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J.& J. Chief To Resign One Role

By KATIE THOMAS and REED ABELSON
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English

William C. Weldon, who presided over Johnson & Johnson during one of the most tumultuous periods in its history, will step down as chief executive in April, the company announced Tuesday.

Alex Gorsky, head of the medical device and diagnostics business, will take over as chief executive. Mr. Weldon will remain as chairman.

The news of Mr. Weldon's retirement comes as Johnson & Johnson has struggled to emerge from a swarm of product recalls, manufacturing lapses and government inquiries that tarnished the name of a company that was once one of the nation's most trusted household brands. In 2010, the company recalled millions of bottles of liquid children's Tylenol and other medications, as well as tens of thousands of artificial hips and millions of contact lenses.

Much of the blame for Johnson & Johnson's stumbles fell on Mr. Weldon, the son of a Broadway stagehand and seamstress who became chief executive in 2002 after spending his entire career at the company. Critics said the company's once-vaunted attention to quality slipped under his watch. The company said in a statement that neither Mr. Weldon nor Mr. Gorsky was available for comment.

There was little doubt that Mr. Weldon, 63, was going to retire this year, said Erik Gordon, who teaches business at the University of Michigan. "I think what he really wanted to do is clean up his image," Mr. Gordon said. "He didn't want to leave at a time when it looked like he was being thrown out."

Plans for Mr. Weldon's exit became clear in December 2010, when the company promoted Mr. Gorsky and Sheri S. McCoy to vice chairman and vice chairwoman of the executive committee in what was seen as a race to succeed Mr. Weldon. There were other signs that Mr. Weldon planned to step down: over the past year he has sold more than one million shares of Johnson & Johnson stock; the sales earned him nearly $69 million.

In 2011, critics of Mr. Weldon, including a group of shareholders, complained of his compensation of about $30 million a year, saying it ignored his troubled leadership.

Mr. Gorsky, who is 51, was considered the favored candidate, said Les Funtleyder, a portfolio manager who owns the stock at Miller Tabak & Company. Mr. Gorsky is well-known by the company's investors. "There is a comfort level with him," Mr. Funtleyder said. Ms. McCoy will continue to lead the pharmaceuticals and consumer groups, the company said, but analysts said she may leave after having been passed over.

The ascension of Mr. Gorsky, who first joined Johnson & Johnson as a sales representative in 1988, continues the company's 126-year tradition of hiring leaders from within. The medical devices division generates the largest amount of sales for the company, and it is expected only to grow with the acquisition last year of Synthes, a Swiss-American medical device maker.

"Alex and Sheri are two extraordinary leaders," Mr. Weldon said in a statement Tuesday. "The future of Johnson & Johnson is in very capable hands."

But Mr. Gordon said the board's decision to hire another insider showed that it was not serious about changing the corporate culture that had created so many of its problems.

"I think it's a big mistake," he said.

In the wake of the product recalls, Mr. Weldon and the company went on the offensive, initiating a public relations campaign aimed at restoring consumer confidence and revamping quality controls to create a single framework for the company's drug, medical device and consumer health care divisions.

"From Johnson & Johnson's perspective, our response to this issue was the most responsible it could possibly be," Mr. Weldon said in a telephone interview in 2010.

Even so, Johnson & Johnson has continued to struggle to put its troubles to rest. As recently as last week, the company announced it would recall about a half-million bottles of liquid Infants' Tylenol because of a faulty dosing system.

Still, Mr. Weldon's retirement comes as the company shows signs of improving, said Jeff Jonas, portfolio manager for Gabelli, which owns the stock for investors. "He's wanted to stay and get through the worst of it," he said.

Some products are back on the market, Mr. Jonas said, and the company has a well-defined plan with the Food and Drug Administration to bring the plant that was a source of many of the over-the-counter recalls up to federal standards. A drug to treat prostate cancer, to be marketed as Zytiga, was approved by the Food and Drug Administration last year, and the consumer business is recovering.

Mr. Jonas said the fact that Mr. Weldon plans to step down in April, during the company's annual meeting, indicates that his departure was not abrupt. "The annual meeting is always a classic time to do the transition," he said.

Johnson & Johnson's stock closed at $65.04 Tuesday, having rebounded from a low of $57.50 a share over the last 12 months.

PHOTO: William Weldon will remain the company's chairman. (PHOTOGRAPH BY JOSHUA PREZANT/BLOOMBERG NEWS) (B8)

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Document: 2009 E-Mail on Hip Device

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English

In August 2009, the Food and Drug Administration notified DePuy Orthopaedics, a Johnson & Johnson subsidiary, through a "non-approvable" letter that it had turned down its application to sell a version of a hip device called the A.S.R. in the United States. On Aug. 21, Pamela Plouhar, vice president for worldwide clinical affairs at DePuy, sent the following e-mail to three company executives -- including David Floyd, then DePuy's president -- reporting the F.D.A. action and its implications. The disclosures in the e-mail contrast with statements made in recent years by the company, which continued to market the device in Europe (and a related model in the United States) before announcing a recall in 2010. Here is the text of the e-mail, followed by a statement issued by DePuy on Tuesday in response to questions from The New York Times.

2009 Internal E-Mail

Sarah, David and Martin

We have finally received the long awaited letter from FDA regarding the ASR PMA. It is a non-approvable letter. A copy of the letter is attached.

The FDA took issue with several aspects of the pooled clinical data and subsequent data analysis and have essential asked us for a new clinical data set and analysis, which are cited for the major cause of the non-approvable classification (the 5 major deficiencies on page 1 and 2). There are also several other deficiencies associated with the clinical data noted in Items 1-3. FDA has also requested additional information related to fatigue testing (item 4), sterilization (item 5 and 6) packaging validation (item 7) Porocoat characterization (Item 8) and HA coating (item 9).

The clinical data deficiencies are the major concern. There are a few issues.

1. There have been a significant number of revisions within the ASR group (both in the IDE and in the OUS study) as opposed to very few in the control group.

2. The demographics of the control group are significantly different than the ASR group, which seriously complicates the analysis.

3. There are insufficient numbers of subjects in the original IDE cohort to demonstrate non-inferiority and even when the data is pooled with data from OUS, we are unable to demonstrate non-inferiority unless we exclude one site with one site with very poor results which was attributed to failure to use ASR specific instruments. FDA took major issue with this and believes that we have not demonstrated the required non-inferiority.

We are currently evaluating the data that is available to address FDA concerns and recommendation to provide a new data set. One possibility, especially to address issue 2 above is to determine if we can identify a demographically matched data set by pooling data from the ASR data sets and the other IDE control datasets. The team's concern is that given the revision rate in the ASR group that we will still not be able to demonstrate non-inferiority with additional downside risk. Any need to enroll new ASR cases will significantly delay the PMA submission and approval by years.

We will provide you with a more detailed evaluation in the coming weeks, but we did want you to be aware of the significant risk associated with the FDA approval of this product. This comes at a time when ASR data from national registries (Australia and UK) is being closely scrutinized because of higher revision rates.

Please let me know if you have any comments or questions.

Pam

DePuy Statement on Tuesday

The ASR Hip Resurfacing System was not "rejected" by the U.S. Food and Drug Administration (FDA), nor did the company inappropriately sell it in other countries.

In the U.S., the ASR XL total hip replacement system was first cleared by the FDA for marketing in 2005 via the 510k process. DePuy filed a submission containing clinical data for pre-market approval (PMA) for the hip resurfacing version of the ASR device with the FDA in July 2007. In August 2009, DePuy received a letter from the FDA stating that based on the data submitted, the FDA was unable to assess safety and effectiveness for the ASR Hip Resurfacing System. The FDA recommended that DePuy provide a new clinical data set to support the potential determination of a reasonable assurance of safety and effectiveness. The letter concluded with the various options available to the company under FDA regulations, including the right to decide not to submit a new dataset and withdraw the application.

At the same time that the company received this FDA letter, market demand for hip resurfacing was declining rapidly. DePuy chose not to move forward with gathering additional data based on the declining demand for hip resurfacing. This was purely a business decision for the U.S. market. The decision not to pursue the ASR Resurfacing PMA application in the U.S. did not impact the use of the ASR Hip System in other countries.

Medical device registration requirements are defined by a country's legislation. The legislation specifies the data required for the submission and approval process. DePuy properly complied with the regulatory process for each separate country where the ASR Hip System was available. At the time of the PMA submission in the U.S., the ASR Resurfacing System had already been approved for marketing by regulatory authorities in other countries. For example, in Europe, the ASR XL Acetabular System and DePuy ASR Hip Resurfacing System met the requirements of the Directives specified by the European Union for all medical devices and received CE mark approval.

It is common to receive letters, such as the FDA's request for more data for evaluation, from a regulatory authority reviewing the product for marketing. Correspondence dealing with requests specific to one country's regulatory authority are not necessarily relevant to another country's regulatory authority, so they are typically not communicated and there is no requirement to do so. Significant safety information regarding a product, however, is communicated to each country where DePuy markets a product, and this was done for the ASR Hip System.

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Hip Maker Discussed Failures

By BARRY MEIER
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English

A year before recalling an artificial hip, an executive at Johnson & Johnson reported in an internal e-mail that the Food and Drug Administration had refused to approve the device, after reviewing company studies that showed it had failed prematurely in "significant" numbers, requiring repeat surgeries for patients.

The statements in that e-mail contrast with those made by the company in recent years about the all-metal hip. Before recalling the device amid rising failure rates in 2010, Johnson & Johnson insisted it was safe and maintained that its internal studies refuted complaints by surgeons and regulators abroad that the device was flawed. The device turned down by the F.D.A. was only sold overseas, but a companion version that was recalled at the same time by Johnson & Johnson was used in 30,000 patients in the United States.

The e-mail at issue was written in August 2009 by a vice president of a Johnson & Johnson subsidiary, DePuy Orthopaedics, just days after the F.D.A. confidentially notified the device maker that it would not approve one version of the hip for sale in this country. In the e-mail, the executive, Pamela Plouhar, explained the reasons for the agency's decision to three other top executives, including DePuy's president at the time, David Floyd.

Ms. Plouhar reported that the device had not met F.D.A. approval standards and that a major concern was its high rate of early failure, or "revision," during clinical trials. She also cautioned that providing the F.D.A. with more data might not change its stance and that it might take years to conduct new studies of the hip, known as the ASR, or articular surface replacement.

"The team's concern is that given the revision rate in the ASR group that we will still not be able to demonstrate non-inferiority, with additional downside risk," Ms. Plouhar wrote.

To win approval, a novel medical device like the DePuy hip must be shown to be reasonably safe and effective. One way to prove that is to show that it is at least as effective as, or not inferior to, a traditional hip implant.

In her e-mail, Ms. Plouhar said there had been "a significant number of revisions in the ASR group" compared with "very few in the control group."

Many artificial hips last 15 years or more before they wear out and need to be replaced. But by 2008, data from orthopedic databases overseas showed that the ASR was failing at high rates in patients after just a few years. The device also sheds metallic debris as it wears, particles that have damaged tissue in some patients or caused crippling injuries.

A DePuy spokeswoman, Mindy Tinsley, declined to respond to specific questions about the e-mail. In a statement, she said that the e-mail was "simply a notification to senior management about the F.D.A. feedback as the company appropriately continued to study data" about the implant so that it could make responsible decisions on the behalf of patients.

Last week, Andrew Ekdahl, the current president of DePuy, said in a statement issued in response to an earlier article in The New York Times that any implication that the F.D.A. had determined there were safety issues with the device was "simply untrue."

In her 2009 e-mail, Ms. Plouhar referred to complaints about early failures of the ASR from doctors and regulators abroad. Regulators in Australia were then pressuring DePuy to withdraw the artificial hip from the market there or face having it forced off.

"This comes at a time when ASR data from national registries (Australia and UK) is being closely scrutinized because of higher revision rates," she wrote.

DePuy does not appear to have violated any laws by not publicly releasing the F.D.A. ruling, which was contained in a so-called nonapprovable letter. The F.D.A., as a matter of policy, does not release such decisions, saying that they may contain confidential business information.

But DePuy's decision not to publicize the agency's findings to doctors, patients and others while continuing to market the device may undercut its defense in the 5,000 related lawsuits pending against it and could also tarnish its reputation.

Throughout the episode, DePuy blamed orthopedic surgeons for the model's failures, saying that doctors were not positioning a component properly. But the clinical findings rejected by the F.D.A. came from A.S.R. studies run by surgeons hand-picked by DePuy, including some who had developed the implant and received royalties or consulting fees in connection with it.

The e-mail containing Ms. Plouhar's report about the F.D.A. decision is among thousands of company documents released to lawyers suing the company under a court-ordered seal.

It is not known how many patients received the implant in the year between the F.D.A. decision and the recall. But during the device's eight years on the market, it was used in an estimated 93,000 people, about one-third of them in the United States.

The version of the device rejected by the F.D.A. was developed by DePuy for use in a hip replacement procedure called resurfacing, which is a bone-sparing alternative to standard surgery. The company started selling the implant abroad around 2003 but because resurfacing was a new procedure, the F.D.A. required DePuy to run clinical trials before selling the device in the United States.

However, while those studies were under way, DePuy used a regulatory loophole in 2005 to start marketing a version of the implant in the United States for use in standard hip replacement surgery. Both versions of the device used the same critical component, a solid metal cup that replaced a patient's hip socket. Experts say the component was flawed in design. In the wake of the F.D.A.'s 2009 decision to reject the resurfacing version of the device, DePuy executives wrote in internal e-mails that the device's fate appeared sealed.

"Can't imagine we would go any further in the U.S.," one executive wrote.

In September 2009, just weeks after the F.D.A. decision, other documents indicate that top DePuy executives decided to phase out the device. The company announced the move that November.

Company executives said then that the move reflected declining sales of the implant, rather than safety issues. In his statement last week, Mr. Ekdahl, the company's president, reiterated that position.

"This was purely a business decision," Mr. Ekdahl stated.

PHOTO: During the eight years the DePuy ASR artificial hip was on the market, it was used in an estimated 93,000 people globally. (PHOTOGRAPH BY ANDREW TESTA FOR THE NEW YORK TIMES) (B8)

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Johnson & Johnson Recalls Infants' Tylenol

By REUTERS

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4
English

Johnson & Johnson, the health care giant, said on Friday that it was recalling its entire United States supply of Infants' Tylenol after parents complained about problems with a new dosing system. It was the latest in a string of recalls for the company.

The recall involves about 574,000 bottles of grape-flavored liquid Tylenol for children younger than 2. After earlier recalls, Johnson & Johnson had just returned to the market with the Infants' Tylenol in November, but now will be out of the market for an indefinite time.

The problems involve a new bottle design, which was intended to prevent accidental ingestion and ensure accurate doses. But when parents inserted a syringe into the bottle, some accidentally pushed a protective cover inside. To date, Johnson & Johnson has received 17 complaints, a company spokeswoman, Bonnie Jacobs, said.

No serious side effects from the Infants' Tylenol have been reported, and the risk of such problems are remote, Johnson & Johnson said.

The recall is from stores and wholesalers; consumers can still use the product provided that the protective cover at the top of the bottle remains in place, the company said.

The recall does not affect Tylenol for children 2 years and older, for which the company also introduced a new but different design.

Ms. Jacobs said the company did not have a specific date for when it would return to the market with Infants' Tylenol.

Other recalls for Johnson & Johnson have included medicines, artificial hips and contact lenses.

Stock in the company, which is based in New Brunswick, N.J., rose 7 cents Friday, to $64.99 a share.

PHOTO: Nearly 600,000 bottles of Infants' Tylenol were recalled. (PHOTOGRAPH BY AMY SANCETTA/ASSOCIATED PRESS)

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JOHNSON & JOHNSON RECALLS INFANTS' TYLENOL

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English

Johnson & Johnson is recalling its entire United States supply of Infants Tylenol after parents complained about problems with a new dosing system. Photo (M)

Photograph

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Hip Implants U.S. Rejected Sold Overseas

By BARRY MEIER
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1
English

The health care products giant Johnson & Johnson continued to market an artificial hip in Europe and elsewhere overseas after the Food and Drug Administration rejected its sale in the United States based on a review of company safety studies.

