 January 2011
14:58
The Wall Street Journal Online
WSJO
English

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Toyota Motor Corp.'s latest massive recall likely won't dent its reputation much, crisis-management experts predict. But the auto maker still should take steps to minimize possible damage, some specialists suggested.

Toyota officials "have done a pretty good job of communicating with their core buyers" since their 2010 recall of 3.4 million vehicles, said Eric Dezenhall, CEO of Dezenhall Resources, a crisis-management firm in Washington. Retaining loyal customers "is a lot of what good crisis management is about," he continued.

Thanks to prior outreach efforts and lack of injuries related to the latest recall, Mr. Dezenhall believes Toyota should proceed in a low-key manner by simply encouraging owners to bring their vehicles in for repairs. A massive ad campaign "doesn't help them at this point," he said. Garden-variety recalls are different "than cars running out of control."

Other experts disagree, however. The latest recall "is damaging the brand more," and may discourage potential Toyota buyers because they see a car maker with persistent quality problems, observed Gerald C. Meyers, a University of Michigan business professor of organization and management. He also is a former auto-industry executive.

Mr. Meyers thinks Toyota should increase its planned spending on Super Bowl ads and offer commercials that promote the brand "as being safe, secure and reliable."

Another tactic would be for Toyota President Akio Toyoda to take a public stance about this week's recall. Last year, he went on a charm offensive following the auto maker's quality woes. Those efforts included a tearful public apology.

Mr. Toyoda "has to get out early" this time because he waited too long last year, said Jerry Doyle, principal of CommCore Inc. a New York firm that handles crisis communications and management. Mr. Doyle proposes that the Toyota president issue a statement or give a news conference stating, "We are now prepared to manage this. We know where the problem is."

Recent safety headaches also have tarnished the reputation for Johnson & Johnson, a maker of products ranging from Band-Aids to the anti-inflammatory drug Remicade. It's trying to recover from a series of product recalls since 2009. In response, J&J suspended manufacturing at a U.S. plant and made changes at a Puerto Rico facility, which together reduced the company's 2010 sales by about \$900 million.

Write to Joann S. Lublin at joann.lublin@wsj.com

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EUROPE EDITION

J&J's profit drops 12% on recalls, sluggish sales

By Peter Loftus
526 words
26 January 2011
The Wall Street Journal Europe
WSJE
21
English
(Copyright (c) 2011, Dow Jones & Company, Inc.)

Johnson & Johnson reported a 12% decline in fourth-quarter earnings and issued a disappointing outlook as the health-care company deals with a slowdown in health spending and the continued fallout from its product recalls.

The New Brunswick, N.J., maker of products ranging from Band-Aids to the anti-inflammatory drug Remicade posted back-to-back years of sales declines for the first time since it went public in 1944, a spokesman said. J&J posted three consecutive years of sales declines in the early 1930s.

J&J has been trying to recover from a series of product recalls since 2009, especially over-the-counter medicines such as Tylenol and Motrin, for quality-related issues such as musty odors and excessive concentrations of active ingredients. In response to the problems, J&J suspended manufacturing at a plant outside Philadelphia and made changes at a plant in Puerto Rico, which together reduced the company's 2010 sales by about \$900 million.

J&J had previously predicted the shutdown of its Fort Washington, Pa., plant would reduce 2010 sales by about \$600 million, but that didn't factor in the impact of the plant in Las Piedras, Puerto Rico, which also has been the source of recalled products and has been cited by U.S. regulators for deficiencies. J&J said Tuesday it is streamlining operations at Las Piedras, temporarily transferring certain products to other sites, or eliminating some other products and promotional items that would have been produced there.

The company said it is facing a broader slowdown in health-care spending trends. In addition, J&J and other drug and medical device makers have incurred new costs related to the U.S. health-care overhaul enacted last year, and European national health programs have imposed price cuts on certain products.

Chief Executive William Weldon said 2010 was a challenging year and the company would continue to see near-term pressures for 2011.

"Consumer trust in our company and products is fundamental to everything we do and that trust has truly been tested." he said.

But he said he was optimistic the company was making progress resolving its quality-related problems, and that J&J would start returning to more normal growth rates later this year and next.

J&J has completed a review of McNeil Consumer Healthcare products manufactured internally -- about 80% of the products -- and is now reviewing externally manufactured products, which could result in further actions such as recalls.

For the fourth quarter, J&J posted earnings of \$1.9 billion, or 70 cents a share, compared with \$2.2 billion, or 79 cents a share, a year earlier. The latest quarter included expenses related to litigation settlements, product-liability costs and last year's recall of hip-replacement products.

Fourth-quarter sales fell 5.5% to \$15.6 billion, with U.S. sales down 8.1% and non-U.S. sales down 3.1%.

Jon Kamp contributed to this article.

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Earnings
J&J Profit Drops 12% on Recall Costs, Sluggish Sales

By Peter Loftus 1,093 words 25 January 2011 12:54 The Wall Street Journal Online WSJO English

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J&J shares fell \$1.02, or 1.6%, to \$61.20 in recent trading and earlier hit their lowest point since September.

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The company said it is facing a broader slowdown in health-care spending trends, partly due to economic sluggishness. In addition, J&J and other drug and medical device makers have incurred new costs related to the U.S. health-care overhaul enacted last year, and European national health programs have imposed price cuts on certain products.

Chief Executive William Weldon said 2010 was a challenging year and the company would continue to see near-term pressures for 2011. "The results of our consumer business were clearly a disappointment," Mr. Weldon told analysts at a meeting Tuesday in New York.

"Consumer trust in our company and products is fundamental to everything we do and that trust has truly been tested." he said.

But he said he was optimistic the company was making progress resolving its quality-related problems, and that J&J would start returning to more normal growth rates later this year and next. "I am confident we are putting the supply chain problems of 2010 behind us," Mr. Weldon said.

J&J has completed a review of McNeil Consumer Healthcare products that are manufactured internally--about 80% of the products—and is now in the process of reviewing externally manufactured products, which could result in further market actions such as recalls.

For the fourth quarter, J&J posted earnings of \$1.9 billion, or 70 cents a share, compared with \$2.2 billion, or 79 cents a share, a year earlier. The latest quarter included expenses related to litigation settlements, product-liability costs and last year's recall of hip-replacement products. Excluding these items, earnings were \$1.03 a share, matching the mean estimate of analysts surveyed by Thomson Reuters.

J&J's DePuy unit in August recalled certain hip-replacement systems due to a high rate of repeat surgeries. The company took a fourth-quarter reserve of \$280 million to cover reasonable and customary testing and treatment for recipients of the implants.

Credit Suisse analyst Catherine Arnold said lower tax provisions and expenses, as well as higher nonoperating income, helped J&J meet fourth-quarter earnings expectations.

Fourth-quarter sales fell 5.5% to \$15.6 billion, short of the Street estimate of \$16 billion, with U.S. sales down 8.1% and non-U.S. sales down 3.1%. Currency-exchange rates reduced sales growth by less than 1%. The year-over-year comparison also suffered from an extra week in 2009.

J&J's biggest unit, medical devices and diagnostics, had fourth-quarter sales of \$6.3 billion, up 0.2%. Vision-care and diagnostics products posted sales growth, while sales of artery-opening stents and joint-replacement parts declined. J&J said the weakened economy curbed growth in joint-replacement procedures.

J&J's pharmaceutical unit had sales of \$5.7 billion, down 4.7%, hurt by generic competition for certain drugs. Sales rose for HIV treatment Prezista and cancer drug Velcade, but declined for Remicade and antipsychotic Risperdal. Remicade, J&J's top-selling drug, lost share from what J&J said was an increasingly competitive U.S. market for anti-inflammatory drugs, which treat rheumatoid arthritis and the skin disease psoriasis.

Consumer-unit sales declined 15% to \$3.6 billion, with over-the-counter and nutritionals sales off 31%, due largely to the recalls. Other consumer products also saw declines, including skin care and women's health.

Louise Mehrotra, head of investor relations, said J&J expects to ramp up the supply of products previously made at its Fort Washington, Pa., plant in the latter half of this year, slightly later than expected. She said J&J pushed back the production plans because it is upgrading its manufacturing and quality processes.

J&J's handling of issues related to the over-the-counter medicine recalls triggered investigations by various government bodies, including a House committee and a criminal probe by the Justice Department. The Food and Drug Administration has found various deficiencies at J&J plants following inspections over the past year. J&J has vowed to correct the problems, including renovation of its Fort Washington plant.

Full-year 2010 sales were \$61.6 billion, down 0.5% versus 2009.

J&J said it expected 2011 earnings of \$4.80 to \$4.90 a share, excluding certain items, on revenue of about \$64 billion. Analysts have been expecting earnings of \$4.97 a share on revenue of \$64 billion. J&J said ongoing costs related to the recalls, health-care overhaul costs and pricing pressure will weigh on 2011 earnings.