During that period, the company also continued to sell in this country a related model, which earlier went on the market using a regulatory loophole that did not require a similar safety review.

It is not known how many people overseas received the replacement hip after the agency decided in 2009 not to approve it, nor the number who received the closely linked implant sold in this country. During some eight years on the market, the two implants were used in about 93,000 patients worldwide, about one-third of them in the United States. Both models were based on the same component, an all-metal hip socket cup that experts say was faulty in design.

The DePuy orthopedic division of Johnson & Johnson, citing declining sales, began phasing out both models of the device -- formally known as an articular surface replacement device, which DePuy marketed under the name ASR -- in November 2009 and formally recalled them in August 2010 amid reports in databases of orthopedic patients abroad showing they were failing prematurely at high rates.

But in a confidential letter, the F.D.A. told Johnson & Johnson in August 2009 that company studies and clinical data submitted to gain approval in the United States to sell the model available overseas were inadequate to determine the implant's safety and effectiveness, according to a summary of the letter reviewed by The New York Times.

The agency also told the company it would need added clinical data to pursue the application, a process that would probably have taken a year or more. DePuy's receipt of the notice came as regulators and surgeons abroad as well as doctors in this country were raising serious questions about growing failures of both models of the implant.

A spokeswoman for DePuy confirmed that the company had received the agency's so-called nonapproval letter. But the spokeswoman, Mindy Tinsley, declined to release the letter or to respond to questions about when, or if, DePuy disclosed the ruling to doctors, patients, investors or regulators abroad.

A principal researcher on the clinical studies submitted by the company to the F.D.A. said he was not informed of the agency's decision. Also, a review of publicly available information indicates that the company did not discuss the agency's nonapproval letter in financial reports or in presentations to analysts while the device remained on the market.

There is no suggestion that Johnson & Johnson broke the law. Regulatory standards in other countries, like those in Europe, for approving the sale of medical devices are typically lower than here. A spokeswoman for a British regulatory agency, the Medicines and Healthcare Products Regulatory Agency, said that companies like Johnson & Johnson were not required to notify it when the F.D.A. refused to approve a product that was used in patients there.

However, the F.D.A.'s rejection may further deepen the company's legal and financial problems surrounding the ASR. Last month, the company took a special $3 billion charge, much of it related to anticipated legal and medical

expenses associated with the recall. An estimated 5,000 lawsuits involving the device are pending, including some from patients crippled by tiny particles of metallic debris shed by the implants.

William Vodra, a lawyer who specializes in F.D.A. regulation, said that, in general, drug and medical device makers typically disclose nonapproval letters if they might have a material impact on a company's finances. Mr. Vodra added that apart from that financial calculation, there was no hard-and-fast rule about making such rulings public.

Mr. Vodra said that if a company decided to withhold a nonapproval letter that contained important safety information about a device used by doctors, it could face damage to its brand. "They have to think long and hard of the reputational impact," he said.

The handling of the ASR highlights how the F.D.A., by keeping its approval process confidential, may affect the health and safety of patients. An agency spokesman, Morgan Liscinsky, declined to disclose the letter on the ASR, saying the agency had a policy of not releasing such notices because they might contain confidential business information.

The version of the ASR rejected by the agency was developed by DePuy for use in a hip replacement procedure called resurfacing, which is a bone-sparing alternative to standard surgery. DePuy started selling the implant abroad around 2003. But because resurfacing was a new procedure, the agency required the company to run clinical trials before selling the device here.

In 2005, while those studies were under way, DePuy used a less rigorous regulatory pathway to win F.D.A. clearance to sell a version of the ASR based on the same metal hip cup for use in traditional joint replacement surgery. Because that version resembled hip implants already on the market, the agency was authorized to clear it for sale without clinical testing.

It was apparently within weeks of getting the F.D.A. letter in August 2009 that DePuy executives began a strategy to slowly phase out ASR sales while shifting surgeons to other company implants.

Three months after the letter, in November 2009, the company publicly announced its decision to phase out the ASR, attributing the move to declining sales. The company also said then that it had withdrawn its F.D.A. application for the resurfacing version of the device.

In a statement, Ms. Tinsley, the DePuy spokeswoman, said the company "weighed the additional data that would be required for approval against the declining market demand for hip resurfacing."

It is not known precisely what the agency's letter stated nor is it clear how, or if, the agency's concerns about the resurfacing version of the hip implant applied to the model used in this country in standard replacement surgeries. The agency can reject approving a device for various reasons, including cases where it is seeking only small amount of added data.

Copies of the letter that might have been provided to lawyers involved in litigation against Johnson & Johnson have been sealed by the court. But the summary of the letter to DePuy suggests that it was long and detailed -- 13 pages in all.

Before the recall, DePuy long defended the articular surface replacement device, saying that any failures associated with it reflected failures by surgeons to properly implant the hip cup. The surgeons who performed the study of the resurfacing version of the device that was rejected by the F.D.A. were handpicked by DePuy and included the model's designers.

Dr. Antoni Nargol, an orthopedic surgeon in England who worked on the study that DePuy submitted to the F.D.A. and later became a critic of the device, said in a telephone interview that the company had never informed him that its application for approval in the United States had been rejected.

In March 2010, The Times disclosed that F.D.A. records showed that the agency had received 300 complaints about the ASR, virtually all of them involving patients who had to undergo replacement operation just a few years after getting the device. That number has since reached into the thousands.

DePuy continued to insist then that it was safe, but in August 2010, after data in a British registry of orthopedic patients showed high failure rates for the ASR, the company recalled both versions of the device.

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Johnson Takes $3 Billion Hit On Hip Recall

By REUTERS
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English

Johnson & Johnson took quarterly charges of more than $3 billion, largely related to the recall of artificial hips, and gave a 2012 earnings forecast below analysts' estimates on Tuesday.

The company's DePuy Orthopaedics unit issued an extensive recall of its "metal-on-metal" hip replacement devices in 2010 after they shed metal fragments, causing disabling injuries.

The fourth-quarter charges will allow money to be set aside for patients and lawyers involved in product liability litigation.

"The hip recalls worry me because their eventual costs are unknown," said Jeff Jonas, an analyst at Gabelli & Company, who noted that the fourth-quarter charges included $800 million for medical costs of the recall.

The company forecast 2012 earnings of $5.05 to $5.15 a share, compared with the consensus Wall Street view of $5.21.

William Price, a company spokesman, said most analysts had not factored in damage from the stronger dollar.

Johnson & Johnson reported better-than-expected fourth-quarter earnings, helped by favorable taxes and sales of new prescription drugs. The company earned $218 million, or 8 cents a share, in the quarter. That compares with $1.9 billion, or 70 cents a share, a year earlier, when it also took charges for recalls of hip replacement devices.

Excluding special charges, Johnson & Johnson earned $1.13 a share. Analysts had expected $1.09, Thomson Reuters said.

Johnson & Johnson, which is based in New Brunswick, N.J., said global sales rose 3.9 percent in the quarter, to $16.26 billion, slightly below analysts' target.

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Johnson & Johnson Hurt by Recalls in Second Quarter

By THE ASSOCIATED PRESS
428 words
20 July 2011
The New York Times
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The New York Times on the Web
English

Johnson & Johnson posted a 20 percent decline in second-quarter profit on Tuesday, hurt by product recalls, flat sales in the United States and costs related to litigation and restructuring.

Johnson & Johnson executives said they were making progress on fixing manufacturing problems that resulted in several recalls and had numerous new drugs, medical devices and toiletries hitting the market or coming soon.

The company said it earned $2.78 billion, or $1 a share, down from $3.45 billion, or $1.23 a share, a year earlier. Revenue rose 8.3 percent, to $16.6 billion, from $15.33 billion a year ago.

Excluding one-time items, income would have been $3.55 billion, or $1.28 a share.

Analysts polled by FactSet, on average, were expecting earnings of $1.24 a share and sales of $16.21 billion. Shares of Johnson & Johnson, which is based in New Brunswick, N.J., fell 37 cents, to $66.72.

"The expectations were austere," said Steve Brozak, an analyst with WBB Securities. He noted that J.& J. executives repeatedly cited pressures from austerity measures by European government health programs and flat or declining prices in the United States for things like joint replacements.

Revenue was flat in the United States; consumer health product sales were down 8.5 percent because recalled products remained off store shelves. Foreign sales were up 16 percent, but mostly because of favorable exchange rates.

Sales were up in all three divisions -- consumer health, prescription drugs and medical devices and diagnostics -- for the first time since the fourth quarter of 2009, shortly after the start of a series of more than 25 product recalls.

Revenue growth was led by prescription drugs, with an increase of 12 percent, to $6.23 billion, in sales.

Sales of medical devices, J.& J.'s biggest division, rose 7 percent to $6.57 billion. Consumer health products, which includes nonprescription medicines and skin, dental and hair care products, increased 4 percent to $3.79 billion.

The company maintained its profit forecast for 2011, at $4.90 to $5 a share, excluding one-time items. Analyst expect $4.95 a share, on average.

"We are making solid progress in our product launches, pipelines and investments" in product development, Dominic Caruso, the chief financial officer, told analysts in a conference call. "I expect to see additional improvement in third-quarter sales as our business momentum continues and as the overall market improves."

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With Deal, J.&J. Tries To Pivot

By REED ABELSON and NATASHA SINGER
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In announcing on Wednesday Johnson & Johnson's biggest acquisition ever, on the eve of its annual shareholder meeting, the company's chief executive tried to pivot from a year of manufacturing lapses, product recalls and a disappointing share price.

The $21.3 billion deal for Synthes, a Swiss-American medical device maker, would make Johnson & Johnson the largest player in the market for surgical tools and implants to treat trauma patients, and would make it a more powerful competitor in the $37 billion worldwide market for orthopedic medical devices.

Synthes is a leading maker of screws, plates and surgical tools used to stabilize traumatic injuries. The deal is a move aimed at appealing to investors who have been troubled by Johnson & Johnson's failure to quickly resolve significant and apparently systemic problems in the company's consumer products division, which have tarnished once-golden brands like Tylenol.

Johnson & Johnson's chief executive, William C. Weldon, championed the new deal in an interview on Wednesday, citing what he hoped would be cooperation between the company's existing orthopedic and spinal implant division, DePuy, and Synthes. "We've got the opportunity to create the most innovative and comprehensive orthopedic business in the world," Mr. Weldon said.

Trauma products are more profitable and less vulnerable than other kinds of medical devices to changes in broad economic trends, he said. The combination of Johnson & Johnson's global presence and Synthes's products, he said, created a new opening in emerging markets for the combined company.

Many Wall Street analysts praised the deal, even as some groused that it would not immediately add to earnings.

"J.& J. will be able to offer hospitals an inescapable breadth and depth of products that will offer one-stop shopping in reconstructive implants and trauma repair," said Rick Wise, an analyst at Leerink Swann. "You are going to have to do business with J.& J."

Johnson & Johnson is offering 159 Swiss francs (about $181) a share for Synthes -- of which 55.65 francs is cash and 103.35 francs is Johnson & Johnson common stock. Derrick Sung, an analyst at Sanford C. Bernstein, said some investors were disappointed that the company was not planning to make use of its stockpile of foreign cash for the deal.

"It's dilutive, at least for the first year," he said. "There was an expectation that it would be accretive in the first year."

At the annual shareholder meeting on Thursday, some investors are expected to raise concerns about Mr. Weldon's management and his compensation. "I don't think they would have done the deal if they didn't need a distraction," said Erik Gordon, an assistant business professor at the University of Michigan who has been a frequent critic of Mr. Weldon's leadership.

The company stands at a crossroads as Mr. Weldon nears the end of his tenure. Even as Johnson & Johnson plans to use the Synthes acquisition to improve its position in the device sector and its performance, the company must still resolve major manufacturing problems in its consumer division and work to regain consumer trust.

During a conference call with investors on Wednesday morning, some analysts asked whether the company was equipped to handle both a substantial acquisition and significant remediation.

Some investors fault a lack of management oversight for major problems, like last year's manufacturing lapses at the company's McNeil Consumer Healthcare unit, which was responsible for the recalls of nearly 300 million items in 2010, including for popular brands like Motrin and Rolaids. McNeil closed its Fort Washington, Pa., manufacturing plant to overhaul it, and is now operating under a consent decree with federal regulators.

Johnson & Johnson bought Pfizer's consumer business, including brands like Listerine, for $16.6 billion in 2006, and some analysts have speculated that the unwieldy acquisition, along with cost-cutting measures, may have contributed to the problems that developed at McNeil.

The company has also been sharply criticized for its recalls of artificial hips made by DePuy. Separately, the company recently agreed to pay $70 million to settle charges that it had bribed doctors abroad in order to promote its medical devices.

Some investors wonder whether the company should have waited to make such a large acquisition until after management had resolved many of these issues. "We think J.& J. should have fixed its consumer unit first before conducting a big transaction," Les Funtleyder, a portfolio manager who owns the stock at Miller Tabak & Company, told investors, "but since acquisitions are part of J.& J.'s operating strategy, this deal is not out of context."

Some former employees agree that Johnson & Johnson needs to focus on turning around its consumer business. "A huge acquisition diverts a lot of company resources and, most critically, the attention of senior management," said David Vinjamuri, a former marketing employee at Johnson & Johnson who is now president of Third Way Brand Trainers. He is concerned about the erosion in confidence among consumers in J.& J.'s brands.

But Mr. Weldon says the company is making strides in addressing the problem and that there are separate management teams devoted to improving quality control at the consumer unit and to integrating the Synthes acquisition.

In addition to investing more than $100 million in upgrading the Fort Washington plant to make it "truly world-class" and ensuring McNeil's compliance with federal manufacturing standards, he said, Johnson & Johnson has issued companywide quality oversight measures.

But not all shareholders are persuaded. Some are voting against a proxy provision that asks shareholders to approve Mr. Weldon's pay on an advisory basis, since the board has already determined his compensation.

Institutional Shareholder Services, a group that counsels large shareholders about how to vote on proxy issues, is recommending that investors vote against advisory ratification of Mr. Weldon's pay, saying the amount ignores the problems under his stewardship.

"The product recalls diminished the company's revenue projection, and J.& J. stock has remained flat even as the recession eased and the market has been rising across most sectors," the group wrote in a report issued April 12. "Despite these issues, C.E.O. Weldon continued to receive annual pay at the $32 million level."

The American Federation of State, County and Municipal Employees, a union that is part of the A.F.L.-C.I.O., is leading a "vote no" campaign at J.& J. over its executive pay.

Lisa Lindsley, the director of capital strategies at the union, said that even though the board justified the high compensation because of Mr. Weldon's efforts to remedy the problems at McNeil and elsewhere, "he's the one who got the company into these tough times." Mr. Weldon said the company's proxy statement provided an explanation of his pay, including a sharp reduction in his bonus for 2010.

The company has learned lessons from its mistakes, he said, including the need for better communication with federal regulators and for a more hands-on approach to investigating and determining the cause of product flaws.

For the shareholder meeting on Thursday, he said he planned to announce new packaging for children's medicines that would help parents give their children the correct dose -- an innovation that grew out of the company's examination of the recalls. Mr. Weldon said the company was sharing the dose-limiting design with other manufacturers.

"We still have an extraordinary reputation, but we have made mistakes and we take accountability for them," Mr. Weldon said. "We are working very hard to regain that trust."

Johnson & Johnson's shares closed Wednesday at $65.57, a gain of 62 cents.

PHOTO: William C. Weldon, chief executive of J.& J., said that buying Synthes would help create openings in emerging markets. (PHOTOGRAPH BY JOSHUA PREZANT/BLOOMBERG NEWS) (B7)

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The New York Times

Health; Money & Policy; Prescriptions
J. & J. Unit Recalls Epilepsy Drug; Prescriptions

By NATASHA SINGER
418 words
14 April 2011
NYT Blogs
NYTB
English

For consumers who have been losing trust and patience with Johnson & Johnson over its manufacturing and quality control issues, the announcement of a recall on Thursday from a company unit that makes neurology drugs may seem all too familiar.

The Johnson & Johnson unit, the neurologics division of Ortho-McNeil-Janssen Pharmaceuticals, said it was recalling about 57,000 bottles of Topamax, a drug that can be prescribed as an anti-seizure medication for epilepsy or to prevent migraine headaches. The company said it was recalling the drug after receiving four complaints from consumers of a strange odor, but added that there had been no reports of serious health problems associated with the complaints.

In 2009 and 2010, similar odor complaints led another unit of Johnson & Johnson, McNeil Consumer Healthcare, to conduct nationwide recalls of millions of bottles of over-the-counter drugs including Tylenol, Motrin, Benadryl, Rolaids, Simply Sleep and St. Joseph's aspirin. A company investigation determined that the moldy odor had been caused by contamination from a byproduct of a chemical used to treat wooden pallets used to transport the drugs.

The recall of Topamax involves two lots of 100mg strength tablets shipped at the end of last year, the company said. Less than 6,000 bottles of the product are believed to remain in stores, the company said.

People taking Topamax who notice a strange odor with the pills should return the tablets to their pharmacist, the company said. Consumers or physicians can contact the Topamax hotline for further information on weekdays between 9am and 5pm at: (866) 536-4398.

The latest recall coincides with efforts by Johnson & Johnson to resolve government charges that it failed to comply with certain manufacturing standards and marketing laws. Last week, Johnson & Johnson agreed to pay $70 million to settle charges with the Justice Department that the company had bribed European doctors.

Last month, the company's McNeil Consumer Healthcare unit entered into a consent decree that will give federal drug regulators greater oversight over three manufacturing plants with a history of quality control problems that have led to recalls.

Johnson & Johnson is scheduled to announce its first quarter earnings to investors next Tuesday.

* The Case of the Missing Pepcid Tablets

* Tylenol Recalls Erode Johnson & Johnson Sales

* More Trouble With Tylenol

* More Federal Scrutiny for Johnson & Johnson

* Tylenol Plant Lays Off 300

Document NYTB000020110414e74e0030d

The New York Times

Health; Money & Policy; Prescriptions
Another Tylenol Recall; Prescriptions

By REED ABELSON
353 words
29 March 2011
NYT Blogs
NYTB
English

It's yet another recall from the makers of Tylenol.

McNeil Consumer Healthcare, a unit of Johnson & Johnson, announced Tuesday afternoon that it was recalling more of its over-the-counter Tylenol products. In a statement, the company said that it was conducting a voluntary consumer recall of one product lot of eight-hour extended-release caplets because of a "musty or moldy odor."

About 34,000 bottles are being recalled, according to a McNeil spokeswoman. The company says any health risk from the caplets is "remote."

The company also announced it was expanding a previous recall announced in January. Unlike the Tylenol caplet recall, the expanded recall, which involves 10 lots of other products, is being undertaken on the wholesale level and is not based on adverse events, according to the company.

About 718,000 bottles or packages of Tylenol, Benadryl and Sudafed products were involved in the recall. Here's a complete list of affected products.

These are the latest recalls involving products made at a now-shuttered plant in Fort Washington, Pa., and they continue what some analysts see as a never-ending problem at Johnson & Johnson. The company has been plagued by manufacturing and quality problems in its popular over-the-counter medicines, including many of its children's products, that forced the closure of one plant and an overhaul of its procedures.

As part of the process to try to address past issues and bring the closed plant up to federal standards, the company has been reviewing manufacturing records of over-the-counter drugs and recalling certain products as a result.

Earlier this month, Johnson & Johnson reached an agreement with federal regulators that imposes greater federal oversight of manufacturing of products made by its McNeil unit. Regulators said manufacturing processes failed to comply with federal law.

* Johnson & Johnson Recalls More Products

* Johnson & Johnson Unit Signs Consent Decree With F.D.A.

* Tylenol Plant Lays Off 300

* Disparities in Recall Disclosure

* The Case of the Missing o.b. Tampons

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The New York Times

Business/Financial Desk; SECTB

U.S. Regulators and J.&J. Unit Reach a Deal on Plant Oversight

By REED ABELSON and NATASHA SINGER
821 words
11 March 2011
The New York Times
NYTF
Late Edition - Final
1
English

Federal regulators reached an agreement on Thursday with a unit of Johnson & Johnson that would impose greater federal oversight at three manufacturing plants responsible for recalls of children's Tylenol and many other popular over-the-counter medicines.

The regulators say that the manufacturing practices failed to comply with federal law.

The proposed consent decree with the Food and Drug Administration stems from recurring problems for over a year with products made by Johnson & Johnson's McNeil Consumer Healthcare division at sites in Pennsylvania and Puerto Rico. Lawmakers and regulators have repeatedly criticized the company for its inability to manage production at these plants.

"We've had a long engagement with McNeil over the last year with regard to their quality system," Douglas Stearn, an F.D.A. official who helps oversee compliance by drug makers, said in an interview on Thursday. "We think this represents necessary important steps to assuring quality across the board."

Under the agreement, which needs approval from a federal judge, Johnson & Johnson would be required to hire an independent expert to determine whether operations at all three plants met federal standards and to ensure that quality systems were in place.

The agreement covers a plant in Fort Washington, Pa., that the company closed last year for an overhaul amid a nationwide recall of children's medicines; a plant in Las Piedras, P.R., that was the subject of an agency warning letter last year; and a plant in Lancaster, Pa., that makes products like Pepcid for a joint venture with Merck. McNeil cannot reopen the Fort Washington plant until an independent expert determines that the plant meets all federal standards and passes an agency inspection, according to the agreement.

The agreement would also give the F.D.A. the authority to require McNeil to stop manufacturing or to institute recalls. While the agency did not levy a fine in this case, McNeil could face fines of $15,000 a day for violating the decree, up to $10 million a year.

While the proposed consent decree covers a civil complaint, the F.D.A. would not comment on the status of any related criminal investigations. Last year, an F.D.A. official testified at a Congressional hearing that the agency had referred the McNeil case to its Office of Criminal Investigations. A spokeswoman for McNeil confirmed that other federal investigations were under way.

Last July, McNeil filed a plan with the F.D.A. that detailed how it expected to upgrade its manufacturing and quality processes. But the terms of the proposed decree indicate that federal regulators thought the company needed outside oversight, said Erik Gordon, an assistant professor at the Ross School of Business at the University of Michigan. He likened the consent decree to a trusteeship or a receivership.

Professor Gordon estimated that the agreement could be costly because of the need to hire independent consultants, who would have to inspect and certify the company's corrective actions. "It's a big embarrassment, and it is going to be expensive," he said.

In a statement issued on Thursday to the company's employees, William C. Weldon, Johnson & Johnson's chief executive, said executives were committed to addressing the manufacturing problems at the plants. While he

emphasized that the company "has made important progress toward improving quality and compliance," he said the agreement "requires additional quality assurance measures, and is a reminder that important work remains to be done."

A McNeil spokeswoman said she could not comment on how much the agreement might cost the company to put in place.

Other units of Johnson & Johnson have also been experiencing problems, leading some industry analysts to raise broader questions about oversight. Last year, the company's DePuy unit recalled two different hip implants, affecting tens of thousands of patients worldwide. Its Animas unit recalled tens of thousands of insulin pump cartridges last month because they had the potential to leak and deliver too little insulin, the company said.

Also last month, the F.D.A. sent a letter to Cordis, a company device unit, warning about problems at a plant in Puerto Rico that makes heart stents.

A spokeswoman for Cordis said the company was working to address the agency's concerns. "We do not believe this issue impacts product safety and efficacy and we are confident our product remains safe and effective for use," she said.

Les Funtleyder, a fund manager at Miller Tabak & Company, which owns shares of Johnson & Johnson, said the agreement underscored concerns about the company's ability to resolve persistent manufacturing problems.

"We're having a hard time reconciling how Johnson & Johnson got to this point," he said. "The board has to be asking questions. If not, investors will be."

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The New York Times

Health; Money & Policy; Prescriptions

Johnson & Johnson Unit Signs Consent Decree With F.D.A. Prescriptions

By REED ABELSON
211 words
10 March 2011
NYT Blogs
NYTB
English

The McNeil Consumer Healthcare Division of Johnson and Johnson, which has been besieged by manufacturing problems and recalls of children's Tylenol and other over-the-counter medicines for more than a year, reached a consent decree with the Food and Drug Administration on Thursday.

The decree focuses on three manufacturing plants that have been highlighted for problems and recalls in recent months. Two of them are in Pennsylvania, and McNeil has already closed one until it can be overhauled. The third plant is in Puerto Rico. (In January, The Times published a lengthy article on problems with McNeil and J&J products.)

The decree also formalizes oversight by an independent expert to ensure that the plants are brought into compliance with federal standards. No fines were announced with the decree.

The F.D.A.'s news release can be found here, and McNeil also issued its own release.

* Johnson & Johnson Recalls More Products

* Lawmakers Grill J&J and F.D.A. Officials

* This Week's Health Industry News

* This Week's Health Industry News

* F.D.A. Orders Prescription Cold Drugs Pulled From Market

Document NYTB000020110310e73a006k7

The New York Times

Health; Money & Policy; Prescriptions
The Case of the Missing Pepcid Tablets; Prescriptions

By NATASHA SINGER
611 words
8 March 2011
NYT Blogs
NYTB
English

Where has all the Pepcid Complete gone?

That's the question people who suffer from heartburn have been asking on blogs and in pharmacies ever since the product, made by Johnson & Johnson Merck Consumer Pharmaceuticals, a joint venture of the two drug giants, began to disappear from store shelves last fall.

The product's Web site, for example, has a "buy now" button for Pepcid Complete. But that sends viewers to a link on drugstore.com for a different product, Pepcid AC.

The lack of a concrete explanation from the company about the reason behind the product's disappearance has led to frustration and speculation among consumers - as well as high asking prices on Amazon.com ($75) and bids of $26 on eBay for 50-count bottles.

The curious disappearance of Pepcid Complete comes as Johnson & Johnson is trying to rectify manufacturing problems at its McNeil Consumer Healthcare unit that have resulted in product recalls dating to September 2009; McNeil provides manufacturing services for the joint venture with Merck that markets Pepcid.

But the dearth of Pepcid Complete - like the recent supply interruption of o.b. tampons, another popular consumer product from Johnson & Johnson - illustrates the company's continuing communication problems with consumers. (The tampons are now back at some retailers, according to the product's Web site.)

Last July, the Food and Drug Administration issued a 12-page inspection report, faulting a company plant in Lancaster, Pa., that makes Pepcid products for numerous manufacturing lapses. The problems cited by the F.D.A. included failure to thoroughly investigate consumer complaints of drug mix-ups and failure to investigate the quality of drug batches made during equipment malfunctions.

Last August, the joint venture recalled one lot, or about 15,000 bottles, of Pepcid Complete in tropical fruit flavor because of defective containers.

After that, consumers began to report the disappearance from stores of Pepcid Complete in flavors -- cool mint and berry -- that had not been involved in the recall.

In response to an inquiry last month, Bonnie Jacobs, a spokeswoman for McNeil, wrote in an e-mail, "When it comes to quality, we are evaluating our processes and making improvements at all the plants that manufacture our OTC [over-the-counter] products," including those made by the joint venture with Merck. "As we do so, some products, such as Pepcid Complete, may occasionally become temporarily unavailable," she wrote.

Ms. Jacobs added that the Pepcid Complete supply situation was not related to a safety issue nor was it related to the same issue behind last summer's Pepcid recall. Consumers can expect to see Pepcid Complete back on store shelves starting this month, she said. But she declined to elaborate about the product's current unavailability.

After my inquiry, the Pepcid Web site posted an announcement on Feb. 22, apologizing for any inconvenience and assuring customers that "we are working diligently to get your products back as quickly as possible."

But the incomplete explanation does not sit well with some loyal consumers, like Brian Oakes, an independent trader in Warren, N.J., who sent me an e-mail asking for information about Pepcid's vanishing act.

In a follow-up phone interview, Mr. Oakes said, "It's amazing how they could pull a product like this off the shelves and not tell anyone why."

* Product Recalls Weaken J.& J. Sales

* House Panel Asks F.D.A. About Inspections in Puerto Rico

* Tylenol Recalls Erode Johnson & Johnson Sales

* More Trouble With Tylenol

* More Federal Scrutiny for Johnson & Johnson

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The New York Times

Business/Financial Desk; SECTB

Johnson & Johnson's Profit Falls 12%, Hurt by Series of Recalls

By THE ASSOCIATED PRESS
469 words
26 January 2011
The New York Times
NYTF
Late Edition - Final
2
English

Johnson & Johnson, hurt by product recalls and a weak economy, posted a 12 percent decline in profit and a 5.5 percent decline in sales for the fourth quarter on Tuesday.

The company reported net income of $1.94 billion, or 70 cents a share, down from $2.21 billion, or 79 cents a share, a year earlier.

Excluding one-time items, earnings would have been $1.03 a share, matching analysts' expectations. The company took an after-tax charge of $922 million for litigation settlements, a recall of poorly fitting DePuy hip implants and an increase in its product liability reserve.

The company's revenue fell to $15.64 billion from $16.6 billion a year earlier. It was also below the $16 billion expected by analysts polled by FactSet.

Johnson & Johnson has been hurt by 17 recalls since September 2009, covering multiple McNeil Consumer Healthcare products, plus contact lenses and hip replacements, and the lengthy shutdown of one of the factories involved. Lost revenue from the recalled products reduced 2010 sales by $900 million, 50 percent more than Johnson & Johnson predicted last year.

The chief executive, William C. Weldon, tried in a conference call to reassure analysts and investors that the company had its manufacturing and other problems under control.

But shares of Johnson & Johnson, which is based in New Brunswick, N.J., fell $1.14, or 1.8 percent, to $61.08.

Johnson & Johnson also forecast a full-year profit of $4.80 to $4.90 a share, below the $4.99 expected by analysts.

Results also were affected by the weak global economy squeezing consumer health spending, the impact of the health care overhaul in the United States and European government demands for lower prices.

During a conference call Tuesday, Mr. Weldon said pricing pressures from hospitals and governments would not go away soon, if ever, but that expected continued sales growth in emerging markets, and several important new drugs awaiting approval, would help J.& J. recover.

Mr. Weldon, 62, also said the company was committed to restoring its over-the-counter medicines to the quality level consumers expected.

Sales of consumer products like Tylenol, Benadryl and Rolaids, all the subject of recalls over product contamination and other problems, were down the most. Sales in that division fell 15 percent to $3.6 billion, with a 29 percent decline in the United States.

Sales of prescription drugs, which include Remicade for immune disorders and Concerta for attention deficit disorder, fell nearly 5 percent to $5.71 billion. The medical device division, now J.& J.'s largest, did best with sales up 0.2 percent to $6.32 billion.

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The New York Times

Health; Money & Policy; Prescriptions
Product Recalls Weaken J & J Sales; Prescriptions

By NATASHA SINGER
516 words
25 January 2011
NYT Blogs
NYTB
English

Shares of Johnson & Johnson dipped in Tuesday trading after the company reported that its fourth quarter sales in 2010 had decreased 5.5 percent to $15.6 billion. Full-year sales for 2010 decreased .5 percent to $61.6 billion.

In addition to recalls last year of many of its popular over-the-counter drugs, the company attributed diminished revenues to weaker sales of certain prescription medicines.

Within the consumer division, over-the-counter drugs and nutritional products had sales in the United States of $381 million in the fourth quarter of 2010, a decline of nearly 53 percent compared to the same quarter in 2009. For the full year 2010, the company's over-the-counter drugs and nutritional products had sales in this country of about $1.8 billion compared to about $2.9 billion in 2009.

William C. Weldon, the chief executive of Johnson & Johnson, described sales in the consumer products division - which makes Tylenol, Motrin, Rolaids and other products recalled by the company last year - as "a disappointment."

Consumer sales are down largely because J & J's McNeil Consumer Healthcare unit had a variety of manufacturing and quality control problems last year. The company temporarily closed one McNeil plant, in Fort Washington, Pa, last year for an overhaul and it has not been reopened yet.