Jon Kamp contributed to this article.

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

Document WSJO000020110125e71p00669

WSJ Blogs, 11:39, 25 January 2011, 281 words, By Katherine Hobson, (English)
The cost of Johnson & Johnson's string of recent McNeil product recalls, most notably those of children's medicines: about \$900 million in lost sales in 2010.

Document WCWSJB0020110125e71p006bv

WSJ Blogs, 07:35, 25 January 2011, 336 words, By WSJ Staff, (English)
Dow Jones' Newswires' John Kell reports: Johnson & Johnson's fourth-quarter profit fell
12% as the company recorded a \$922 million charge related to the DePuy ASR hip recall
and sales slid more than analysts expected.

Document WCWSJB0020110125e71p00439

U.S. EDITION

Health & Wellness: J&J Recalls Medicines, Citing Quality

By Peter Loftus
333 words
18 January 2011
The Wall Street Journal
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English
(Copyright (c) 2011, Dow Jones & Company, Inc.)

Johnson & Johnson recalled nearly 47 million units of over-the-counter medicines Friday, the latest in a string of quality-related product recalls.

J&J also said the latest recall resulted from a thorough examination of historical manufacturing records that the company had undertaken in the wake of earlier recalls. J&J signaled additional recalls may result from these reviews.

The company said the latest recalls were at the wholesale level, and that no action is required by consumers or health-care providers. Consumers can continue to use previously purchased products, J&J said.

The New Brunswick, N.J., company was recalling 42.9 million bottles of certain Tylenol, Benadryl, Sudafed and Sinutab products distributed in the U.S., the Caribbean and Brazil.

J&J said these products were made at its McNeil Consumer Healthcare plant in Fort Washington, Pa., before April 2010, when production was suspended. J&J said it reviewed past production records and found cases where equipment-cleaning procedures were insufficient, or cleaning wasn't adequately documented.

J&J said it was "very unlikely" these issues affected the quality of the recalled products.

In addition, J&J recalled 3.9 million bottles, rolls and packages of Rolaids antacid distributed in the U.S., to update the product labeling. The company said the labeling didn't include a notice that the product wasn't tested using U.S. Pharmacopeia, which is a nongovernmental testing method for medicines. The FDA doesn't require the use of USP, but labels on products that don't use this testing are required to include the language "Does not meet USP," said McNeil spokeswoman Bonnie Jacobs.

J&J has issued a series of recalls of over-the-counter medications since late 2009, citing quality problems such as excessive concentrations of active ingredients, and floating metal specks.

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Document J000000020110118e71i00020

Health
J&J Recalls Medicines, Citing Quality

By Peter Loftus
335 words
18 January 2011
The Wall Street Journal Online
WSJO
English

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

Document WSJO000020110117e71i009vn

WSJ Blogs, 16:09, 14 January 2011, 496 words, By Katherine Hobson, (English) We are continuing to keep tabs on Johnson & Johnson's string of recalls. Most notably, the company pulled about 40 kinds of kids' medicinesfrom store shelves last year. And, as the WSJ has reported, more recalls are likely as ...

Document WCWSJB0020110114e71e008kd

EUROPE EDITION

CEOs face big repairs in 2011

By Joann S. Lublin 801 words 5 January 2011 The Wall Street Journal Europe WSJE 21 English (Copyright (c) 2011, Dow Jones & Company, Inc.)

Most chief executives are entering 2011 with big decisions to make -- especially how to revive sales.

But some have deeper problems. Among the chiefs facing big challenges in 2011 are Nokia Corp.'s Stephen Elop, Yahoo Inc.'s Carol Bartz, Johnson & Johnson's William Weldon and Chrysler Group LLC's Sergio Marchionne.

Facing down fierce competition will be key for some, such as Nokia's Mr. Elop, who must try to reverse market share declines in smartphones amid major inroads by Apple Inc.'s iPhone and Google Inc.'s Android software.

Other CEOs will focus on getting their houses in order. J&J's Mr. Weldon, for instance, must restore the company's reputation for quality after a string of product recalls.

Here's a look at some of the big corporate challenges to watch in 2011:

Stephen Elop, Nokia

Mr. Elop, a former Microsoft Corp. executive who took the helm at Nokia in September, needs to make smart moves to turn around the company's struggling smartphone business.

Mr. Elop faces increasing pressure to justify Nokia's hanging on to its shrinking Symbian smartphone operating system rather than adopting Android. The share of smartphones running Symbian fell to 36.6% of the global market in the third quarter from 44.6% a year ago, while Android's share rose to 25.5% from 3.5%, according to Gartner Inc.

At the same time, Mr. Elop must revamp the corporate culture and revive its focus on innovation, said Umesh Ramakrishnan, a telecom specialist and vice chairman of recruiters CTPartners.

Mr. Elop acknowledged his top challenge during an October investor call: "We must reassess our role in and our approach to this industry," he said.

The CEO has nothing new to add about his strategy, a spokeswoman said.

Carol Bartz, Yahoo

Ms. Bartz is under the gun to show faster progress in her turnaround effort at Yahoo.

She joined the struggling Internet concern in early 2009, quickly pulling off a search deal with Microsoft and cutting costs. Yet Yahoo still struggles to increase ad sales.

In October, the company reported another quarter of sluggish revenue growth. Investors and analysts worry about Yahoo's expansion prospects amid stiff competition from rivals such as Google and Facebook.

"We are pleased with the progress Carol is making turning around Yahoo," said Roy Bostock, its independent chairman, in a prepared statement.

William Weldon, J&J

In 2011, Mr. Weldon must revive J&J's squeaky-clean image of corporate responsibility as he looks to preserve his legacy.

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Manufacturing problems at J&J triggered a string of recalls and a still-pending federal criminal investigation being handled by the U.S. Justice Department.

In announcing a manufacturing reorganization in August, Mr. Weldon said: "The people who use our products are our first priority, and we've let them down."

Mr. Weldon created a company-wide quality team and is upgrading plants. He also named a new head of the consumer business, and appointed a vice chairman to oversee that newly elevated executive.

Some investor activists are skeptical that Mr. Weldon's corrective steps go far enough. Mr. Weldon "has failed to manage reputation risk concerning product safety," said William Patterson, executive director of the investment arm of labor federation Change to Win.

James G. Cullen, the board's lead independent director, disagrees. "Everyone feels Bill has handled these series of crises as best as he could," he said.

Sergio Marchionne, Chrysler

In 2011, the strength of the Chrysler-Fiat partnership will be put to the test.

Mr. Marchionne needs to convince customers Chrysler's new and upgraded auto designs are attractive and well-built enough to accelerate Chrysler's turnaround.

The car maker has made progress, but isn't moving forward at the same pace as its Detroit rivals. In the third quarter, Ford posted a \$1.7 billion profit and General Motors -- which returned to the public markets in November -- earned \$2 billion.

Chrysler meanwhile had a third-quarter net loss of \$84 million.

On Monday, Mr. Marchionne, who is also Fiat SpA's CEO, said that Chrysler "will have to deliver" its predicted break-even net profit for 2011. He also said Fiat may lift its 20% Chrysler stake above 50% this year if the U.S. company returns to the stock market.

Mr. Marchhionne "has proved a lot of critics wrong," said David Whiston, an automotive equity analyst for Morningstar Inc.

Some Chrysler board members also are impressed by his progress so far. Mr. Marchionne "has outlined a clear, concise sense of strategic direction and executes against it," said Stephen M. Wolf, an independent director, in a statement released by Chrysler.

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Document WSJE000020110105e7150000g

Management Some CEOs Face Big Repair Jobs in 2011

By Joann S. Lublin 1,282 words 3 January 2011 The Wall Street Journal Online WSJO English

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Most chief executives are entering 2011 with big decisions to make—especially how to revive sales.

But some have deeper problems to address. Among the chiefs facing big challenges in 2011 are Nokia Corp.'s Stephen Elop, Yahoo Inc.'s Carol Bartz, Johnson & Johnson's William Weldon, Chrysler Group LLC's Sergio Marchionne and Eastman Kodak Co.'s Antonio Perez.

Facing down fierce competition will be key for some, such as Nokia's Mr. Elop, who must try to reverse market share declines in smartphones amid major inroads by Apple Inc.'s iPhone and Google Inc.'s Android software.

Similarly, Yahoo's Ms. Bartz must convince skeptical investors that Yahoo's turnaround is gaining steam while fighting toughened rivalry from Google as well as Facebook Inc. Chrysler's Mr. Marchionne is dealing with reinvigorated Detroit rivals Ford Motor Co. and General Motors Co.

Other CEOs will focus on getting their houses in order. J&J's Mr. Weldon, for instance, must restore the company's reputation for quality after a string of embarrassing product recalls. Kodak's Mr. Perez soon confronts a key milestone in his attempt to transform the photography company.