As a result, many popular products, like children's liquid Motrin, have not been available, although a few are now back on store shelves.

During a conference call with investors Tuesday, executives said that they expected to resume full production in the second half of this year, slightly later than expected.

That is because the company has made a commitment to review and upgrade the manufacturing and quality control practices across McNeil, executives said, a process that is still under way.

In a recent article in The New York Times, industry observers questioned whether Johnson & Johnson will be able to woo back consumers who have switched to other brands or less expensive drugstore alternatives while the company works to bring McNeil into compliance with federal manufacturing standards.

On Tuesday during the conference call, executives said the company plans to invest in a marketing campaign at a later date.Despite weaker sales, Johnson & Johnson reported fourth-quarter earnings per share of $1.03, a one percent increase.

But, in notes to investors on Tuesday morning, a number of industry analysts said that the earnings were unimpressive because they were not the result of sales income.

"It appears to be a low quality number," Catherine J. Arnold, an analyst at Credit Suisse wrote, "as revenues came in $400 million under our estimate and this weakness was offset, in order, by taxes, non-operating income and lower expenses."

Bloomberg has additional details.

* More Trouble With Tylenol

* Tylenol Plant Lays Off 300

* The Case of the Missing o.b. Tampons

* This Week's Health Industry News

* House Panel Asks F.D.A. About Inspections in Puerto Rico

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The New York Times

Money and Business/Financial Desk; SECTBU

Can Johnson & Johnson Get Its Act Together?

By NATASHA SINGER and REED ABELSON
3,094 words
16 January 2011
The New York Times
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Late Edition - Final
1
English

LITTLE red flags jut out from the shelves at a CVS drugstore in suburban Boston, alerting shoppers to shortages of nearly a dozen Johnson & Johnson products. Among them are Motrin, Rolaids, children's Tylenol liquid and adult Tylenol, Mylanta, Pepcid AC and even some Neutrogena skin care products.

"Looking for Tylenol pain relief products?" asks one of the signs. The notices at CVS serve as a stark reproof to Johnson & Johnson, whose brands have for more than a century been synonymous with quality. Some of its products are in short supply at drugstores and supermarkets because the McNeil Consumer Healthcare unit of J.& J. last year recalled about 288 million items, including about 136 million bottles of liquid Tylenol, Motrin, Zyrtec and Benadryl for infants and children.

Johnson & Johnson has had to recall such a variety of products because of quality-control problems across product lines, in multiple factories and in several units last year. Some of its consumer products, for instance, may have contained bits of metal. Others came in bottles with a moldy smell. And some products have gone missing from stores with hardly an explanation. All of this has put the company and its manufacturing under the intense scrutiny of lawmakers and officials at the Food and Drug Administration.

"It looks like a plane spinning out of control," says David Vinjamuri, a former J.& J. marketing employee who now trains brand managers at his company, ThirdWay Brand Trainers.

While the drugstore signs that helpfully suggest "Try CVS/pharmacy brand" are intended to assist frustrated shoppers in identifying alternatives to missing brand-name products, they also serve as constant reminders of another of J.& J.'s continuing problems: It must persuade millions of disappointed customers to once again pay a premium for products that may no longer seem to be of any higher quality than the less expensive store brand.

"I don't even consider buying them any more," says Thien-Kim Lam, a mother of two and a blogger in Silver Spring, Md. In a post last spring titled "Makers of Tylenol, I'm Disappointed in You" on the blog DC Metro Moms, Ms. Lam wrote about the huge recall of J.& J. infants' and children's medicines.

Now, she says, the frequent recalls have prompted her to switch to generic cold and cough medicines for her children. "It's like a breakup," she says. "I'm done. I've moved on."

Bonnie Jacobs, a McNeil spokeswoman, says the company is committed to restoring McNeil's reputation as a world-class manufacturer of over-the-counter medicines. "We will invest the necessary resources and make whatever changes are needed to do so, and we will take the time to do it right," she wrote in an e-mail last Thursday.

If Queen Elizabeth II had been the chief executive of Johnson & Johnson, she might have called 2010 an "annus horribilis."

J.& J.'s troubles with some of its consumer products began in earnest last January, when McNeil recalled millions of pill bottles after some consumers complained that they smelled like mold. By December, when it recalled 13 million packages of Rolaids soft chews that may have been contaminated with metal or wood particles, the company had closed one plant in Fort Washington, Pa., for an overhaul and had yet to solve the quality problems at another, in Puerto Rico.

The response of J.& J.'s chief executive, William C. Weldon, has been to allocate more than $100 million to upgrade McNeil's plants and equipment, appoint new manufacturing executives, hire a third-party consulting firm to improve procedures and systems at McNeil and shore up quality control companywide. In Congressional testimony last fall, he promised that when the Pennsylvania plant reopened, it would "represent the state of the art in medicine production." And he has repeatedly tried to reassure consumers, as he did when he promised that J.& J. had "no higher concern than providing parents with the highest-quality products for their children."

Those reassurances, however, have been followed by yet more recalls. What is most perplexing is the seeming inability of executives to solve -- and satisfactorily explain -- the manufacturing issues that dog the company. Federal regulators have continued to fault the McNeil unit for failing to identify and address systemic problems at its plants, and consumers remain mystified about why simple products like O.B. tampons can disappear from drugstore shelves.

In July, McNeil submitted a plan to the F.D.A. detailing how it intends to overhaul its operations. To comply with regulatory standards, McNeil is undertaking thorough manufacturing and quality-control reviews for all its products, Ms. Jacobs says.

That means the recalls may continue. Last Thursday, Ms. Jacobs said the company would "take whatever steps are needed to ensure our products meet quality standards, including further recalls if warranted."

Only a day later, McNeil recalled 47 million units of Sudafed, Sinutab, Benadryl and other drugs from wholesalers because of issues like inadequate equipment cleaning practices. The company said that the recalls were not a result of health problems and that consumers could continue to use the products.

JOHNSON & JOHNSON, with about $62 billion in sales in 2009, makes thousands of different kinds of products, including Band-Aids, baby shampoo, cardiac stents and advanced drug treatments for rheumatoid arthritis. It solidified a reputation for product quality with a company credo, dating from 1943, saying that the company owed its first responsibility to the mothers and fathers, doctors, nurses and patients who use its products.

With such a diversity of products and operating companies, Johnson & Johnson's overall business has not suffered significantly. But the string of recent recalls at McNeil threatens to weaken the kind of trust that made many people willing to pay more for J.& J. brands.

"Nothing is more valuable to Johnson & Johnson than the brand bond of trust with consumers," says Erik Gordon, a professor at the Ross School of Business at the University of Michigan. "But this is almost like, 'If it's an even-numbered day, it's time for another quality problem at Johnson & Johnson.' "

And, as the signs in CVS indicate, competitors -- whether drugstore brands or other household names like Advil from Pfizer or Triaminic from Novartis -- have muscled into the shelf space vacated while J.& J. puts its plants in order. In the year ended on Dec. 26, for example, sales of children's liquid Tylenol and Motrin decreased 60 percent or more while drugstore brands have gained 93 percent, according to the SymphonyIRI Group, a market research firm that tracks mass-market sales excluding those at Wal-Mart.

Mark Mandel, a father in Chicago, says his family previously bought infants' Tylenol and Motrin drops on the assumption that the branded products were of better quality than generics. But to regain his business now, Mr. Mandel says, J.& J. would have to demonstrate that it had better manufacturing standards.

"There were reasons we weren't buying generics before," says Mr. Mandel, a microbiologist at the Feinberg School of Medicine at Northwestern. "But they are lower than the concerns we have about Johnson & Johnson right now."

YouGov BrandIndex, a market research firm that tracks consumer attitudes, says it has noticed a steady, albeit not steep, erosion over the last 18 months in how consumers perceive not just drug brands like Tylenol but also J.& J. While many consumers are still loyal, says Ted Marzilli, a senior executive at the firm, the company needs to avoid death by a thousand cuts.

"They've really got to stop the bleeding," Mr. Marzilli says. "What the company really needs to do is not have any more recalls for six months, nine months, 12 months."

Ms. Jacobs says the company intends to "build back our brands by producing the reliable, high-quality products that consumers expect of us and we expect of ourselves."

Consumers have typically been willing to forgive a brand for one incident or product problem, industry analysts say, if a company acts swiftly to rectify the situation and to issue an apology -- as J.& J. did in 1982 when seven people died in the Chicago area after a tampering incident in which Tylenol was laced with cyanide.

The most recent recalls of Tylenol and other products have been more of an inconvenience to consumers than a serious health risk. Federal officials have said there was no evidence that deficiencies in the recalled products caused severe illness or death.

But the number and variety of problems have stirred concern among government officials and consumers that the McNeil unit has suffered from a systemic breakdown of its manufacturing procedures. Last May, the House Committee on Oversight and Government Reform opened an investigation into the recalls.

Questions are still swirling around another event, described by some House committee members as a "phantom recall," in 2009 -- in which McNeil hired outside contractors to quietly buy back certain defective Motrin products from store shelves. The products did not dissolve properly, a problem that could cause the pills to work less effectively.

Last week, the state of Oregon filed a lawsuit accusing Johnson & Johnson and McNeil of misrepresenting the quality and efficacy of those products.

"They did not want the negative publicity that would come with admitting they had a defective product, the negative publicity that comes with any recall," John Kroger, Oregon's attorney general, said.

Ms. Jacobs of McNeil said the unit's actions "were consistent with applicable law, and there was no health or safety risk to consumers associated with this limited recall."

The company disputed the allegations, she said, and would seek to have the lawsuit dismissed.

But Mr. Weldon, while saying that he believed McNeil had acted with good intentions, has emphasized that in retrospect, the company should have handled things differently.

"This episode was not a model for how I would like to see Johnson & Johnson companies approach problems with defective products when they arise," he said during Congressional testimony last September.

NOTHING better illustrates Johnson & Johnson's difficulties in remedying McNeil's woes -- and the longstanding frustration of federal regulators -- than the events at the company's plant in Las Piedras, Puerto Rico. Consumers started complaining as early as April 2008 about moldy-smelling Tylenol arthritis caplets that they said nauseated them or gave them stomach problems.

McNeil did not alert the F.D.A. until September 2009 and then didn't start a substantial recall until December 2009 -- during an F.D.A. inspection of the plant, according to F.D.A. documents.

In January 2010, the agency sent a warning letter to Peter Luther, the president of McNeil, complaining that the company's initial investigation "was unjustifiably delayed and terminated prematurely." It said that even though consumers had also complained about a moldy smell in Rolaids and Extra-Strength Tylenol, the company had not widened its investigation to include those products.

Only after the F.D.A. inspection did McNeil executives recall millions of bottles of Tylenol, Motrin, Benadryl and other pills. The company identified an unusual source for the moldy odor: chemical contamination from a byproduct of a pesticide used to treat wooden pallets. It has since stopped using the pallets.

The F.D.A. says the company should have acted faster. "When something smells bad literally or figuratively, companies must aggressively investigate and take all necessary actions to solve the problem," said Deborah M. Autor, director of the office of compliance at the F.D.A. Center for Drug Evaluation and Research, during a press conference last year.

But Johnson & Johnson executives say that identifying the root cause of the problem was a difficult and lengthy process. Indeed, F.D.A. documents indicated that the consumer complaints subsided for a time in 2008 -- leading the company to conclude the issue had gone away -- only to resume months later.

In a letter to the agency last February, Mr. Luther, the McNeil president, explained that the odor issue was an extremely unusual problem. The investigation, he wrote, had been challenging because there were very few research labs able to test for the chemical later identified as the cause of the smell. McNeil, he assured the

F.D.A., was making changes in the ways that it handled consumer complaints, conducted investigations and notified the agency.

Last October, McNeil recalled yet another lot of Tylenol because consumers again complained of an odor, and the next month in an inspection report, the F.D.A. cited additional lapses at the Puerto Rico plant.

McNeil says that it has been working diligently to ensure that its manufacturing operations meet F.D.A. standards and that it plans to address the agency's most recent concerns.

J.& J.'s troubles have not been limited to its over-the-counter products, which could suggest that the company may suffer from even broader problems. Last year, its DePuy medical device unit recalled two kinds of hip implants, affecting tens of thousands of patients worldwide. Its vision care unit recalled millions of soft contact lenses sold abroad.

A shareholder lawsuit filed last month against Johnson & Johnson's directors, meanwhile, catalogs a long list of "federal and state regulatory investigations, subpoenas and requests for documents, F.D.A. warning letters, news articles and the recall of products accounting for hundreds of millions of dollars of corporate losses."

Ms. Jacobs says the company intends to defend itself in court.

THE manufacturing problems over the last year have clearly cost J.& J. In the third quarter, overall consumer sales in the United States fell 25 percent, to $1.3 billion from $1.7 billion for the same period in 2009, but sales of over-the-counter medicines and nutritional products declined about 40 percent, to $438 million, the company said. The company plans to report fourth-quarter results later this month.

While the company is estimating that the total hit to sales in 2010 from problems at the Pennsylvania plant is likely to be around $600 million, it has begun reintroducing only a few of the products that were once available. Executives say they hope to get more of the missing medicines back on the shelves by the middle of this year and to reopen the plant by year-end.

Although some in the industry are optimistic that the company can quickly regain its perch, some Wall Street analysts are not convinced. This month, Goldman Sachs lowered its 2011 earnings estimates for the company, partly because of the time it might require to bring the closed plant up to the F.D.A.'s standards.

"We believe recovery could be slower than expected," Jami Rubin, a Goldman analyst, warned investors, noting that generic alternatives may now be entrenched with consumers.

Nor has the company improved its communication with the public. Last year, drugstores across the country started running out of O.B. tampons, a product made by McNeil-P.P.C., another company unit.

The product shortage -- and limited information provided by the company about the reasons behind the supply problem -- caused even louder howls of frustration among some women than the children's medicine recall.

"It was like a brick wall," says Susan Pickin, a mother of a 5-year-old daughter in Manhattan, describing her phone conversation with a McNeil customer service representative. The conversation, Ms. Pickin says, left her wondering whether the company had permanently retired the tampons because of a safety issue or whether the items might soon reappear in stores.

Ms. Jacobs, the McNeil spokeswoman, says the company discontinued the most absorbent of the products, called "Ultra," last year, but that there had been no unusual reports of health problems. The company has begun shipping other O.B. products, now available in some stores.

Ms. Jacobs declined to explain the nature of the supply disruptions that caused the shortage.

THE variety, magnitude and duration of the manufacturing and quality problems perplex some industry watchers.

"This is really unusual to have this gross systemic failure," says Donald Riker, the editor of OTC Product News, an industry newsletter on over-the-counter drugs.

The reasons for McNeil's woes remain unclear. Some critics, including former employees, say Johnson & Johnson has lost sight of its credo, while others suggest that the company decentralized its oversight of manufacturing and quality control in error.

Others say it was simply a matter of cost-cutting. The December lawsuit, for example, cited two unnamed former employees who contended that the company failed to address the manufacturing problems at McNeil because it was trying to save money.

Other former employees who are not involved in the lawsuit say that J.& J. seemed to hesitate in recent years to invest in new manufacturing equipment.

"It takes a lot of money to buy equipment and maintain quality," says Patrick Bols, who left Johnson & Johnson's pharmaceutical division in the late 1990s and owns stock in the company.

McNeil declined to comment on what specifically led to its manufacturing troubles. But Ms. Jacobs said the company was taking steps to address all the factors that could have contributed. Since last summer, the company has met the monthly goals it set in its overhaul plan submitted to the F.D.A. And Johnson & Johnson has since revamped and centralized its quality-control operations, naming a longtime executive to oversee a new system of quality control across the corporation and to report directly to Mr. Weldon.

Even some critics say Johnson & Johnson seems to be taking steps to remedy its problems. "It takes a while," Mr. Bols says, "to get it right again."

PHOTOS: PHOTO (BU1); Drugstores like CVS are highlighting generic alternatives to products recalled by Johnson & Johnson. Some consumers say they have sworn off the name brands. (PHOTOGRAPH BY MARILYNN K. YEE/THE NEW YORK TIMES).; William Weldon of J.& J. told Congress that when a troubled plant reopened, it would "represent the state of the art." (PHOTOGRAPH BY KEVIN WOLF/ASSOCIATED PRESS) (BU4)

CHARTS: Changing Attitudes Toward J.& J.: A series of product recalls have had an effect on Johnson & Johnson brands. Surveys show fewer consumers would recommend J.& J. and products like Tylenol and Rolaids to family and friends. (Source: YouGov BrandIndex) (BU4)

Document NYTF000020110116e71g0008d

The New York Times

B
MORE RECALLS FROM JOHNSON & JOHNSON'S MCNEIL UNIT

By NATASHA SINGER
42 words
15 January 2011
The New York Times Abstracts
NYTA
2
English

Johnson & Johnson says it is recalling about 43 million packages of popular over-the-counter drugs from wholesalers as precautionary measure; McNeil Consumer Healthcare unit oversees production (S)

Document NYTA000020110718e71f00009

The New York Times

BUSINESS BRIEFING HEALTH CARE
Business/Financial Desk; SECTB
More Recalls From Johnson & Johnson's McNeil Unit

By NATASHA SINGER
512 words
15 January 2011
The New York Times
NYTF
Late Edition - Final
2
English

Johnson and Johnson announced late Friday afternoon that it was recalling about 43 million packages of Tylenol, Benadryl, Sudafed and Sinutab products from wholesalers because of past manufacturing practices like insufficient equipment cleaning systems.

McNeil Consumer Healthcare, the consumer products unit of the company, also was recalling about 4 million packages of Rolaids Multi-Symptom Berry tablets because of incomplete labels.

The company said it was recalling the products as a precautionary measure and not because of any reports of health problems. Consumers can continue to use the products, the firm said.

McNeil has been plagued by manufacturing and quality control problems, leading to recalls last year of about 225 million bottles of over-the-counter drugs, according to company estimates.

And the total number for McNeil products recalled last year is even higher when other kinds of packages are included. The Food and Drug Administration said Friday that McNeil had recalled "approximately 288 million drug product units" in 2010 - including bottles, blister packs, vials, boxes and other objects.

Johnson and Johnson said in a statement Friday that the latest recalls were the result of a comprehensive action plan, submitted to the F.D.A. last summer, to bring its manufacturing operations into compliance with federal standards.

As part of that effort, McNeil has temporarily closed a company plant in Fort Washington, Pa., for an overhaul and has hired outside consultants to assess its manufacturing and quality control practices. The company said it had also conducted an extensive review to evaluate whether each product made by McNeil's own plants and sold in the United States had been made correctly. For example, the statement said, McNeil identified instances of insufficient equipment cleaning procedures and inadequately documented cleaning.

The manufacturing lapses occurred at the Fort Washington plant prior to April, 2010, when the company stopped production there. Last spring, the F.D.A. cited that plant for numerous manufacturing violations, leading McNeil last April 30th to recall some 136 million bottles of liquid children's Tylenol and other children's medicines made there.

Friday's recall involves lots of Tylenol 8 Hour, Tylenol Arthritis Pain, Tylenol upper respiratory products, Benadryl, Sudafed PE and Sinutab, as well as the mislabeled Rolaids. McNeil said that it was very unlikely that past production processes had impacted the quality of these products.

William C. Weldon, the chief executive of Johnson and Johnson, said in the statement said that steps like the historical product reviews "help us assure that moving forward, any of our products in the marketplace live up to the trusted standards and expectations that consumers have for all products coming from a Johnson & Johnson company, anywhere in the world."

Friday's recalls come after Wells Fargo and Goldman Sachs recently downgraded shares in Johnson & Johnson in part because analysts predicted that McNeil's recovery could be slow.

This is a more complete version of the story than the one that appeared in print.

Document NYTF000020110115e71f00013

The New York Times

Business/Financial Desk; SECTB

Oregon Sues J.&J. In Motrin Buyback

By NATASHA SINGER and REED ABELSON
653 words
13 January 2011
The New York Times
NYTF
Late Edition - Final
3
English

An effort by Johnson & Johnson to buy back defective Motrin pills from store shelves -- described as a "phantom recall" by some members of Congress -- has come under fire in a lawsuit filed by the state of Oregon against the company.

McNeil Consumer Healthcare, the Johnson & Johnson unit involved in several product recalls, had hired outside contractors to buy back vials of Motrin in early 2009 because the pills failed to dissolve properly, a problem that could diminish the product's effectiveness.

The Oregon lawsuit suggests that the problems with those Motrin pills were wider than previously known to the public, extending to certain 24-count packages of Motrin as well as those containing eight-count vials.

In a phone interview on Wednesday, John R. Kroger, the attorney general of Oregon, criticized the company's use of outside contractors to purchase Motrin from retailers, saying it was an effort to avoid the negative publicity that would have accompanied a formal recall from store shelves.

"It would be a disaster if these kinds of phantom recalls became an acceptable business practice," Mr. Kroger said. "The real significance is to send a message to pharmaceutical companies and other companies that make medical products that they have to do proper recalls that give consumers real notice."

In response to a question from a reporter, Bonnie Jacobs, a spokeswoman for McNeil, wrote in an e-mail message: "McNeil's actions were consistent with applicable law and there was no health or safety risk to consumers associated with this limited recall."

After the Food and Drug Administration inquired about the issue in July 2009, McNeil completed a recall of the eight-count vials of Motrin. On Feb. 17, 2010, McNeil announced a recall of the 24-count vials from wholesalers and retailers, according to the Oregon complaint.

The Motrin buyback program came to light last year during an investigation into recent recalls of over-the-counter McNeil drugs by the House Committee on Oversight and Government Reform. McNeil recalled more than 200 million product units last year, including different kinds of Tylenol, Motrin and Rolaids.

After a hearing into the recalls last May, several members of the House committee began referring to the Motrin buyback program as a phantom recall. The legislators said they found it highly unusual -- even suspect -- for a drug company to resort to such methods to buy back defective products rather than initiate an official recall.

The Oregon complaint, for example, cited a repurchase form, developed by employees at Johnson & Johnson and McNeil, that instructed contractors involved in the Motrin buyback program: "Do not communicate to store personnel any information about this product. Just purchase all available product. If you are questioned by store personnel, simply advise that you have been asked to perform an audit."

But, in public testimony before the House committee last year, Colleen Goggins, a Johnson & Johnson executive then in charge of the company's consumer products division, said that McNeil had hired a third-party contractor simply to determine how much of the defective Motrin remained on the market. McNeil, she said, had alerted the F.D.A. about the buyback effort.

The Oregon lawsuit accuses Johnson & Johnson and McNeil of violating the state's unlawful trade practices act by misrepresenting the effectiveness and quality of the Motrin in question. It also accused the company of failing to disclose to consumers that the Motrin might have been ineffective. If the company were found liable, it could be fined up to $25,000 for each container of defective Motrin sold to a consumer in Oregon.

Ms. Jacobs, the McNeil spokeswoman, said that the company would seek to have the lawsuit dismissed.

"There is no legal basis for the claims advanced by Oregon," she wrote in the e-mail.

Document NYTF000020110113e71d00053

The New York Times

Business/Financial Desk; SECTB

North Carolina Plant Made Rolaids Recalled by J.&J.

By NATASHA SINGER

594 words
18 December 2010
The New York Times
NYTF
Late Edition - Final
3
English

Best Sweet, a maker of candy and chewy over-the-counter drug products in Mooresville, N.C., made the millions of Rolaids soft chews involved in a recall last week by a unit of Johnson & Johnson, according to Representative Darrell Issa, Republican of California.

McNeil Consumer Healthcare, the Johnson & Johnson unit, recalled about 13 million packages of Rolaids on Dec. 9, saying that metal and wood particles may have contaminated the items during production at a third-party manufacturer. But McNeil declined last week to identify the Rolaids contractor.

Mr. Issa, the chairman-designate of the House Oversight and Government Reform Committee, which has been investigating McNeil for its conduct in previous recalls, disclosed Best Sweet as the Rolaids manufacturer in a letter sent Friday to the Food and Drug Administration.

Since Best Sweet's "facility produces more than four billion products each year, I am concerned about F.D.A.'s knowledge of Best Sweet's contractual relationship with Johnson & Johnson in manufacturing Rolaids and whether or not the F.D.A. is acting appropriately to determine if there are other similar public safety concerns about products manufactured by Best Sweet," Mr. Issa wrote in the letter to Dr. Margaret Hamburg, the commissioner of the F.D.A.

A McNeil spokesman, Marc Boston, confirmed on Friday that Best Sweet had made the Rolaids and said that McNeil had shared the contractor's name with the F.D.A.

In response to a reporter's query, Rhonda Barnat, a spokeswoman for Best Sweet who works for the Abernathy MacGregor Group, a firm that specializes in crisis communication, wrote in an e-mail: "We have an excellent safety track record. We are cooperating with all parties."

According to the Best Sweet Web site, the company makes nearly a billion soft chews like antacids and calcium supplements each year, as well as more than three billion cough and throat drops, most as private label products for leading retailers like CVS. Best Sweet also makes hard candy for Baskin-Robbins, according to the site.

The revelation increases the risk of reputational damage to Johnson & Johnson, which some legislators and industry analysts have faulted previously for failing to be forthcoming with government officials and consumers about the circumstances surrounding recent recalls of Tylenol, Motrin and other products.

At the time of last week's recall, both McNeil and F.D.A. spokesmen declined to provide specific information about the producer of the Rolaids.

"The product was manufactured for McNeil Consumer Healthcare division of McNeil-PPC by a third-party manufacturer," Mr. Boston wrote in an e-mail on Dec. 9. "We're not providing further details."

Christopher Kelly, an F.D.A. spokesman, said last week that "the identity of a subcontractor is considered confidential, commercial information, and is not releasable by F.D.A. pursuant to federal law. McNeil is responsible for the quality of its products even if they contract out the manufacturing."

In the letter, Mr. Issa asked Dr. Hamburg for more information about the recall, including any inspection reports or warning letters the agency may have issued to Best Sweet. A search of the F.D.A.'s Web site showed no agency warning letters to Best Sweet.

"Does the Rolaids recall raise concerns for the F.D.A. about the safety of other products manufactured by Best Sweet?" Mr. Issa asked in the letter.

He asked for a reply by Jan. 5.

Document NYTF000020101218e6ci00011

The New York Times

B

NORTH CAROLINA PLANT MADE ROLAIDS RECALLED BY J.&J.

By NATASHA SINGER
51 words
18 December 2010
The New York Times Abstracts
NYTA
3
English

Best Sweet, maker of candy and chewy over-the-counter drug products in North Carolina, made millions of Rolaids soft chews that were involved in Dec 9 recall by Johnson & Johnson unit McNeil Consumer Healthcare (M)

Document NYTA000020110629e6ci0001h

The New York Times

Business/Financial Desk; SECTB

J.&J. Unit Issues Recall Of Rolaids

By NATASHA SINGER

828 words
10 December 2010
The New York Times
NYTF
Late Edition - Final
1
English

A unit of Johnson & Johnson announced a nationwide recall on Thursday of all lots -- more than 13 million packages -- of the soft chewable versions of Rolaids, its popular antacid drug, after reports of consumers finding metal and wood particles in the products.

The unit, McNeil Consumer Healthcare, has been troubled by manufacturing deficiencies over the last year, which has led to a series of recalls of some of the country's most popular over-the-counter brands. A recall in April alone involved about 136 million bottles of liquid children's Tylenol and other pediatric products.

Although McNeil said early this year that it was instituting a comprehensive plan to improve its manufacturing and quality control systems -- including the temporary closure of a plant in Pennsylvania for an upgrade -- some manufacturing problems have continued.

The foreign particles found in the Rolaids were potentially introduced during production at a third-party manufacturer, McNeil said in a statement. McNeil declined to identify the manufacturer.

The recall involves all lots of Rolaids Extra Strength Softchews, all lots of Rolaids Extra Strength Plus Gas Softchews and Rolaids Multi-Symptom Plus Anti-Gas Softchews sold in the United States. While the risk of health problems is remote, McNeil said consumers should stop using the Rolaids involved.

Also on Thursday, Wells Fargo downgraded shares of Johnson & Johnson to market perform, citing risks associated with McNeil's problems.

Last month, for example, the Food and Drug Administration posted a report on its Web site citing a McNeil plant in Puerto Rico that was inspected this fall for manufacturing problems. The report cited the facility for, among other issues, distributing products that failed quality requirements, failing to identify product defects during routine testing, failing to adequately investigate product problems and inadequate training of laboratory staff.

In an interview last month, Karen Riley, an F.D.A. spokeswoman, said the report indicated that McNeil "continues to have serious quality control issues at its plant and that it is not in compliance with current good manufacturing practices required by federal law."

Earlier this year, the agency said its office of criminal investigations had opened an inquiry into the company's conduct surrounding the recent recalls.

Separately, the House Committee on Oversight and Government Reform has held two hearings in which legislators questioned company executives and F.D.A. officials about their conduct in the recalls.

The Rolaids recall "reinforces the committee's ongoing investigation surrounding the safety protocols in place at J.& J.'s facilities and how the F.D.A. is managing food and drug safety," Kurt Bardella, a spokesman for the committee chairman-designate, Representative Darrell Issa, Republican of California, said. "The committee is in the process of and will continue to seek answers from J.& J. and the F.D.A."

Johnson & Johnson executives estimated earlier that the recalls and closure of the Pennsylvania plant would reduce sales by about $600 million this year.

In a note to investors on Thursday, Larry Biegelsen, an analyst at Wells Fargo, estimated that there was a 25 to 50 percent chance that McNeil would close the plant in Puerto Rico because of the latest F.D.A. report.

"We believe there is risk to JNJ's McNeil" over-the-counter business in 2011, he wrote, "and see few potential offsets and prefer to stay on the sidelines until there is some clarity."

In September, Johnson & Johnson said that the executive in charge of the consumer business, including McNeil, would retire in March, a move analysts interpreted to mean that she was taking the blame for the problems.

In the latest recall, McNeil said it had suspended production of the Rolaids products and would not restart production until it had taken corrective actions.

Consumers who bought the products may call 1-888-222-6036 or go to www.rolaids.com for instructions about a refund, McNeil said.

Since the problems with Tylenol and other children's liquid medicines this spring, the company has heightened its vigilance in recalling products that may not meet manufacturing standards.

Last month, for example, after a review identified manufacturing problems, McNeil recalled nine million bottles of liquid Tylenol Cold Multi-Symptom to update labels, 71,000 packages of soft chewable Rolaids because of an unusual texture caused by crystallized sugar, four million packages of Benadryl and 850,000 bottles of Motrin.

Unlike Thursday's consumer recall, the November recalls were at the wholesale and retail levels. That meant stores stopped selling the products, but people could continue to use them, McNeil said.

Other Johnson & Johnson units have experienced problems this year. In August, for example, the DePuy Orthopaedics unit recalled two kinds of hip implants because many patients required a second replacement after the implants failed.

PHOTO: The Rolaids recall came after reports of metal and wood particles in the products. (B6)

Document NYTF000020101210e6ca0003e

The New York Times

B

J.&J. UNIT ISSUES RECALL OF ROLAIDS

By NATASHA SINGER
85 words
10 December 2010
The New York Times Abstracts
NYTA
1
English

Johnson & Johnson's McNeil Consumer Healthcare unit issues nationwide recall of more than 13 million packages of soft chewable versions of its popular Rolaids antacid drug, citing reports of consumers finding metal and wood particles in the products; recall is latest trouble for unit plagued by manufacturing deficiencies over last year, which has led to series of recalls of some of country's most popular over-the-counter brands; photo (M)

Photograph

Document NYTA000020101211e6ca0000r

The New York Times

Business/Financial Desk; SECTB

Drug Maker Cited On Quality Issues

By NATASHA SINGER
860 words
27 November 2010
The New York Times
NYTF
Late Edition - Final
1
English

Months after McNeil Consumer Healthcare, a unit of Johnson & Johnson, recalled millions of bottles of Tylenol and other over-the-counter drugs, the division is still plagued with manufacturing flaws, according to the Food and Drug Administration.