Here's a look at some of the big corporate challenges to watch in 2011:

Stephen Elop, Nokia

Mr. Elop, a former Microsoft Corp. executive who took the helm at Nokia in September, needs to make smart moves to turn around the company's struggling smartphone business.

The new CEO acknowledged as much during his first address to investors in late October, during which he said the Finnish concern would have to undergo changes to better compete with rivals.

Mr. Elop faces increasing pressure to justify Nokia's hanging on to its shrinking Symbian smartphone operating system rather than adopt Android. The share of smartphones running Symbian fell to 36.6% of the global market in the third quarter from 44.6% a year ago, while Android's share rose to 25.5% from 3.5%, according to Gartner Inc., a research and advisory company.

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The CEO has nothing new to add about his strategy, a spokeswoman said.

Carol Bartz, Yahoo

Ms. Bartz is under the gun to show faster progress in her turnaround effort at Yahoo.

She joined the struggling Internet concern in early 2009, quickly pulling off a search deal with Microsoft and cutting costs. Yet Yahoo still struggles to increase ad sales, especially in North America, its most important region.

In October, the company reported another quarter of sluggish revenue growth. Investors and analysts worry about Yahoo's expansion prospects amid stiff competition from rivals such as Google and Facebook.

In December, Yahoo said it was cutting about 600 jobs, or about 4% of its work force. Meanwhile, AOL Inc. recently hired financial advisers to explore various strategic options including a possible tie-up with Yahoo, people familiar with the matter have said.

AOL Chief Executive Tim Armstrong recently said the two companies could benefit from partnering, although he didn't specifically comment about a merger.

"We are pleased with the progress Carol is making turning around Yahoo and the board of directors fully supports her long-term strategic plan," said Roy Bostock, its independent chairman, in a prepared statement.

William Weldon, J&J

In 2011, Mr. Weldon must revive J&J's squeaky-clean image of corporate responsibility as he looks to preserve his legacy.

Manufacturing problems at J&J triggered a string of recalls and a still-pending federal criminal investigation being handled by the U.S. Justice Department. The most massive of J&J's recent recalls involved children's Tylenol and other over-the-counter medicines, which resulted in the temporary shutdown of a Ft. Washington, Pa., plant. The company previously said that recall alone would cost it an estimated \$600 million in lost sales for 2010.

In announcing a manufacturing reorganization in August, Mr. Weldon said: "The people who use our products are our first priority, and we've let them down."

Mr. Weldon created a company-wide quality team and is upgrading plants. He also recently named a new head of the consumer business, and appointed a vice chairman to oversee that newly elevated executive.

Some investor activists are skeptical that Mr. Weldon's corrective steps go far enough. Mr. Weldon "has failed to manage reputation risk concerning product safety," said William Patterson, executive director of the investment arm of labor federation Change to Win. CtW union pension funds hold about 13.5 million, or less than 1%, of J&J average outstanding shares.

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On Monday, Mr. Marchionne, who is also Fiat SpA's CEO, said that Chrysler "will have to deliver" its predicted break-even net profit for 2011. He also said Fiat may lift its 20% Chrysler stake above 50% this year if the U.S. company returns to the stock market.

As part of its effort to jump-start sales, Chrysler is rolling out upgraded or redesigned versions of 17 vehicles.

Mr. Marchionne "has proved a lot of critics wrong," said David Whiston, an automotive equity analyst for Morningstar Inc. But before Chrysler goes public again, Mr. Whiston said he would like to see "a year or two of profitable results."

Some Chrysler board members also are impressed by his progress so far. Mr. Marchionne "has outlined a clear, concise sense of strategic direction and executes against it," said Stephen M. Wolf, an independent director, in a statement released by Chrysler.

Antonio Perez, Kodak

When Mr. Perez advanced to Kodak CEO from its second in command in 2005, the former Hewlett-Packard Co. executive was expected to help transform the film giant into one focused on digital technologies.

He's still developing the transformation. Amid restructuring and attempts to build new businesses, Kodak has generated only one full-year profit—in 2007—since 2004.

This year marks a key milestone in that transition. It's the year the consumer inkjet printer business—which the CEO considers one of the cornerstones of Kodak's business going forward—is supposed to break even.

Mr. Perez "hasn't delivered on most of his financial targets for the past five years," said Chris Whitmore, a Deutsche Bank analyst. His strategy "has not worked."

Shares of Kodak have fallen about 80% since Mr. Perez became CEO.

Some Kodak directors say they view their chief differently. Mr. Perez "is the right person to lead the historic transformation of Kodak," said Rick Braddock, the board's presiding director.

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ASIA EDITION

Corporate News: Firms learn PR lessons the hard way --- From Toyota's auto-safety problems to BP's U.S. oil spill, 2010 saw more than its fair share of corporate crises

By Suzanne Vranica 2,005 words 31 December 2010 The Wall Street Journal Asia AWSJ 18 English

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Amid harsher government scrutiny and lingering public mistrust of business, 2010 saw more than its fair share of corporate crises.

Some of the biggest stemmed from unexpected events, such as Toyota Motor Corp.'s safety problems and BP PLC's oil spill. But crisis-management experts say some companies compounded their woes by botching the initial public-relations response.

With legislators quick to call executives to account and a recession-battered public wary of big business, the result was a year full of corporate crises.

"In 2010, some of the most valued companies in the world had problems," says Andrew Gilman, president and chief executive of CommCore Consulting.

In some cases, increased government scrutiny added to the pressure on corporations and their top executives. Crisis advisors say executives increasingly need to be more mindful not just of their companies' image with consumers, but also with government officials. Indeed, the year saw top brass at BP and Toyota hauled before legislators to answer questions.

"We are in the midst of a highly regulatory regime in Washington and government is being more aggressive in policing companies," says Chris Gidez, U.S. director of risk management and crisis communication at WPP PLC's Hill & Knowlton.

Here's a look at how companies handled some of the year's corporate crises:

BP PLC

Case: BP's image suffered after the Deepwater Horizon disaster, which saw torrents of oil spew into the Gulf of Mexico.

Experts say: As part of its crisis plan, BP aired an ad that featured a personal pitch and apology from its then-CEO, Mr. Hayward. In the commercial, Mr. Hayward promised taxpayers they wouldn't be footing the clean-up bill.

But Mr. Hayward's other gaffes -- most notably saying he wanted his "life back" -- undermined his credibility with the public, PR experts say.

Although many PR professionals believe that in some cases a chief executive should be a company's primary spokesperson during a major crisis, in other cases the CEO may not be the right fit. "The CEO needs to be visible at the outset but can designate the person in the U.S. to be the face of the crisis." says Harlan Loeb, director of U.S. crisis and issue management at Edelman.

Davis Weinstock, chairman of Clark & Weinstock, a reputation-management firm, says Mr. Hayward "was not the right face" for the crisis. A study by Interbrand, a branding firm owned by Omnicom Group Inc. that tracks and publishes the top 100 global brands every year, found that the BP brand fell off its top-100 global brand list this year. The oil company had been on the list for nine years, and ranked as the 83rd most valuable brand last year.

Coda: Experts say subsequent ads featuring BP employees from the Gulf region seemed to resonate better. However, the brand is still in need of repair, say public relations experts, and the company must develop a new corporate campaign to replace its "Beyond Petroleum" pitch, PR experts add. "BP presented itself as beyond petroleum, which implied we are a better oil company than others and the spill said maybe they are not," said Mr. Gidez at Hill & Knowlton.

"Our philosophy right from the moment the tragedy happened was to 'do the right thing' for those affected; we knew that the chief exec should be in charge and be seen to be in charge. As the crisis developed so did the tools we used for messaging," said a statement from a BP spokesman.

Apple Inc.

Case: In "Antennagate," Apple Inc. was besieged by criticism that the antenna design on the iPhone 4 caused reception problems. The brouhaha reached a crescendo when Consumer Reports said it couldn't recommend buying the phone and that its tests showed a hardware defect caused the phone to lose reception when held a certain way.

The magazine's analysis ran counter to Apple's claims that the problem was rooted in software that could be easily fixed.

Experts say: "Always listen to your customer -- and if they are telling you something, say 'thank you' and offer to remediate the problem immediately," says James S. O'Rourke, a professor of management at the University of Notre Dame. "Apple tried to minimize the problem, which is always a mistake."

Coda: Eventually, Apple offered a free "bumper" case to iPhone 4 customers. Despite the dent to Apple's reputation, iPhone 4 sales have been brisk. Earlier this year, the company said it has not seen any decline in demand for the phone because of the antenna problems.

A spokeswoman for Apple declined to comment.

Toyota Motor Corp.

Case: Toyota was forced to recall over eight million vehicles because of several problems including sticky gas pedals that caused automobiles to suddenly accelerate, challenging Toyota's reputation for quality. The car maker had to pay a \$16.4 million fine in the U.S. for its failure to quickly disclose potential safety defects and more recently, the Obama administration slapped the company with \$32.4 million in civil penalties for failing to properly disclose what it knew about safety defects.