Agency officials who filed an inspection report, posted on the agency's Web site this month, about a McNeil plant in Puerto Rico cited a variety of problems: distribution of drugs that failed quality requirements, a failure to identify product defects during routine testing, failure to detect incorrect expiration dates on drug labels, failure to adequately investigate product problems, failure to follow laboratory controls and inadequate training of lab staff.

Last January, the agency sent a warning letter to Peter Luther, the president of McNeil, about significant manufacturing violations at the same plant. The new inspection report indicates that some problems have not been corrected, said Karen Riley, a spokeswoman for the F.D.A.

"Clearly, this inspection shows that the company continues to have serious quality control issues at its plant and that it is not in compliance with current good manufacturing practices required by federal law," Ms. Riley said Friday. The agency, she added, was not aware of any harm to consumers associated with the latest problems at that plant.

Bonnie Jacobs, a spokeswoman for McNeil, said on Friday that the company had responded in detail to the F.D.A.'s concerns.

The inspection report represents a setback for Johnson & Johnson as it tries to rebuild public trust in its drug brands after a series of recalls involving millions of products for more than a year. These included a recall in April of an estimated 136 million bottles of liquid children's Tylenol and other pediatric products, made at a plant in Fort Washington, Pa., and a recall in January of millions of bottles of Tylenol, Motrin and other products made at the Puerto Rico site.

A Congressional committee and the F.D.A. office of criminal investigations are separately investigating conduct surrounding McNeil's recalls.

In July, McNeil submitted a plan to the F.D.A. describing the steps the company planned to take to comply with manufacturing standards. McNeil temporarily closed the Pennsylvania plant this year for an overhaul and replaced some employees. In September, Colleen A. Goggins, a Johnson & Johnson executive in charge of the company's consumer product division, said she planned to retire next year, an announcement that some Wall Street analysts interpreted to mean she was taking the fall for McNeil's problems.

The company has also heightened its vigilance in recalling products that might not meet manufacturing standards. This month, for example, after a review identified manufacturing problems, McNeil recalled nine million bottles of liquid Tylenol Cold Multi-Symptom to update labels, 71,000 packages of Rolaids soft chews because of an unusual texture caused by crystallized sugar, four million packages of Benadryl and 850,000 bottles of Motrin, the company said.

These were wholesale and retail -- not consumer --recalls and were not undertaken because of potential health risks, the company said. People can continue to use the products, McNeil said.

But the latest F.D.A. report, a 10-page document covering inspections from late September through early November, noted some recurrent problems at the plant, including inadequate quality control and incomplete investigations of product deficiencies.

For example, the report said that laboratory staff members who tested product quality had made a number of errors and that the company had not yet improved their training.

The report concluded that there was no assurance at the Puerto Rico plant "that the current laboratory controls are adequate to assure that drug products conform to appropriate standards of identity, strength, quality and purity."

Officials also noted problems with equipment cleaning and drug mix-ups.

"The established procedures and controls for cleaning and maintenance may not be sufficient to prevent mix-ups and/or contamination during the manufacturing and packaging process as evidenced by the mix-up deviations and incidents involving manufacturing and packaging operations," the report said.

The F.D.A. warning letter issued in January about the same plant included similar concerns. On the same day as the warning, McNeil recalled millions of bottles of Tylenol, Benadryl, Motrin, Rolaids, Simply Sleep and St. Joseph aspirin because some consumers had earlier complained about moldy odors emanating from some bottles. The company later determined that a byproduct of a chemical used to treat wooden transport pallets had caused the odor.

In a statement, McNeil said that it had been working diligently since January to ensure that its manufacturing operations met F.D.A. standards.

"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," the statement said.

Over the last 10 months, the statement said, McNeil has taken a number of significant steps to improve its manufacturing.

PHOTO: Motrin Junior Strength tablets were among the products recalled this year by the McNeil division of Johnson & Johnson. (PHOTOGRAPH BY DANIEL ACKER/BLOOMBERG NEWS) (B2)

Document NYTF000020101127e6br00022

The New York Times

Health; Money & Policy; Prescriptions
House Panel Asks F.D.A. About Inspections in Puerto Rico; Prescriptions

By REED ABELSON and NATASHA SINGER
293 words
8 November 2010
NYT Blogs
NYTB
English

In a sign of what may be the new kind of post-election scrutiny of the Food and Drug Administration, leading members of the House Committee on Oversight and Government Reform sent a letter Monday to the agency asking whether understaffing at a district office led to oversight problems of drug manufacturing.

The letter, sent by Representative Edolphus Towns of New York, the committee's current Democratic chairman, and Representative Darrell Issa of California, the ranking Republican, questions the actions of F.D.A. employees in Puerto Rico regarding their supervision of problems with drugs made at plants owned by the McNeil Consumer Healthcare unit of Johnson & Johnson and by GlaxoSmithKline.

The congressmen want the agency to provide by Nov. 17 a list of all manufacturing sites overseen by the F.D.A.'s Puerto Rico office, a list of all inspections conducted by agency inspectors in Puerto Rico over the last 10 years, and related documents.

In addition, the congressmen asked for an update on a recall of Motrin made by the Johnson & Johnson unit in Puerto Rico and F.D.A. actions surrounding that move.

A spokeswoman for the F.D.A. said the agency plans to respond to the inquiry after it receives the letter.

The House committee previously held two hearings related to manufacturing problems at McNeil plants, involving recalls of children's Tylenol and other medicines.

* Glaxo Case May Not Be Over

* Tylenol Recalls Erode Johnson & Johnson Sales

* More Trouble With Tylenol

* Allergan Settles Botox Case With Plea Agreement

* Lawmakers Grill J&J and F.D.A. Officials

Document NYTB000020101108e6b8006vb

The New York Times

Business/Financial Desk; SECTB

Sales Decline, but Earnings Rise for Johnson & Johnson

By NATASHA SINGER
717 words
20 October 2010
The New York Times
NYTF
Late Edition - Final
2
English

A series of recalls of Tylenol and other popular brand-name medicines this year is largely to blame for a decline in third-quarter sales at Johnson & Johnson to $15 billion, a decrease of 0.7 percent, the company said on Tuesday.

Even so, Johnson & Johnson's earnings in the third quarter rose 2.2 percent to $3.4 billion, the company said, because of a lower tax rate and nonoperating income.

Johnson & Johnson reported earnings for the third quarter of $1.23 a share -- representing a 2.5 percent increase compared with the same quarter of last year -- beating consensus estimates of $1.15. In light of the third-quarter earnings, the company raised full-year 2010 earnings guidance to $4.70 to $4.80 a share, from $4.65 to $4.75.

Although worldwide consumer sales for Johnson & Johnson declined to $3.6 billion in the third quarter, a decrease of 10.6 percent compared to the same period last year, pharmaceutical sales grew to $5.5 billion, an increase of 4.7 percent compared with the previous year, the company said.

But some industry analysts described Johnson & Johnson's performance this quarter as weak, given the overall decline in sales.

"The low quality of the beat will likely be viewed negatively by investors," Catherine J. Arnold, an analyst at Credit Suisse, wrote in an note to investors on Tuesday, "although there may be some relief that consumer sales did not fall even further than they did given the issues that J.& J. is dealing with in that business."

McNeil Consumer Healthcare, a unit of Johnson & Johnson, has been troubled over the last year by a series of recalls of popular products, including infants' and children's liquid Tylenol, Motrin, Zyrtec and Benadryl as well as different kinds of Tylenol and other products for adults.

As a result, the company's consumer division posted sales in the United States of about $1.3 billion in the third quarter of this year, down from about $1.7 billion in the same quarter of 2009. Within that consumer division, sales of over-the-counter drugs and nutritional products in the United States plummeted to $438 million in the third quarter from $732 million in the same time period last year, a decrease of about 40 percent, the company said.

Although Johnson & Johnson's chief executive, William C. Weldon, has been making a public effort of late to rebuild consumers' confidence in the company's over-the-counter drugs, some analysts said the string of problems at McNeil may do long-term damage to the brand's image. The office of criminal investigation of the Food and Drug Administration and, separately, the House Committee on Oversight and Government Reform, have been investigating the company's conduct surrounding the recalls.

The company's weak sales of consumer products in the United States "could potentially signal some systemic damage to J.& J.'s brand name in light of the recent McNeil recalls and negative publicity," Rick Wise, an analyst with Leerink Swann, wrote in a note Tuesday to investors. Even so, he is rating Johnson & Johnson's stock as outperform.

McNeil has temporarily closed its plant in Fort Washington, Pa., for an upgrade and is putting in place a companywide plan to strengthen manufacturing and quality control, company executives said earlier this year. But the shutdown has led to a dearth of popular products in many drugstores.

McNeil expects to return to full production by the middle of next year, at first by making the products at other company plants, Dominic J. Caruso, the chief financial officer of Johnson & Johnson, said in a conference call with investors on Tuesday morning. The Fort Washington plant should be operational by the end of next year, he said.

In the meantime, Perrigo, a generic maker of drugstore-branded over-the-counter drugs, has increased its market share. Even when Tylenol and other McNeil products fully return to the market, Perrigo should be able to maintain about half of its gain in market share, Christopher Schott, an analyst at J.P. Morgan, wrote to investors on Tuesday.

Document NYTF000020101020e6ak0002n

The New York Times

PRESCRIPTIONS
Business/Financial Desk; SECTB
McNeil Recalls Tylenol Caplets

By NATASHA SINGER
479 words
19 October 2010
The New York Times
NYTF
Late Edition - Final
6
English

The troubled McNeil Consumer Healthcare unit of Johnson & Johnson said on Monday evening that it was voluntarily recalling nearly 128,000 bottles of Tylenol eight-hour caplets.

McNeil said it had taken the action after some consumers complained of a musty or moldy odor in the products which are sold in the United States and Puerto Rico. In a statement, the company said that even though the risk of problems is remote, people should stop using the Tylenol caplets involved in the recall.

The announcement is the latest in a series of recalls - involving more than 150 million units of Tylenol, Motrin, Benadryl and Zyrtec for adults, infants and children - by McNeil over the last year. The products were made at McNeil plants in Puerto Rico and Fort Washington, Pa. The company has temporarily closed the Fort Washington plant for an upgrade.

The latest recall by McNeil comes the night before Johnson & Johnson is scheduled to present its third quarter earnings results. Company executives estimated, in a previous earnings conference call with investors in July, that the recalls and plant closure would reduce sales by about $600 million this year.

The news of the recall coincides with a public relations effort by the company's chief executive, William C. Weldon, over the past few months to reassure investors and regain the trust of consumers in the products.

The House Committee on Oversight and Government Reform and, separately, the office of criminal investigation of the Food and Drug Administration, have been investigating the company's conduct surrounding the recalls.

The current recall is not the first time that McNeil has withdrawn medicines from store shelves after consumers complained about a moldy or mildewy smell emanating from the products.

McNeil recalled products in January, June and July of this year, made at its Puerto Rico plant, because of such complaints. The company said at the time that chemical contamination, caused by a substance used to treat wooden transport pallets that had leached into the products, was to blame for the odor.

A few consumers complained of stomach problems like nausea, stomach pain and vomiting, the company said, but the problems were temporary and non-serious.

The current recall involves 50-count bottles of Tylenol eight-hour caplets made at the Fort Washington plant in March, before the facility was closed, Carol Goodrich, a company spokeswoman said. The company believes the uncharacteristic odor in these products was caused by trace amounts of the same chemical that was to blame for the product contamination at the Puerto Rico plant, she said.

Consumers seeking a refund or replacement coupon may call the company's recall line - 888-222-6036 - or visit www.tylenol.com

This is a more complete version of the story than the one that appeared in print.

Document NYTF000020101019e6aj0001y

The New York Times

B
MCNEIL RECALLS TYLENOL CAPLETS

31 words
19 October 2010
The New York Times Abstracts
NYTA
6
English

McNeil Consumer Healthcare unit of Johnson & Johnson recalls nearly 128,000 bottles of Tylenol, citing consumer complaints of musty or moldy odor from product (S)

Document NYTA000020110505e6aj00073

The New York Times

Business/Financial Desk; SECTB

Official Says J.&J. Plants Had Widespread Failings

By REED ABELSON
699 words
1 October 2010
The New York Times
NYTF
Late Edition - Final
4
English

A top official at the Food and Drug Administration told lawmakers on Thursday that quality control failures at the Johnson & Johnson unit involved in the recalls of popular medications like children's liquid Tylenol were not isolated to one plant, but were far more widespread.

At a Congressional hearing, Dr. Joshua M. Sharfstein, the agency's principal deputy commissioner, contradicted company executives' assertions that the kinds of lapses causing the recall were limited to a site in Fort Washington, Pa., that has since been shut down for an overhaul.

Dr. Sharfstein said the F.D.A. "has found inspectional deficiencies of varying degrees of seriousness at all of these facilities" under the umbrella of McNeil Consumer Healthcare, the unit of Johnson & Johnson that manufactures the popular products. "The company had an inadequate quality system, and you can see that in a number of facilities," he said.

At those sites, Dr. Sharfstein said, there was "the failure to investigate and correct product problems in a prompt and thorough manner." The company has responded by making several changes to its quality and manufacturing operations, he said, and the agency is evaluating those steps.

Johnson & Johnson has said that the company undertook a sweeping reorganization of its operations after the recalls and that it has invested more than $100 million in McNeil facilities.

Lawmakers on the House Committee on Oversight and Government Reform did not spare the F.D.A. in their criticisms of how the company and federal regulators handled the recalls of 136 million bottles of liquid infants' and children's medicines in April and a controversial recall of adult Motrin pills last year.

"That failure will mar Johnson & Johnson's image for many, many years," said Representative Darrell Issa of California, the ranking Republican on the committee, who also singled out the F.D.A. for what he called its "carelessness" and "deficiencies." He criticized the agency for not being clear about what it knew about the recalls, and about its role in causing delays in getting some of these products off the market and in recognizing the extent of the problems.

Thursday's hearing was the second one held on the recalls, and the stakes were particularly high for Johnson & Johnson and William C. Weldon, its chief executive.

Mr. Weldon, who did not appear at the first hearing because of back surgery, was quick to acknowledge to lawmakers that the company had made mistakes. "I know that we let the public down," he said. "We did not maintain our high-quality standards, and as a result, children do not have access to our important medicines."

He said consumers would start seeing the liquid children's products made by the company's McNeil Consumer Healthcare unit within a few weeks. (The recalls led to shortages of certain medications, frustrating many parents.)

In response to repeated questions by lawmakers about whether the executives responsible for the issues had been replaced, Mr. Weldon said personnel changes had been made. "The players we needed to replace we replaced," he said.

"I can only assure you that we will not let this happen again," Mr. Weldon said.

The hearing also focused on a second recall, the so-called phantom recall, which happened when the company tried to remove certain vials of Motrin from store shelves without alerting the public. "McNeil should have handled this differently," Mr. Weldon said, and he did not defend its decision to buy back the products without fully informing the agency. "We made a mistake," he said.

Dr. Sharfstein also said that the agency should have done more, but he insisted that it had not known that Johnson & Johnson was buying back or removing medicine from store shelves without alerting retailers about its reasons.

The person overseeing the agency's district office who had been involved in those discussions could not testify at the hearing because of a criminal investigation into the related events, he said.

PHOTO: William Weldon, the chief executive of Johnson & Johnson, testified in Congress on Thursday. (PHOTOGRAPH BY KEVIN WOLF/ASSOCIATED PRESS)

Document NYTF000020101001e6a10005p

The New York Times

Health; Money & Policy; Prescriptions
Lawmakers Grill J&J and F.D.A. Officials

By REED ABELSON
557 words
30 September 2010
NYT Blogs
NYTB
English

There was plenty of blame to go around during the Congressional hearing held Thursday over the recall of popular liquid children's medicines made by Johnson & Johnson. Lawmakers faulted executives at Johnson & Johnson and regulators at the Food and Drug Administration for their handling of the recall, as well as a separate controversial recall of adult Motrin pills.

The hearing was the second to focus on the sweeping recall by McNeil Consumer Healthcare, a unit of Johnson & Johnson, in April of about 136 million bottles of liquid infants' and children's medicines, and the panel's members continued to raise serious concerns about the corporate and regulatory failings that may have caused the recall.

"That failure will mar Johnson & Johnson's image for many, many years," said Representative Darrell Issa of California, the ranking Republican on the House Committee on Oversight and Government Reform, which was responsible for holding Thursday's hearings.

But Representative Issa also singled out "carelessness" and "deficiencies" of the F.D.A. in relation to these incidents. He criticized the agency for not being clear about what it knew about the recalls, and about its own role in causing the delays in getting some of these products off the market as well as faulting it for not recognizing the extent of the problems.

The stakes were particularly high for Johnson & Johnson and William C. Weldon, the company's chief executive. Mr. Weldon, who did not appear at the first hearing because of back surgery, was quick to acknowledge to lawmakers that the company made mistakes. "I know that we let the public down," he said. "We did not maintain our high quality standards, and as a result, children do not have access to our important medicines."

"The company had an inadequate quality system, and you can see that in a number of facilities," Dr. Sharfstein told lawmakers.

Across the sites, Dr. Sharfstein said, there was "the failure to investigate and correct product problems in a prompt and thorough manner." The company has responded by making several changes to its quality and manufacturing operations, he said, and the agency is currently evaluating those steps.

In response to repeated questions by lawmakers about whether the executives responsible for the issues had been replaced, Mr. Weldon insisted that whatever changes the company needed to make had been made. "The players we needed to replace we replaced," he told the lawmakers. "I can only assure you that we will not let this happen again," Mr. Weldon said.

The hearing also focused on a second recall, the so-called "phantom" recall, which occurred when the company tried to remove certain vials of Motrin from store shelves without alerting the public. "McNeil should have handled this differently," said Mr. Weldon said. While he acknowledged the company had been in discussions with the F.D.A. about its actions, he did not defend its decision to buy back the products without fully informing the agency. "We made a mistake," he said.

* J&J Chief Acknowledges Errors in Recalls

* Amgen and Johnson & Johnson Recall Anemia Drugs

* Tylenol Plant Lays Off 300

* This Week's Health Industry News

* A Day of Reckoning for Insurers

Document NYTB000020100930e69u0073n

The New York Times

Business/Financial Desk; SECTB

After Recalls of Drugs, a Congressional Spotlight on J.& J.'s Chief

By NATASHA SINGER and REED ABELSON
1,382 words
29 September 2010
The New York Times
NYTF
Late Edition - Final
1
English

In recent weeks, the chief executive of Johnson & Johnson has gone on the offensive in a very public way, trying to assure customers and company employees that the recalls of popular over-the-counter drugs like children's liquid Tylenol did not reflect systemic problems across the corporation.

And on Thursday, the executive, William C. Weldon, is expected to appear at a Congressional hearing, for the first time providing his own account to lawmakers of the manufacturing problems that led to the recalls. Mr. Weldon has asserted that missteps at the company's McNeil Consumer Healthcare unit, which was responsible for the withdrawal of certain products from the marketplace, have been contained.

"From Johnson & Johnson's perspective, our response to this issue was the most responsible it could possibly be," Mr. Weldon said in a recent telephone interview. After months of silence, he has also appeared on CNBC and has toured the company's own sites to talk about McNeil. "We want to ensure nothing like this happens again," he said.

His testimony before Congress comes as the company confronts other highly publicized problems that have swirled around Mr. Weldon's stewardship and the once unassailable integrity of one of the world's most respected companies.

In recent months, the company has recalled tens of thousands of artificial hips as well as several million contact lenses, made by distinct units. The company is also the subject of numerous government inquiries and a spate of consumer lawsuits. In McNeil's case, the unit recalled about 136 million bottles of liquid infants' and children's medicines in April, and millions of bottles of Tylenol and other pills for adults earlier in the year.

"These problems are accumulating," said Les Funtleyder, who invests in health care stocks for Miller Tabak & Company in New York. "At some point, investors are going to start to question J.& J.'s management."

Representative Darrell Issa, the ranking Republican on the House Committee on Oversight and Government Reform, which is holding Thursday's hearing, said in a telephone interview that the company had failed to adequately oversee the McNeil unit and did not correct the manufacturing problems there quickly.

"Does Johnson & Johnson oversee its divisions properly, or do they have too much autonomy?" Mr. Issa asked. "Does the big name -- Johnson & Johnson -- mean quality, or do you have to judge each division separately?"

Both Democratic and Republican lawmakers plan to delve into communications between corporate executives and the Food and Drug Administration as recalls were considered or taking place, including attempts by the company to buy back certain vials of Motrin pills rather than formally recall them from the shelves.

Mr. Weldon said in the interview earlier this month that the company had acted quickly to recall the products, inform consumers and explain that the medicines posed no serious health hazard. While the company has temporarily shut the plant in Fort Washington, Pa., that manufactured the children's over-the-counter products for an overhaul, Mr. Weldon said the company planned to reintroduce certain products later this year.

"We have a standard and we hold all our companies to that standard," Mr. Weldon said, adding that he took full responsibility for McNeil's problems. Johnson & Johnson has also announced a series of moves meant to address the concerns over the quality of its products.

In addition to a systemic review of the manufacturing operations at all of its units, the company has overhauled and centralized its quality control operations. This month, it also said Colleen A. Goggins, the senior executive who was in charge of all of Johnson & Johnson's consumer businesses, would leave. Ms. Goggins also is expected to testify at Thursday's hearing, her second appearance before the committee on these issues.

To date, some people fault the company's response as inadequate.

"It's too little, too late," said Erik Gordon, a business professor at the University of Michigan. Mr. Weldon had an obligation to address the concerns about McNeil and the decentralized nature of the company earlier this year, he said. The company has long prided itself on, and derived strong yearly profit growth from, its decentralized management structure. By having a diverse array of companies, with more than 250 separate units, the company has managed to innovate and prosper despite its size.

"J.& J. has been a master of that," said Richard N. Foster, a former McKinsey partner who has written about Johnson & Johnson. "There are very few companies in J.& J.'s class."

Until the first quarter of 2009, for example, Johnson & Johnson had managed to increase its earnings, adjusted for special items, for 94 consecutive quarters.

The company has also been smart and aggressive about acquisitions, including a recent bid for Crucell, a leading vaccine company in which J.& J. already owns a stake, said Michael Weinstein, an analyst at J. P. Morgan. Even with the hip implant recall, the company's medical device franchises remain strong, he said, and its pharmaceutical group has promising products like an antistroke drug and an experimental drug for prostate cancer in development.

The same diversification also protects the company from such problems as the McNeil recall, which is expected to cost the company just 1 percent of revenue, or an estimated $600 million in sales this year.

"If you have 250 grains of sand and 240 are going up and 10 are not doing so well, it doesn't really affect you," Mr. Weldon said. "It's really the magic of decentralization that allows things to work at Johnson & Johnson."

But despite all the advantages of the company's management structure, some financial analysts question whether there is enough oversight.

"It's surprising, frankly, that this was allowed to happen and fester for so long," said Jami Rubin, an analyst at Goldman Sachs, of the McNeil quality issues.

F.D.A. inspection reports outline a history of manufacturing problems at two McNeil plants dating back to 2001 that include mix-ups of drugs, inadequate training, incomplete investigations of consumer product complaints, failure to determine the root cause of product problems and failure to correct problems. While other prominent drug makers have received similar inspection reports, Elaine Gansz Bobo, an F.D.A spokeswoman, said last week that McNeil had "a concerning number of violations." The agency's criminal division is currently investigating the McNeil recalls.

Johnson & Johnson said it had put into place a comprehensive plan to bring McNeil up to code, including the temporary closure and revamping of the Fort Washington, Pa., plant and the replacement of the plant's manager and its head of quality.

In addition, Mr. Weldon said, there have been corporate changes to Johnson & Johnson's oversight of its supply chain and manufacturing. Last month, he appointed a longtime company executive to oversee a new system of companywide quality control that involves a single framework for quality across all of the operating units and a new reporting system.

While the step may indicate greater centralization, it also reflects a new calculus about the value of investing in modernizing old facilities and in quality control.

"The return on investment equation has just changed dramatically," said Jim Prutow, a partner at PRTM, a management consulting firm that works with drug makers. "Look at the cost for a company if you get into F.D.A. issues -- the potential fines, the cost of remediation, the actual loss of product sales, all that consumer good will lost -- it's a huge amount."

PHOTOS: Pediatric drugs recalled by a unit of Johnson & Johnson. (PHOTOGRAPH BY TONY CENICOLA/THE NEW YORK TIMES) (B1); William Weldon is expected to discuss problems at J.& J.'s McNeil Consumer

Healthcare unit.; Colleen Goggins, who heads J.& J.'s consumer businesses, will testify for a second time. (PHOTOGRAPHS BY JAY MALLIN/BLOOMBERG NEWS) (B4)

CHART: A Series of Troubles at Johnson & Johnson: Johnson & Johnson has been plagued in recent years by multiple recalls and government investigations, which have affected each of the company's three divisions. (B4)

Document NYTF000020100929e69t0005b

The New York Times

Health; Money & Policy; Prescriptions
J&J Chief Acknowledges Errors in Recalls

By REED ABELSON
574 words
29 September 2010
NYT Blogs
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English

William C. Weldon, the chief executive of Johnson & Johnson, is expected to acknowledge to lawmakers on Capitol Hill on Thursday that the company mishandled the removal of certain medicines from store shelves last year. He also planned to announce that after a recall of children's liquid medicines, new batches would begin to reach stores as early as next week, according to a copy of his prepared testimony submitted to a House committee.

Mr. Weldon was to appear before the House Committee on Oversight and Government Reform, at a time when the congressional investigators and outside inquiries have highlighted some company problems. As Natasha Singer and I reported in a story on Wednesday, the stakes are high.

In his prepared testimony, Mr. Weldon, who missed the committee's first hearing on the recall because of back surgery, makes the case that he is committed to fixing whatever went wrong at the company's McNeil Consumer Healthcare unit, which was responsible for the withdrawal of certain products from the marketplace. "Mr. chairman, I know that we let the public down. We did not maintain our high quality standards, and as a result, children do not have access to our important medicines. I accept full accountability for the problems at McNeil, and I will take full accountability for fixing them," he said.

In the testimony, Mr. Weldon promises consumers will start seeing McNeil liquid children's products back on the shelves as soon as next week.

Mr. Weldon also offers a mea culpa of sorts about the so-called "phantom recall" of certain vials of Motrin pills, an action taken by an outside contractor that went to convenience stores and bought up the product. That has continued to bother some lawmakers, who first criticized the practice at a May hearing. "Based on what I have learned since the May hearing about the way the Motrin retrieval was handled, including the points that this committee brought to light, it is clear to me that in retrospect, McNeil should have handled things differently. And going forward, if similar situations arise, they will be handled differently," he says in his testimony.

Colleen A. Goggins, the senior Johnson & Johnson executive who was in charge of all the company's consumer businesses, will also be making a return performance. Ms. Goggins, who has since announced she is leaving the company, is expected to testify about, among other things, the phantom recall. She pleaded ignorance at the time. "At the time of the hearing in May, I had no personal knowledge of and had not seen the contractor or McNeil instructions. Since then, however, I have reviewed the McNeil instructions to the contractor that instructed the contractor to purchase the product without engaging in discussions with the store personnel. Based on what I have learned since May, I believe that McNeil should have handled things differently. We, as a company, have learned from this process," she says in a copy of her prepared testimony.

The Weldon statement. The Goggins prepared statement.

If you were sitting on the congressional panel, what questions would you ask the top executives after these recalls?

* Tylenol Plant Lays Off 300

* Amgen and Johnson & Johnson Recall Anemia Drugs

* A Day of Reckoning for Insurers

* The Race to Replace Warfarin

* Human Eggs for Sale and Other Tales

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The New York Times

B

AFTER RECALLS OF DRUGS, A CONGRESSIONAL SPOTLIGHT ON J.&J.'S CHIEF

131 words
29 September 2010
The New York Times Abstracts
NYTA
1
English

Johnson & Johnson chief executive William C Weldon is set to appear at Congressional hearing to provide testimony as to why recalls of popular over-the-counter drugs do not reflect systemic problems across company; will detail manufacturing problems that led to recalls, asserting that missteps at company's McNeil Consumer Healthcare unit have been contained; among most notable recalls, company has recalled tens of thousands of artificial hips as well as several million contact lens made by distinct units, 136 million bottles of children's medicines and other products; Weldon will work to allay concerns from investors and public about company's response amid numerous government inquiries and consumer lawsuits related to recalls; photos (M)

Photograph

Document NYTA000020100930e69t00009

The New York Times

Health; Money & Policy; Prescriptions
Amgen and Johnson & Johnson Recall Anemia Drugs

By ANDREW POLLACK
622 words
24 September 2010
NYT Blogs
NYTB
English

Amgen's anemia drugs have been embroiled in controversy about their safety for several years as evidence has mounted that their overuse can cause heart attacks or strokes or make cancer worse. Now comes yet another problem, though presumably a temporary one.

Amgen announced on Friday morning that it and Johnson & Johnson were recalling various lots of their anemia drugs, Epogen and Procrit, because extremely thin, barely visible glass flakes had been found in the vials.

Amgen said the particles could cause clots and other problems if the drugs were given by intravenous infusion, or lumps and immune system reactions if injected under the skin.

The company said it had received no complaints or had heard of no problems that could be "directly attributed to" the glass particles, however. A spokeswoman for Amgen, Emma Hurley, said the company's evaluation "found a low potential to impact patients."

Amgen said the recall was being done in coordination with the Food and Drug Administration.

Both drugs are the same substance, a protein called erythropoietin, or epoetin alfa, which is made by Amgen in Puerto Rico. Amgen sells the protein as Epogen for the treatment of anemia in kidney dialysis patients.Johnson & Johnson sells it as Procrit for other uses, like anemia caused by kidney disease that does not yet require dialysis and for anemia caused by cancer chemotherapy.

Ms. Hurley said Amgen did not anticipate that the problem would affect the availability of Epogen and would not have a material financial impact on Amgen. Johnson & Johnson also said supply of Procrit should not be affected.

Amgen discovered the flakes, Ms. Hurley said, during a recent inspection of vials of the drug. The flakes were formed by the interaction of the drug formulation with the glass vials over the shelf life of the product.

Amgen has now reduced the shelf life to either 12 or 15 months, depending on the type of vial, from 36 months.

No recent change in the formulation of the drug would explain the problem, she said. That raises the possibility that the problem has been occurring undetected for a some time. Epogen was first approved in 1989.

A third anemia drug, Amgen's Aranesp, is a slightly different protein and is made separately from the other two.

Interactions between a drug and a vial are not unknown and can be serious. Several years ago, dozens of patients in Europe who were treated with Johnson & Johnson's Eprex - basically the European version of Procrit - developed a serious condition called pure red cell aplasia, which left them dependent on blood transfusions. Johnson & Johnson eventually attributed the problem to a reaction between the drug formulation and the stoppers used in the vials.

The anemia drugs have all been huge sellers with sales of two billion dollars a year or more. But concerns have arisen in recent years that overuse of the drugs has contributed to problems like heart attacks and strokes and, in cancer patients, a worsening of the cancer.

Sales, particularly for use in treating cancer patients, have plummeted as the Food and Drug Administration has put extra warnings on the drugs' labels and as Medicare has become more restrictive in paying for the drugs.

The F.D.A. will hold another advisory committee meeting on Oct. 18 to review the latest findings of possible harm to patients with kidney disease from the drugs.

* F.D.A. Postpones Rule on Breast Cancer Drug

* F.D.A. Panel Rejects Diet Pill

* F.D.A. Approves New Drug for Gout

* This Week's Health Industry News

* Leukemia Drug Trial Fails

Document NYTB000020100924e69o004sf

The New York Times

Business/Financial Desk; SECTB

Chief of Unit With Recalls To Exit J.&J.