Experts say: PR consultants say Toyota was slow to respond and didn't clearly explain the cause of the problem. "They didn't engage quick enough," says Michael Sitrick, chairman and chief executive of Sitrick & Co., a crisis PR firm that recently represented Mark Hurd during his ouster from Hewlett-Packard Co.

Interbrand found that Toyota's brand value fell 16% this year because of the recall. The car maker had been the eighth largest brand in the world in 2009 but slipped to No. 11 this year. Interbrand's metric takes into account the company's financial condition, third party consumer polling data and its specialists' opinions.

Coda: Although its market share has fallen, experts say Toyota is repairing its image with the help of ads that talk about its Star Safety System and showing that they are changing some processes, such as assigning many engineers to investigate quality problems and extending time devoted to testing new models.

"While it looked to the outside world that we weren't moving fast enough, our engineers were working hard to find the root cause, an effective remedy to perform on millions of vehicles and reviewing it with government regulators," says Mike Michels, a spokesman for Toyota. "The engineering solution for a recall very often lags behind the point of which the announcement is made that there will be a recall. That is particularly challenging from a PR standpoint."

Toyota says it's seen "encouraging signs" that its customer loyalty has remained intact based on data that show that customers affected by the recall are more satisfied than regular Toyota customers and that it is seeing competitor trade-ins "return to historic levels."

Hewlett-Packard Co.

Case: In August, H-P announced CEO Mark Hurd was stepping down. The board cited business-conduct violations related to a relationship with a former contractor.

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Experts say: "There was paucity of information from H-P," says Irv Schenkler, clinical associate professor of management communication at New York University's Stern School of Business.

The company, he says, gave a legalistic statement of what they were doing and found, but left too many "gaps," which opened them up to criticism about their decision, including some blasts from Oracle Corp. CEO Larry Ellison, who later hired Mr. Hurd as co-president.

Coda: H-P's board won both criticism and praise, with some management experts saying directors were right to oust Mr. Hurd if they felt he had demonstrated ethical lapses. In December, The Wall Street Journal reported that federal regulators were investigating Mr. Hurd's departure, including a claim that the former chief shared inside information, according to people familiar with the matter.

"H-P is focused on the future," said an H-P spokeswoman.

Facebook Inc.

The case: Facebook came under fire on Capitol Hill earlier this year after it rolled out new features that might make users' data more public and a series of changes to its privacy settings that could lead users to expose more information about themselves. The outcry prompted the company to switch to simplified privacy controls in June.

In October, the Journal reported that many of the most popular applications on the social-networking site were sending user ID numbers to advertising and tracking companies, violating Facebook's rules.

Facebook later said a data broker had been paying app developers for information about its users, and that it had placed some developers on a six-month suspension from its site because of the practice. It also told lawmakers it had taken steps to prevent the sharing of personal information about users.

Experts say:

Michael Robinson, a senior vice president of Levick Strategic Communications, a crisis communications firm based in Washington, D.C., says he would like to see Facebook portray itself as a stronger leader on privacy issues. Users' enthusiasm for Facebook has largely shielded the brand from damage so far, but he says that goodwill may erode as Facebook grows up. "People very quickly tire of managing by whack-a-mole and will want to understand what is happening to their information," he says.

Coda: Experts note that Facebook has grown tremendously despite the privacy dings; the site has continued to grow and now has over 500 million active users. They also applaud Mr. Zuckerberg's higher public profile, including a December "60 Minutes" interview where he discussed privacy among other matters.

A Facebook spokesman disagreed with the notion that the company has been reactive on privacy, saying that its Places location product, for instance, had been developed in consultation with "the privacy and safety community."

He continued: "We feel a tremendous responsibility to the many people who trust their information to Facebook. In fulfilling that responsibility, we developed many new ways for people to control and share their information in 2010. We're proud of these innovations but also recognize that we can always do better and more. We will continue to listen to the people who use Facebook to ensure that we do."

Johnson & Johnson

Case: Johnson & Johnson faced a series of serious manufacturing problems that led the company to have more than a half-dozen recalls this year for its over-the-counter medicines, some contact lenses and certain hip-replacement parts. One of the most high profile involved a massive recall of children's Tylenol, one of its flagship brands, and other popular over the counter medicines. (No fatalities occurred.)

Experts say: PR experts say that J&J's Chief Executive Officer William Weldon should have taken a more active role in the crisis earlier in the process, rather than letting a lieutenant take a front-line role.

"J&J did not fully centralize all crisis communication and left much of the recall and the public explanation in the hands of its business units and Colleen Goggins," the executive that oversaw J&J's consumer business, says Mr. O'Rourke, a Notre Dame professor. Mr. Weldon "not showing up to one of the hearings and his lack of visibility early in the process hurt them," he added.

Mr. Weldon was invited to testify at that congressional hearing, but didn't attend because he was recovering from back surgery.

Coda: PR consultants say despite the problem consumers are still confident in the brand; experts say much of the goodwill stems from how the company handled a famous 1982 tampering incident, which is widely regarded as one of the best examples of how to handle a PR crisis. Mr. Weldon has apologized, and Ms. Goggins is to retire next year.

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Management **Public Relations Learned the Hard Way**

By Suzanne Vranica 2,023 words 29 December 2010 The Wall Street Journal Online WSJO English

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Amid harsher government scrutiny and lingering public mistrust of business, 2010 saw more than its fair share of corporate crises.

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In some cases, increased government scrutiny added to the pressure on corporations and their top executives. Crisis advisors say executives increasingly need to be more mindful not just of their companies' image with consumers, but also with government officials. Indeed, the year saw top brass at BP and Toyota hauled before legislators to answer questions.

"We are in the midst of a highly regulatory regime in Washington and government is being more aggressive in policing companies," says Chris Gidez, U.S. director of risk management and crisis communication at WPP PLC's Hill & Knowlton.

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BP PLC

Case: BP's image suffered after the Deepwater Horizon disaster, which saw torrents of oil spew into the Gulf of Mexico.

Experts say: As part of its crisis plan, BP aired an ad that featured a personal pitch and apology from its then-CEO, Mr. Hayward. In the commercial, Mr. Hayward promised taxpayers they wouldn't be footing the clean-up bill.

But Mr. Hayward's other gaffes—most notably saying he wanted his "life back"—undermined his credibility with the public. PR experts say.

Although many PR professionals believe that in some cases a chief executive should be a company's primary spokesperson during a major crisis, in other cases the CEO may not be the right fit. "The CEO needs to be visible at the outset but can designate the person in the U.S. to be the face of the crisis." says Harlan Loeb, director of U.S. crisis and issue management at Edelman.

Davis Weinstock, Chairman of Clark & Weinstock, a reputation-management firm, says Mr. Hayward "was not the right face" for the crisis.

A study by Interbrand, a branding firm owned by Omnicom Group Inc. that tracks and publishes the top 100 global brands every year, found that the BP brand fell off its top-100 global brand list this year. The oil company had been on the list for nine years, and ranked as the 83rd most valuable brand last year.

Coda: Experts say subsequent ads featuring BP employees from the Gulf region seemed to resonate better. However, the brand is still in need of repair, say public relations experts, and the company must develop a new corporate campaign to replace its "Beyond Petroleum" pitch, PR experts add. "BP presented itself as beyond petroleum, which implied we are a better oil company than others and the spill said maybe they are not," said Mr. Gidez at Hill & Knowlton.

"Our philosophy right from the moment the tragedy happened was to 'do the right thing' for those affected; we knew that the chief exec should be in charge and be seen to be in charge. As the crisis developed so did the tools we used for messaging," said a statement from a BP spokesman.

Apple Inc.

Case: In "Antennagate," Apple Inc. was besieged by criticism that the antenna design on the iPhone 4 caused reception problems. The brouhaha reached a crescendo when Consumer Reports said it couldn't recommend buying the phone and that its tests showed a hardware defect caused the phone to lose reception when held a certain way.

The magazine's analysis ran counter to Apple's claims that the problem was rooted in software that could be easily fixed.

Experts say: "Always listen to your customer—and if they are telling you something, say 'thank you' and offer to remediate the problem immediately," says James S. O'Rourke, a professor of management at the University of Notre Dame. "Apple tried to minimize the problem, which is always a mistake."

Coda: Eventually, Apple offered a free "bumper" case to iPhone 4 customers. Despite the dent to Apple's reputation, iPhone 4 sales have been brisk. Earlier this year, the company said it has not seen any decline in demand for the phone because of the antenna problems.

A spokeswoman for Apple declined to comment.

Toyota Motor Corp.

Case: Toyota was forced to recall over eight million vehicles because of several problems including sticky gas pedals that caused automobiles to suddenly accelerate, challenging Toyota's reputation for quality. The car maker had to pay a \$16.4 million fine in the U.S. for its failure to quickly disclose potential safety defects and more recently, the Obama administration slapped the company with \$32.4 million in civil penalties for failing to properly disclose what it knew about safety defects.

Experts say: PR consultants say Toyota was slow to respond and didn't clearly explain the cause of the problem. "They didn't engage quick enough," says Michael Sitrick, chairman and chief executive of Sitrick & Co., a crisis PR firm that recently represented Mark Hurd during his ouster from Hewlett-Packard Co.

Interbrand found that Toyota's brand value fell 16% this year because of the recall. The car maker had been the eighth largest brand in the world in 2009 but slipped to No. 11 this year. Interbrand's metric takes into account the company's financial condition, third party consumer polling data and its specialists' opinions.

Coda: Although its market share has fallen, experts say Toyota is repairing its image with the help of ads that talk about its Star Safety System and showing that they are changing some processes, such as assigning many engineers to investigate quality problems and extending time devoted to testing new models.

"While it looked to the outside world that we weren't moving fast enough, our engineers were working hard to find the root cause, an effective remedy to perform on millions of vehicles and reviewing it with government regulators," says Mike Michels, a spokesman for Toyota. "The engineering solution for a recall very often lags behind the point of which the announcement is made that there will be a recall. That is particularly challenging from a PR standpoint."

Toyota says it's seen "encouraging signs" that its customer loyalty has remained intact based on data that show that customers affected by the recall are more satisfied than regular Toyota customers and that it is seeing the number of competitor trade-ins "return to historic levels."

Hewlett-Packard Co.

Case: In August, H-P announced CEO Mark Hurd was stepping down. The board cited business-conduct violations related to a relationship with a former contractor.

Page 137 of 164 © 2021 Factiva, Inc. All rights reserved.

Experts say: "There was paucity of information from H-P," says Irv Schenkler, clinical associate professor of management communication at New York University's Stern School of Business.

The company, he says, gave a legalistic statement of what they were doing and found, but left too many "gaps," which opened them up to criticism about their decision, including some blasts from Oracle Corp. CEO Larry Ellison, who later hired Mr. Hurd as co-president.

Coda: H-P's board won both criticism and praise, with some management experts saying directors were right to oust Mr. Hurd if they felt he had demonstrated ethical lapses. In December, The Wall Street Journal reported that federal regulators were investigating Mr. Hurd's departure, including a claim that the former chief shared inside information, according to people familiar with the matter.

"H-P is focused on the future," said an H-P spokeswoman.

Facebook Inc.

The case: Facebook came under fire on Capitol Hill earlier this year after it rolled out new features that might make users' data more public and a series of changes to its privacy settings that could lead users to expose more information about themselves. The outcry prompted the company to switch to simplified privacy controls in June.

Then in October, the Journal reported that many of the most popular applications on the social-networking site were sending user ID numbers to advertising and tracking companies, violating Facebook's rules.

Facebook later said a data broker had been paying app developers for information about its users, and that it had placed some developers on a six-month suspension from its site because of the practice. It also told lawmakers it had taken steps to prevent the sharing of personal information about users.

Experts say: Michael Robinson, a senior vice president of Levick Strategic Communications, a crisis communications firm based in Washington, D.C., says he would like to see Facebook portray itself as a stronger leader on privacy issues. Users' enthusiasm for Facebook has largely shielded the brand from damage so far, but he says that goodwill may erode as Facebook grows up. "People very quickly tire of managing by whack-a-mole and will want to understand what is happening to their information," he says.

Coda: Experts note that Facebook has grown tremendously despite the privacy dings; the site has continued to grow and now has over 500 million active users. They also applaud Mr. Zuckerberg's higher public profile, including a December "60 Minutes" interview where he discussed privacy among other matters.

A Facebook spokesman disagreed with the notion that the company has been reactive on privacy, saying that its Places location product, for instance, had been developed in consultation with "the privacy and safety community."

He continued: "We feel a tremendous responsibility to the many people who trust their information to Facebook. In fulfilling that responsibility, we developed many new ways for people to control and share their information in 2010. We're proud of these innovations but also recognize that we can always do better and more. We will continue to listen to the people who use Facebook to ensure that we do."

Johnson & Johnson

Case: Johnson & Johnson faced a series of serious manufacturing problems that led the company to have more than a half-dozen recalls this year for its over-the-counter medicines, some contact lenses and certain hip-replacement parts. One of the most high profile involved a massive recall of children's Tylenol, one of its flagship brands, and other popular over the counter medicines. (No fatalities occurred.)

Experts say: PR experts say that J&J's Chief Executive Officer William Weldon should have taken a more active role in the recall crisis earlier in the process, rather than letting a lieutenant take a front-line role.

"J&J did not fully centralize all crisis communication and left much of the recall and the public explanation in the hands of its business units and Colleen Goggins," the executive that oversaw J&J's consumer business, says Mr. O'Rourke, a professor at Notre Dame. Mr. Weldon "not showing up to one of the hearings and his lack of visibility early in the process hurt them," he added.

Mr. Weldon was invited to testify at that congressional hearing, but didn't attend because he was recovering from back surgery.

Coda: PR consultants say despite the problem consumers are still confident in the brand; experts say much of the goodwill stems from how the company handled a famous 1982 tampering incident, which is widely regarded as one of the best examples of how to handle a PR crisis.

In August, Mr. Weldon publicly apologized, and in October testified before Congress. J&J announced in September that Ms. Goggins will retire next year. A spokesman for J&J declined to comment.

Shown in illustration above: J&J's Colleen Goggins, Apple's Steve Jobs and Toyota's Akio Toyoda.

Write to Suzanne Vranica at suzanne.vranica@wsj.com

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Health
Pfizer Recalls 19,000 Lipitor Bottles

By Peter Loftus 244 words 20 December 2010 16:39 The Wall Street Journal Online WSJO English

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Pfizer Inc. said Monday it plans to recall about 19,000 bottles of its blockbuster cholesterol-lowering drug Lipitor in the U.S., marking the fourth such recall since August due to reports of malodorous bottles.

The New York-based drug maker said in a statement on its website the latest recall stems from one customer report of an uncharacteristic odor related to the bottles, which were supplied by a third-party manufacturer. Pfizer hasn't identified the supplier.

Pfizer has cited reports of musty or moldy odors emanating from bottles in recalling about 370,000 bottles of Lipitor in three previous alerts beginning in August.

Pfizer said the risk of health problems to Lipitor users appears to be minimal.

The company said the recall was triggered by increased surveillance of odor-related issues following reports of problems at another drug maker. The odor is consistent with the presence of a chemical used as a wood preservative on shipping pallets. Johnson & Johnson cited similar odor-related problems in recalling certain Tylenol products beginning late last year.

Pfizer said it has taken steps to eliminate the odor problem but the latest batch of recalled products was manufactured before improvements were made.

Lipitor is the top-selling prescription drug in the world, generating \$8.1 billion in sales in the first nine months of 2010.

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

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Health

FDA Is Asked to Probe J&J's Rolaids Contractor

By Peter Loftus 412 words 20 December 2010 The Wall Street Journal Online WSJO English

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The incoming chairman of a congressional committee probing Johnson & Johnson's product recalls asked U.S. regulators to look into the company's use of a contract manufacturer to make Rolaids antacids that were recalled for quality problems.

Rep. Darrell Issa (R., Calif.) identified the manufacturer as BestSweet Inc., a Mooresville, N.C., maker of confectionary-based consumer health-care products.

Marc Boston, a spokesman for J&J's McNeil Consumer Healthcare unit, confirmed Friday that the contractor was BestSweet.

McNeil hadn't identified the contract manufacturer last week when the company recalled more than 13 million packages of Rolaids heartburn products. The recall followed consumer complaints of foreign materials, including metal and wood particles, in the products. McNeil said the foreign materials might have been introduced during the manufacturing process at a third-party manufacturer.

Mr. Issa, ranking member of the House Committee on Oversight and Government Reform, said in a letter to Food and Drug Administration Commissioner Margaret Hamburg that his staff determined the contractor was BestSweet.

The company's website says it produces cough drops and soft-chew tablets for store brands and other marketers. BestSweet says it is a supplier for CVS Caremark Corp.'s store brand.

"I am concerned about FDA's knowledge of BestSweet's contractual relationship with Johnson & Johnson in manufacturing Rolaids and whether or not the FDA is acting appropriately to determine if there are other similar public safety concerns about products manufactured by BestSweet," Mr. Issa wrote. He asked Ms. Hamburg if J&J disclosed to the FDA that BestSweet was the source of the recalled Rolaids.

Mr. Boston, the McNeil spokesman, said the company shared that information with the FDA.

Mr. Issa also sought any FDA inspection reports or warning letters for BestSweet facilities.

"We have an excellent safety track record," an outside spokeswoman for BestSweet said. "We are cooperating with all parties."

An FDA spokesman said the agency received the letter Friday and will respond directly to Mr. Issa.

The Rolaids recall was the latest in a series of J&J recalls of over-the-counter medicines over the past year. The House committee has held two public hearings on J&J's handling of the recalls. The Justice Department is conducting a criminal probe in connection with the recalls.

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

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U.S. EDITION

Corporate News: FDA Is Asked to Probe J&J's Use of Contractor

By Peter Loftus
412 words
20 December 2010
The Wall Street Journal
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English
(Copyright (c) 2010, Dow Jones & Company, Inc.)

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M DePuy's Hip Replacement: The New Big Thing in Product Liability Suits?

WSJ Blogs, 16:45, 17 December 2010, 388 words, By Dionne Searcey, (English)
A story over at Brand Xtoday discusses a troubling loophole that exists in the Food and Drug Administration's regulation of implants. Unlike new drugs that must go through clinical trials before getting FDA approval, some implants can be ...

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U.S. EDITION

Corporate News: Corporate Watch

894 words
17 December 2010
The Wall Street Journal
J
B7
English
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HONDA

Auto Maker, Hero to Cut

Ties on India Joint Venture

India's Hero Group agreed to acquire Honda Motor Co.'s stake in their joint venture, ending a quarter-century-long association that created India's biggest seller of two-wheel vehicles.

Hero Group will complete the acquisition of Honda's 26% stake in Hero Honda Motors Ltd. over the next year. The companies declined to disclose financial details. At current market prices, Honda's stake is valued at nearly \$2 billion.

Hero Group, which is owned by India's Munjal family and based in New Delhi, already owns about a 26% stake in Hero Honda. Hero Group will fund the purchase through debt.

Under the current pact, Hero Group is responsible for marketing and distributing Hero Honda's two-wheelers, while Japan's Honda primarily provides technology.

Selling its stake will help Honda focus on its fully owned two-wheeler venture in India -- Honda Motorcycle & Scooter India Pvt. Ltd., said Fumihiko Ike, Honda's managing director and chief operating officer for Asia and Oceania.

Hero Honda, in turn, will benefit from the freedom to export more motorcycles and scooters, providing higher profit margins than it gets from those sold in its home market. Because of the Japanese company's global presence, Hero Honda is currently limited to exporting motorcycles to India's neighboring countries.

-- Nikhil Gulati

TIME WARNER CABLE

Cable Operator, Sinclair

Trade Barbs Over Fees

A year-end programming negotiation between Sinclair Broadcast Group Inc. and Time Warner Cable Inc. became heated Thursday as the two companies disagreed publicly over the terms of an arbitration process.

The dispute is just the latest in a long line of public standoffs between broadcast station owners seeking higher programming fees, known as retransmission consent, and cable and satellite companies struggling to control rising costs. As usual, consumers are stuck in the middle, with the looming threat of a blackout of a major broadcast network on New Year's Day for more than five million U.S. homes.

Both sides appear to be ready to let an independent arbitrator settle at least part of the deal. However, both are battling over the arbitration terms and trading public insults in the process.

"We told Sinclair we would arbitrate, and then yesterday, Sinclair said that they declined our consent to arbitrate," Time Warner Cable said in a statement. "Unfortunately, this sort of behavior is typical when negotiating with Sinclair."

"It's outrageous for Time Warner Cable to have publicly said they want to arbitrate and then put unreasonable conditions on arbitration," said Barry Faber, a spokesman for Sinclair.

-- Nat Worden

JOHNSON & JOHNSON

FDA Cites Problems

At Plant in Pennsylvania

U.S. Food and Drug Administration inspectors found more deficiencies at a Johnson & Johnson plant in Pennsylvania that manufactured some over-the-counter medicines that have been recalled over quality lapses.

The inspection findings illustrate the heightened regulatory scrutiny that J&J has fallen under following a series of recalls of products such as Tylenol, Motrin and Benadryl over the past year. Problems ranging from excessive concentrations of active ingredients to musty-smelling products have spurred the recalls.

FDA inspectors visited J&J's McNeil Consumer Healthcare plant in Fort Washington, Pa., between late October and earlier this month. But because production at the plant has been suspended since April, their focus was primarily on activities that occurred at the plant before the suspension, dating back to 2008. J&J is in the process of upgrading the plant to improve quality.

McNeil spokesman Marc Boston said Thursday that the company will quickly provide a detailed response to the FDA and work to address the most recent issues.

-- Peter Loftus

NOKIA

Handset Maker Sues

Apple Again Over Patents

Nokia Corp., the world's largest mobile-phone maker, said Thursday it has filed patent-infringement complaints against Apple Inc. in the U.K., Germany and the Netherlands, the latest in a string of suits in the mobile-device industry.

Nokia's suit said Apple products, including the iPhone, iPad and iPod Touch, infringed on the company's patents in those countries related to features such as the touch user interface, device application stores and antenna design.

"These actions add 13 further Nokia patents to the 24 already asserted against Apple in the U.S. International Trade Commission and the Delaware and Wisconsin federal courts," said Paul Melin, Nokia vice president for intellectual property.

Apple spokesman Adam Howorth declined to comment on the latest suit, which follows a range of earlier legal battles in the mobile-device industry.

-- Gustav Sandstrom

YAHOO

Internet Giant to Close

Several Web Sites

Yahoo Inc. said Thursday it plans to shut down several "underperforming" and "noncore" Web properties as it continues a years-long turnaround effort.

Sites that could be affected include Delicious, a so-called social bookmarking service, and Buzz, which aggregates news stories from around the Web and allows people to vote on their importance, a Yahoo spokeswoman said.

"Part of our organizational streamlining involves cutting our investment in underperforming or off-strategy products to put better focus on our core strengths," she said in a statement.

Yahoo on Tuesday said it was cutting about 600 jobs, or about 4% of its work force.

-- Amir Efrati

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Health

FDA Cites Problems at J&J Plant in Pennsylvania

By Peter Loftus
583 words
16 December 2010
13:22
The Wall Street Journal Online
WSJO
English

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U.S. Food and Drug Administration inspectors found more deficiencies at a Johnson & Johnson plant in Pennsylvania that manufactured some over-the-counter medicines that have been recalled over quality lapses.

The inspection findings illustrate the heightened regulatory scrutiny that J&J has fallen under due to a series of recalls of products such as Tylenol, Motrin and Benadryl over the past year. Problems ranging from excessive concentrations of active ingredients to musty-smelling products have spurred the recalls, which have hurt sales and damaged J&J's reputation.

FDA inspectors visited J&J's McNeil Consumer Healthcare plant in Fort Washington, Pa., between late October and earlier this month. But because production at the plant has been suspended since April, their focus was primarily on activities that occurred at the plant before the suspension, dating back to 2008. J&J is in the process of upgrading the plant to improve quality.

The FDA posted the inspection report on its website Wednesday. Among their findings, FDA inspectors wrote that McNeil's procedures for handling consumer complaints about product quality were "deficiently written or followed."

In some instances, consumer complaints tied to Tylenol included stomach pain, vomiting and diarrhea, and were miscategorized by McNeil as it investigated them, the report said. The complaints appeared to be related to musty or moldy odors in some products that triggered recalls beginning late last year. J&J, based in New Brunswick, N.J., has attributed the odors to a chemical used on wooden pallets that transported product packages.

The report also said McNeil mishandled certain consumer complaints, filed between 2008 and 2010, that certain children's Benadryl products didn't dissolve in children's mouths, which in some cases may have caused gagging or choking.

The 16-page report identifies a number of instances in which the FDA alleges McNeil failed to thoroughly investigate various manufacturing errors.

It isn't the first time the FDA has found deficiencies at a J&J manufacturing plant. Last month, the FDA issued an inspection report finding quality lapses at a plant in Puerto Rico, such as consumer reports of product mix-ups, in which one drug is found in packaging for a different drug. The same plant was subject to an FDA warning letter earlier this year.

The recalls have continued. Last week J&J recalled more than 13 million packages of Rolaids heartburn relievers following consumer reports of finding foreign particles in the products, including wood and metal.

J&J has indicated that some of the more recent recalls have been triggered by more thorough reviews of manufacturing processes that were implemented as a result of the prior recalls.

McNeil spokesman Marc Boston said Thursday that the company will quickly provide a detailed response to the FDA and work to address the most recent observations.

"The company has been working diligently to ensure that our manufacturing operations meet the level of quality that consumers and the FDA expect of us, and that we expect of ourselves," he said. "While the company has made progress toward that goal, this is an ongoing commitment and we will invest all necessary resources in order to achieve it."

J&J's handling of the recalls has sparked investigations by government entities, including a criminal probe by the Justice Department.

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

Document WSJO000020101216e6cg0096n

Health J&J Sets CEO Race for Two Executives

By Jonathan D. Rockoff and Joann S. Lublin 771 words 16 December 2010 The Wall Street Journal Online WSJO English

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Johnson & Johnson promoted the heads of its two largest businesses to the company's highest executive suite, intensifying the race to succeed William Weldon as chairman and chief executive officer of the health-care giant.

Sheri McCoy, who has been running J&J's pharmaceuticals group, and Alex Gorsky, previously chief of the company's medical-devices and diagnostics division, were named vice chairmen in the expanded Office of the Chairman. Each lieutenant will also take on some responsibility for fixing the quality problems in the consumer unit that have led to recalls of the painkiller Tylenol and other popular products.

The appointments, akin to executive moves made in 2001 that ended with Mr. Weldon's appointment as chairman and CEO about a year later, set the stage for the selection of the company's next leader.

"Our organizational changes are an appropriate step in furthering our long-term succession plans," Mr. Weldon said in announcing the news to J&J's 114,000 employees, according to an internal company announcement. The changes take effect Jan. 3.

Mr. Weldon, 62 years old, isn't expected to step down for at least a year, and perhaps longer, giving his potential successors a chance to prove themselves in their new roles. The company, based in New Brunswick, N.J., doesn't have a mandatory retirement age for CEOs.

Under the changes, Ms. McCoy, 52, and Mr. Gorsky, 50, will split the company's various responsibilities, from government affairs to the company's think tank. Ms. McCoy will take charge of businesses generating three-fifths of the company's revenue, while Mr. Gorsky will manage more employees.

Notably, each will play a role in fixing the beleaguered consumer business, where numerous product recalls since late 2009 and a temporary shutdown of a key plant due to manufacturing problems are costing the company hundreds of millions of dollars in lost sales and plant upgrades. The manufacturing issues have included the presence of metal shavings in some children's medicine bottles.

Mr. Gorsky will take control of the new manufacturing and supply group created in the wake of the problems to make sure all plants meet rigorous quality standards. Meantime, Ms. McCoy will gain oversight of the consumer business that includes the McNeil Consumer Healthcare unit responsible for the bulk of the recalls. Mr. Gorsky and Ms. McCoy weren't available for comment, a company spokeswoman said.

Jesse Wu was appointed chief of the consumer group. The 54-year-old Mr. Wu, a Taiwanese-born executive who most recently has been spearheading the company's efforts to expand sales of consumer products in China and other emerging markets, will succeed Colleen Goggins, who in September announced her plans to retire. Since joining J&J in 1989, Mr. Wu has been based overseas.

"I am confident that Jesse's proven leadership and deep knowledge of global markets will help the consumer group achieve success in coming years," Ms. McCoy said in announcing the appointment to employees.

Joaquin Duato and Paul Stoffels, two 48-year-old J&J pharmaceutical executives, were given joint management of the group. Michael Mahoney, 45, who had been running the hip and knee parts business, will take over the medical-devices and diagnostics division.

Ms. McCoy had run a variety of businesses across J&J before taking over its pharmaceuticals group last year. After a new-product drought, the company has launched some promising treatments recently, such as psoriasis

therapy Stelara. And it is poised to seek approval for potential blockbusters to treat Hepatitis C and prevent blood clots.

Mr. Gorsky is a former U.S. Army ranger who held various drug jobs at J&J and Novartis AG. He took over J&J's medical-devices and diagnostics group in 2009, the year it became the company's most profitable segment, eclipsing pharmaceuticals. Analysts have high expectations for several products in development, including a sophisticated bandage called the Fibrin Pad.

Though the executive changes set up a clear horse race, both executives face big challenges, aside from addressing the recalls. Ms. McCoy must make sure that therapies that showing promise in clinical trials pass the muster of regulators, while helping Mr. Wu acclimate to running the entire consumer group. Meantime, Mr. Gorsky must navigate pricing and other pressures that analysts say are crimping device sales.

Write to Jonathan D. Rockoff at jonathan.rockoff@wsj.com and Joann S. Lublin at joann.lublin@wsj.com

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→ FDA Identifies More Problems at J&J Plant

WSJ Blogs, 11:57, 16 December 2010, 563 words, By Katherine Hobson, (English)
The FDA says it found additional problems at the Johnson & Johnson plant that made some of the medications recalled earlier this year. As Dow Jones Newswires reports, an inspection report from the agency identified further deficiencies ...

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U.S. EDITION

Corporate News: J&J Sets CEO Race For Two Executives

By Jonathan D. Rockoff and Joann S. Lublin 659 words 16 December 2010 The Wall Street Journal J B6 English (Copyright (c) 2010, Dow Jones & Company, Inc.)

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Ms. McCoy had run a variety of businesses across J&J before taking over pharmaceuticals last year. After a new-product drought, the company has launched some promising treatments recently, such as psoriasis therapy Stelara. And it is poised to seek approval for potential blockbusters to treat Hepatitis C and prevent blood clots.

Mr. Gorsky is a former U.S. Army ranger who held various drug jobs at J&J and Novartis AG. He took over J&J's medical-devices and diagnostics group in 2009, the year it became the company's most profitable segment, Page 152 of 164 © 2021 Factiva, Inc. All rights reserved.

eclipsing pharmaceuticals. Analysts have high expectations for several products in development, including a sophisticated bandage called the Fibrin Pad.

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Health J&J Recalls Rolaids

By Peter Loftus 353 words 10 December 2010 The Wall Street Journal Online WSJO English

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Johnson & Johnson recalled more than 13 million packages of Rolaids heartburn products following consumer complaints of foreign materials in the product, including metal and wood particles.

The Rolaids recall adds to the growing list of over-the-counter products recalled by J&J over the past year, hurting its sales and tarnishing its once-sterling reputation for product quality.

J&J's McNeil Consumer Healthcare unit said Thursday it was recalling all lots of Rolaids Extra Strength Softchews, Rolaids Extra Strength plus Gas Softchews and Rolaids Multi-Symptom plus Anti-Gas Softchews distributed in the U.S.

The company said the foreign materials may have been introduced during the manufacturing process at a third party supplier, which it didn't identify. While the risk of serious adverse health consequences is remote, McNeil advises consumers who have purchased these recalled products to discontinue use.

The company suspended production of the recalled products and won't restart production until corrective actions have been implemented.

J&J has issued a series of recalls of medicines including Tylenol, Benadryl and Motrin, for various quality lapses such as excessive concentrations of active ingredients and musty odors. J&J's handling of the recalls has sparked investigations by government entities, including a criminal probe by the Justice Department.

The House Committee on Oversight and Government Reform also has probed the recalls. The incoming chairman, Rep. Darrell Issa (R., Calif.) issued a statement Thursday saying the "most recent recall reinforces the Committee's ongoing investigation surrounding the safety protocols in place at J&J's facilities and how the [Food and Drug Administration] is managing food and drug safety." The committee will continue to seek answers from J&J and the FDA, the statement said.

Earlier Thursday, Wells Fargo downgraded its rating for J&J shares, citing the potential for further regulatory action on J&J that could shut down a manufacturing plant in Puerto Rico where quality problems have been detected.

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U.S. EDITION

Corporate News: J&J Issues Rolaids Recall After Consumer Complaints

By Peter Loftus
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10 December 2010
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Europe Business
J&J Leaves Crucell Deal Terms Open

By Anna Marij van der Meulen 583 words 2 December 2010 The Wall Street Journal Online WSJO English

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AMSTERDAM—U.S. pharma giant Johnson & Johnson said Wednesday it plans to proceed with its agreed €1.75 billion (\$2.27 billion) cash takeover offer for Crucell NV.

However, J&J left the option open to change the terms if problems at the Dutch biotechnology company's manufacturing plant in South Korea prove worse than thought.

Crucell in late October abandoned its full-year targets after suspending operations at its Shingal site in South Korea and temporarily halting shipments of two vaccines due to sterility issues at the plant. The companies said they expect the facility to resume manufacturing in February 2011.

J&J said in a statement on Wednesday that the two companies have agreed to go ahead with the deal, but added that "while the immediate financial impact of the Korea manufacturing issues to Crucell, as described in Crucell's financial results for the third quarter of 2010, would not alone constitute a material adverse effect, all effects relating to the Korea manufacturing issues, including those related to the period prior to commencement of the offer, may be taken into account, but only in combination with further developments that may arise or become known to Johnson & Johnson after the commencement of the offer as a result of, and/or in connection with, the Korea Manufacturing Issues."

The Dutch market regulator Autoriteit Financiele Markten (AFM) said that once it has approved a merger, the rules to amend the offer are very strict, making it difficult to adjust the bid.

"Only if certain conditions, as laid out in the offer memorandum, have been met, can the bidder withdraw the offer and put in a new bid," said AFM spokeswoman Imre de Roo. She declined to comment on the Crucell case in particular.

In early October, Crucell and J&J said they had reached an agreement on the U.S. pharmaceutical giant's €1.75 billion cash offer for the portion in the Dutch vaccine maker it doesn't already own, despite the concerns of some major Crucell shareholders who think the bid is too low.

J&J holds about 17.9% of Crucell shares, and the €24.75 per share offer is for the outstanding shareholding. In its statement, J&J said it expects to get final approval from the Dutch regulator for the offer before Crucell's general shareholder meeting on Dec. 10.

Separately, J&J widened a recall of contact lenses in Japan and other countries because residual traces of an acid have caused stinging or pain in users' eyes—the latest in a series of product recalls for the company.

J&J recalled about 492,000 boxes of 1-Day Acuvue TruEye, a type of contact lens intended to be disposed of daily, the company confirmed Wednesday. This follows a recall of about 100,000 boxes of the same product announced in August.

J&J attributed the problem to the presence of decanoic acid, which is used in the lens-manufacturing process but is supposed to be rinsed away from the final product. J&J said residual levels of the acid can cause stinging, pain, redness, tearing and blurred vision when the lens is placed on the eye, but that more serious health consequences such as corneal ulcer are unlikely.

Write to Anna Marij van der Meulen at Anna. Van Der Meulen @dowjones.com

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U.S. EDITION

Corporate News: J&J Sets Dutch Deal; Leaves Option Open

By Anna Marij van der Meulen 539 words 2 December 2010 The Wall Street Journal J B3 English (Copyright (c) 2010, Dow Jones & Company, Inc.)

AMSTERDAM -- U.S. health-care products giant Johnson & Johnson said Wednesday it plans to proceed with its agreed 1.75 billion euros (\$2.27 billion) cash takeover offer for Dutch biotechnology company Crucell NV.

However, J&J left open the option to change the terms if problems at Crucell's manufacturing plant in South Korea prove worse than thought.

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But J&J added that while the impact of the Korean manufacturing issues, as described in Crucell's financial results for the third quarter, wouldn't alone constitute a material adverse effect, "all effects relating to the Korea manufacturing issues, including those related to the period prior to commencement of the offer," may be taken into account in combination with further developments that might become known to J&J.

The Dutch market regulator, Autoriteit Financiele Markten, said that once it has approved a merger, the rules to amend the offer are very strict, making it difficult to adjust the bid.

In early October, Crucell and J&J said they had reached an agreement on the U.S. company's 1.75 billion cash offer for the portion of the Dutch vaccine maker it doesn't already own.

J&J holds about 17.9% of Crucell shares, and the 24.75 euros-a-share offer is for the shares outstanding. In its statement, J&J said it expects to get final approval for the offer from the Dutch regulator before Crucell's general shareholder meeting Dec. 10.

Separately, J&J widened a recall of 1-Day Acuvue TruEye contact lenses in Japan and other countries because residual traces of an acid have caused stinging or pain in users' eyes -- the latest in a series of product recalls for the company.

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J&J said residual levels of the acid can cause stinging, pain, redness, tearing and blurred vision when the lens is placed on the eye, but that more serious health consequences such as corneal ulcer are unlikely.

About 75% of the recalled products were distributed in Japan, said Gary Esterow, spokesman for J&J's Vistakon vision-care unit. Versions of the product sold in the U.S. weren't affected by the recall.

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WSJ Blogs, 17:34, 1 December 2010, 412 words, By Katherine Hobson, (English) Johnson & Johnson has had its share of recalls in recent months, most notably, that of about 40 kinds of kids' medicines. And, as the WSJ reported last week, more are likely as the company reviews its manufacturing operations.

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Latin America
J&J Suffers Another Manufacturing Blow

By Peter Loftus 580 words 28 November 2010 13:34 The Wall Street Journal Online WSJO English

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The U.S. Food and Drug Administration cited a Johnson & Johnson drug manufacturing plant in Puerto Rico for various deficiencies, a new setback in the company's efforts to recover from a series of medicine recalls due to quality problems.

In an inspection of the plant between September and early November, FDA officials found that J&J failed to follow written quality-control procedures, didn't properly investigate manufacturing snafus, released into the market drug products that should have been rejected for quality violations, and several other problems.

The FDA findings were included in an inspection report posted on the agency's site earlier this month. The New York Times reported the inspection earlier on its website.

J&J, of New Brunswick, N.J., has been plagued by a series of product-quality problems, mainly at its McNeil Consumer Healthcare unit, which makes over-the-counter medicines. The company has recalled Tylenol, Motrin, Benadryl and other products for problems ranging from musty odors that caused nausea in consumers, to excessive concentrations of active ingredients.

J&J has shuttered its Fort Washington, Pa., plant, where many of the products were made, to undergo a refitting to address manufacturing problems there. The effort is costing J&J hundreds of millions of dollars in lost sales and facility upgrades, not to mention potential liability stemming from suits filed in connection with the recalls. The Justice Department is conducting a criminal probe of issues related to the recalls.

J&J has made some progress in bouncing back from the recalls by recently reintroducing limited supplies of children's liquid Tylenol to pharmacy shelves. But another round of recalls announced the past two weeks, together with the new FDA inspection report, show it will be no easy task for J&J to convince government authorities and consumers that its products are top-notch.

The latest setback concerns McNeil's plant in Las Piedras, Puerto Rico, another facility that manufactured some of the recalled products. In January, the FDA had issued a warning letter to McNeil, saying it found "significant violations" of manufacturing rules at the plant that resulted in faulty products. Consumers had complained of musty or moldy odors in products made at the facility, which J&J eventually traced to a chemical used on wooden pallets to transport packaging materials.

A more recent inspection found that J&J continues to have problems at the plant. The FDA report, for instance, said J&J has received consumer reports of product mix-ups, in which one drug is found in a container for another product. In July, plant workers found Motrin inside a Tylenol container, the report said.

The FDA said procedures at the Las Piedras plant may not be sufficient to prevent future product mix-ups.

J&J said in a written statement that since the January warning letter from the FDA, "McNeil Consumer Healthcare has been working diligently to ensure that our manufacturing operations meet the level of quality that consumers and the FDA expect of us, and that we expect of ourselves. While the company has made progress toward that goal, this is an ongoing commitment and we will invest all necessary resources in order to achieve it."

J&J said it has provided a detailed response to the FDA and will work to address these most recent observations.

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U.S. EDITION

Corporate News: J&J Recalls More Products Over Labeling

By Jonathan D. Rockoff 367 words 26 November 2010 The Wall Street Journal J B3 English (Copyright (c) 2010, Dow Jones & Company, Inc.)

Johnson & Johnson, which has been recalling a number of popular over-the-counter medicines, said it is withdrawing more Tylenol because of a labeling problem.

The company's McNeil Consumer Healthcare unit is recalling nearly 9.3 million bottles of three Tylenol Cold Multi-Symptom products from drug stores and suppliers because the bottles' front labels didn't show they contain small amounts of alcohol from ingredients that flavor the medicine.

The bottles' boxes and back labels did reflect the presence of alcohol. The company said Wednesday the alcohol amounted to less than a percent of the medicine's contents.

The labeling problem doesn't threaten the health of consumers, who don't need to return or stop using the medicines, according to the company. "Consumers don't need to take action and can continue to take the product," said a company spokeswoman. Yet it highlights the continuing fallout from the manufacturing problems that have bedeviled J&J.

The company has indicated more such actions are likely, as it tries to bring its manufacturing up to compliance under the watchful eye of regulators.

That scrutiny follows a string of more-serious manufacturing problems at the company that have led to more than a half-dozen withdrawals of Tylenol and other over-the-counter medicines, some contact lenses and certain hip-replacement parts. Due to those issues, some over-the-counter medicines could have been more potent than they should have been, contained metal shavings or had a musty smell causing nausea. Only in recent weeks has some grape-flavored children's Tylenol started returning to shelves, after a half-year of being out of stores.

In the wake of the problems, the company has been conducting a review of its operations. That review led to a recall of some Benadryl and Motrin last week and of the Tylenol Wednesday. The eight-ounce Tylenol multisymptom bottles recalled are daytime citrus burst, nighttime cool burst and severe day cool burst. For more information, consumers can go to tylenol.com or call 1-888-222-6036.

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The recalls are costing the company hundreds of millions of dollars in lost sales and prompted the temporary shutdown of a key manufacturing plant and a revamp of manufacturing. The company has also shuffled management.

Only in recent weeks has some grape-flavored children's Tylenol started returning to shelves, after a half-year of being out of stores.

In the wake of the problems, the company has been conducting a review of its operations. That review led to a recall of some Benadryl and Motrin last week and of the Tylenol Wednesday. Because the recalls aren't considered to pose a safety issue, the company has posted the news on its websites but hasn't otherwise given public notice.

The company is likely to conduct more recalls, as it goes over the results from its review.

The latest recalled products were made for J&J's McNeil unit by a contract manufacturer, whom the spokeswoman wouldn't name.

The eight-ounce Tylenol multisymptom bottles recalled are daytime citrus burst, nighttime cool burst and severe day cool burst. For more information, consumers can go to www.tylenol.com or call 1-888-222-6036.

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

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