By NATASHA SINGER and REED ABELSON
736 words
17 September 2010
The New York Times
NYTF
Late Edition - Final
1
English

A longtime senior executive at Johnson & Johnson in charge of the consumer products division is leaving the company early next year, signaling a shake-up after a troubling series of recalls, including of children's Tylenol, tarnished the company's reputation in the last year.

The company said Thursday that the executive, Colleen A. Goggins, who testified this spring before a Congressional committee investigating the recalls, would retire in March. Ms. Goggins, 56, has worked at Johnson & Johnson since 1981 and was a member of the company's senior leadership.

Her departure shuffles the lineup of successors to William C. Weldon, who has served as the company's chairman and chief executive since 2002.

In an interview before the announcement on Thursday, Mr. Weldon said the company had a strong history of choosing an internal candidate to lead it.

Ms. Goggins has been overseeing one of the company's three major divisions. Her portfolio includes the company's most famous family brands: Johnson's baby shampoo and Band-Aids. She is responsible not only for McNeil Consumer Healthcare, the unit that recalled Tylenol, Motrin, Benadryl and Zyrtec earlier this year, but also popular and lucrative products like Listerine, Rembrandt, Neutrogena, Aveeno, Rogaine, Visine and the sweetener Splenda.

In the earlier interview on Thursday morning, Mr. Weldon gave no clue that Ms. Goggins would be retiring. But he said the company had taken steps to address the problems at McNeil and to ensure quality control companywide.

"What we want to instill in people is that quality is the most important thing at Johnson & Johnson," Mr. Weldon said. "We have to ensure that this never happens again."

Despite the company's recent woes, investors say they still have confidence in Mr. Weldon's stewardship.

Ms. Goggins could not be reached for comment.

News of the retirement of Ms. Goggins came on the same day that the House committee looking into the recall of about 136 million bottles of liquid children's Tylenol and other products made by McNeil, scheduled another hearing, on Sept. 30, about the company's problems. The chairman of the House Committee on Oversight and Government Reform, Representative Edolphus Towns, Democrat of New York, said that he had called a second hearing because of lingering questions related to the company's conduct in the Tylenol recall and another involving Motrin.

Mr. Weldon, who did not testify at the first hearing because he was recovering from back surgery, said he would appear for the next round. "I will definitely testify," Mr. Weldon said. "I wanted to testify at the last one."

After the first hearing, Mr. Weldon met with Mr. Towns and the ranking Republican member of the committee, Representative Darrell Issa of California, he said. "I told them that I accepted full accountability and responsibility for what had happened and that I was committed to remedying the situation," Mr. Weldon said.

The children's Tylenol recall led to a shortage of such medicines on the market, frustrating many parents, and prompted Johnson & Johnson to close a McNeil plant in Pennsylvania this summer, laying off its employees, to upgrade the site.

During the first Congressional hearing, committee members questioned Ms. Goggins, the worldwide chairwoman of Johnson & Johnson's consumer group, about the company's actions in what Mr. Towns termed a "phantom recall."

In that instance, the company hired outside contractors to buy certain kinds of Motrin from several thousand convenience stores -- without instituting a formal recall in conjunction with the Food and Drug Administration. The F.D.A. later insisted that the company conduct a formal recall, an agency official testified during the hearing.

During the hearing, Ms. Goggins acknowledged the problems at McNeil but defended the company's integrity.

"There was never any intent to deceive or hide anything," Ms. Goggins said.

According to the company's proxy filing, Ms. Goggins received compensation of $8.3 million in fiscal year 2009. A separate regulatory filing indicated that she sold nearly $3 million in company stock a week ago.

In a statement, Mr. Weldon praised Ms. Goggins and said she had helped put a plan in place for remedying the issues at McNeil. The company said it would make an announcement soon about a successor.

PHOTO: Colleen A. Goggins (B4)

Document NYTF000020100917e69h0005g

The New York Times

B

CHIEF OF UNIT WITH RECALLS TO EXIT J.&J.

By NATASHA SINGER and REED ABELSON

73 words
17 September 2010
The New York Times Abstracts
NYTA
1
English

Longtime Johnson & Johnson senior executive Colleen A Goggins resigns following troubling series of recalls that have tarnished company's reputation in past year; departure signals larger shake-up as drug maker works to undo damage done by recalls and subsequent investigation; Johnson & Johnson is expected to make announcement soon regarding successor; photo (M)

Photograph

Document NYTA000020100918e69h0000m

The New York Times

Business/Financial Desk; SECTB

Hip Implants Are Recalled By J.&J. Unit

By NATASHA SINGER
1,180 words
27 August 2010
The New York Times
NYTF
Late Edition - Final
1
English

More than two years after the Food and Drug Administration began receiving complaints about the failure of a hip replacement implant made by the DePuy Orthopaedics unit of Johnson &Johnson, the company said Thursday that it was recalling two kinds of hip implants.

DePuy said that it had made the decision to withdraw the products because many patients required a second hip replacement after the company's implants had failed.

The news compounded problems for Johnson &Johnson, which has recalled a succession of some of its best-selling and best-known products, including liquid children's Tylenol in the United States and, just this week, Acuvue contact lenses in Japan and other countries in Asia and Europe. The Tylenol recall led to the temporary closing of a plant owned by the McNeil Consumer Health Care unit, which is the subject of a federal inquiry over its handling of recent recalls of over-the-counter products.

In addition to DePuy's recall, the F.D.A. this week criticized the company in a warning letter, contending that it had illegally marketed an unapproved knee device and had also sold a hip implant for an unapproved use. (A spokeswoman for DePuy said that the company was examining the F.D.A.'s concerns.)

"All this makes it seem like it's pile-on time for J.&J.," said William Trombetta, a professor of pharmaceutical marketing at Saint Joseph's University in Philadelphia. "This is a company that was purer than Caesar's wife, this was the gold standard, and all of a sudden it just seems like things are breaking down."

In the latest Johnson &Johnson case, DePuy said in a statement that it was recalling two products: the ASR XL Acetabular System, a hip socket used in traditional hip replacement, and the ASR Hip Resurfacing System, a partial hip replacement that involves placing a metal cap on the ball of the femur, a method intended to preserve more bone. The traditional implant has been available worldwide, and the resurfacing implant was approved for use in countries outside the United States.

About 93,000 of these devices have been implanted worldwide, said Lorie Gawreluk, a DePuy spokeswoman. The New York Times reported in March that for more than two years, the F.D.A. had been receiving complaints that the devices failed early in some patients, requiring expensive and painful operations to put in new hip replacements. Since the start of 2008, the F.D.A. has received about 400 complaints involving patients in the United States who received the devices, an agency spokeswoman said Thursday.

DePuy said that the majority of hip replacements using the ASR devices had been successful. But the company advised patients who had had hip replacements with the recalled products to visit their surgeons for an evaluation and annual monitoring. The company said it would pay reasonable and customary medical costs associated with the recalled products, including new hip replacement operations.

DePuy had sales last year of about $5.4 billion, according to a Johnson &Johnson earnings report.

The high early failure rate of the ASR implants was reported this year in severalarticles in The New York Times. These devices have come under scrutiny over the last few years because they are part of a category of implants called metal-on-metal bearings, which can generate debris from wear, causing inflammation and tissue damage in certain patients.

In March, the British agency that regulates medical devices issued an advisory on metal debris generated by hip implants. A spokeswoman for the F.D.A. said the agency was planning to meet soon with professional medical groups to discuss the British advisory.

Late last year, DePuy said it was phasing out the implants because of slowing sales. In March, the company warned doctors that the implants might have a high failure rate in some patients.

In one New York Times article, some orthopedic experts expressed dismay that DePuy had not halted sales of the devices earlier. About 12 to 13 percent of patients needed a second hip replacement within five years of receiving an ASR implant, the statement from DePuy said, citing new unpublished data from a national registry in Britain. Previously reported follow-up data, including internal company information and clinical trials, had reported lower rates of second hip replacement comparable to similar devices by other companies, the statement said.

But many medical centers in the United States that specialize in joint replacement surgery had already noticed a higher failure rate with the DePuy hip implants, said Dr. Joshua J. Jacobs, the chairman of orthopedic surgery at Rush University Medical Center in Chicago.

"Most major medical centers have seen issues with this device," Dr. Jacobs said. "This does not come as a surprise."

Dr. Jacobs added that the DePuy recall pointed to the importance of having a national registry for joint implants that can serve as an early warning system for product problems. Britain, Australia and some other countries have such national registries, he said, but the reporting system currently used by the F.D.A. does not necessarily capture every device failure.

David Floyd, president of DePuy, said in a statement that the recall would be a concern for patients and their family members and for surgeons.

"We are committed to assisting patients and health care providers by providing information through multiple channels and paying for the costs of doctor visits, tests and procedures associated with the recall," he said.

Johnson &Johnson comprises more than 250 different operating companies in 60 countries. But the recent recalls and F.D.A. warning letters to several units at Johnson &Johnson raise questions about whether there may be companywide problems, industry analysts said.

"No. 1, is there a systemic issue at J.&J.?" said Rick Wise, an analyst at Leerink Swann, a health care investment bank. "No. 2, is this" hip implant recall "reflective of that systemic issue? And, No. 3, is there more to come?"

Mr. Wise added that F.D.A. warnings and J.&J. recalls had come at a time of increased vigilance about product safety by the agency and health care companies. He said that he believed the various problems at J&J were separate and not part of a systemic issue.

Dr. Trombetta, the pharmaceutical marketing professor, compared Johnson &Johnson to Toyota, another multinational firm whose reputation has suffered this year during a series of recalls. The recalls may be tarnishing Johnson &Johnson's apple-pie image, Dr. Trombetta said, but he predicted that the company would eventually recover public trust as Toyota largely had.

Shares of Johnson &Johnson closed at $57.80 on Thursday, down 18 cents.

PHOTOS: Dr. Joshua J. Jacobs said medical centers had already noticed a high failure rate for the DePuy Orthopaedics hips that were recalled Thursday. (PHOTOGRAPHS BY JOSHUA BOROUGH FOR THE NEW YORK TIMES; RUSH UNIVERSITY MEDICAL CENTER) (B5)

Document NYTF000020100827e68r00014

The New York Times

B

JOHNSON & JOHNSON UNIT RECALLS MILLIONS OF CONTACT LENSES IN ASIA AND EUROPE

By NATASHA SINGER
48 words
24 August 2010
The New York Times Abstracts
NYTA
4
English

Eye care unit of Johnson & Johnson recalls several million disposable soft contact lenses sold primarily in Japan, but also five other Asian countries and 19 European countries; photo (M)

Photograph

Document NYTA000020110324e68o0003r

The New York Times

Business/Financial Desk; SECTB

Johnson &Johnson Unit Recalls Millions of Contact Lenses in Asia and Europe

By NATASHA SINGER
612 words
24 August 2010
The New York Times
NYTF
Late Edition - Final
4
English

The eye care unit of Johnson &Johnson said on Monday that it was recalling several million disposable soft contact lenses sold primarily in Japan, but also in five other countries in Asia and 19 counties in Europe.

The recall of 1-Day Acuvue TruEye does not include soft disposable lenses sold in the United States or other countries under the same brand name, the company said.

Johnson &Johnson Vision Care made the recall in some countries in Asia and Europe after some consumers in Japan complained that they developed unusual stinging or pain after inserting certain lots of 1-Day Acuvue TruEye lenses, the company said Monday in a statement. A company investigation identified an isolated issue in one part of the lens rinsing process on a particular manufacturing line, the statement said.

The action takes place amid a Food and Drug Administration investigation of another Johnson &Johnson unit, McNeil Consumer Healthcare, for its conduct during several recent recalls of millions of bottles of over-the-counter drugs like Tylenol, Motrin, Zyrtec and Benadryl. McNeil is also the subject of a Congressional investigation into the recalls by the House Committee on Oversight and Government Reform.

Last year, for example, McNeil announced recalls of certain children's Tylenol products in September, a limited recall of certain adult Tylenol caplets for arthritis in November and an expanded Tylenol arthritis recall in December.

This year, McNeil has recalled at least 150 million bottles for adults and children -- in January, March, April, June and July.

McNeil has temporarily closed a company plant in Fort Washington, Pa., which made liquid children's and infants' medicines involved in a recall in April, while it upgrades equipment and reorganizes quality control there.

In an interview last week with The Wall Street Journal, William C. Weldon, the chief executive of Johnson &Johnson, described the McNeil unit as an "outlier" in the company and said the quality control problems that led to the recalls were localized to that unit. But the new contact lens recall at a separate eye care division broadens the scope of the company's problems.

Bill Price, a spokesman for Johnson &Johnson, said that the McNeil and Vision Care recalls were unrelated. A spokesman for the vision care unit said the contact lens recall was relatively small.

The vision care unit recalled about 100,000 boxes of the product containing 30 to 90 lenses each, said Gary Esterow, a company spokesman. That represents less than 1 percent of all the lenses made by the unit, he said. J.&J. Vision Care had worldwide sales of about $2.5 billion last year, according to a company earnings statement.

The recall involves one-day disposable lenses sold mainly in Japan, as well as in Australia, Austria, Belgium, Britain, Denmark, Finland, France, Germany, Greece, Hong Kong, Ireland, Italy, Liechtenstein, Luxembourg, Malaysia, Norway, Portugal, Russia, Singapore, South Korea, Spain, Sweden, Switzerland and Turkey, he said.

The 1-Day Acuvue TruEye lenses involved in the recall are made with a pliable silicon hydrogel material called narafilcon A, Mr. Esterow said.

This year, Johnson &Johnson introduced a similar Acuvue product in the United States under the same brand name. But the product sold here is made with a different material, narafilcon B, he said, and is not affected by the recall.

PHOTO: Disposable contact lenses sold primarily in Japan are being recalled. The action comes amid various inquiries into how another unit of the company handled other recalls. (PHOTOGRAPH BY JOHNSON &JOHNSON, VIA ASSOCIATED PRESS)

Document NYTF000020100824e68o00025

The New York Times

Business/Financial Desk; SECTB

J.&J. Moves To Ensure Drug Safety

By NATASHA SINGER
405 words
19 August 2010
The New York Times
NYTF
Late Edition - Final
3
English

Beset by a series of recalls of Tylenol and other popular over-the-counter drugs, Johnson &Johnson said Wednesday that it planned to revamp its quality controls, creating a single framework for its drug, medical device and consumer health care divisions.

Ajit Shetty, the corporate vice president responsible for supply chain operations, will oversee the new system, reporting directly to William C. Weldon, Johnson &Johnson's chief executive. The company said it also planned to appoint chief quality officers for each of its three major divisions.

Mr. Weldon first gave details of the plan in an interview Wednesday with The Wall Street Journal.

The quality control reorganization comes after a number of recent recalls of Tylenol, Motrin and other products by McNeil Consumer Healthcare, a unit of Johnson &Johnson. The recalls have led to the temporary shutting of one manufacturing plant.

McNeil's conduct surrounding the recalls is the subject of inquiry by both the House Committee on Oversight and Investigations and by the Food and Drug Administration's office of criminal investigations. In the last two years, F.D.A. inspectors have found significant violations of manufacturing standards at two McNeil plants, according to the agency's Web site.

In January, McNeil recalled millions of bottles of adult Tylenol, Motrin and other products made at a company plant in Puerto Rico after consumers complained about a moldy or musty odor in the products. The company said a byproduct of a chemical used to treat wooden transport pallets had leached into the products, causing the moldy smell.

In April, McNeil recalled an estimated 136 million bottles of liquid children's Tylenol and other products made at a company plant in Fort Washington, Pa. The company recalled the products because they might have contained too much of the active drug ingredient or foreign particles, the F.D.A. said.

In July, McNeil said it was starting a program to improve manufacturing and quality and it has temporarily closed the Fort Washington plant.

The recalls and plant shutdown cut Johnson &Johnson's sales by $200 million and its earnings by 5 cents a share in the second quarter, Dominic J. Caruso, the company's chief financial officer said during a recent conference call. He estimated that annual sales would decline by $600 million because of the plant closing.

Document NYTF000020100819e68j0003s

The New York Times

Business/Financial Desk; SECTB

Pill Maker Declines to Specify Size of a Recall

By NATASHA SINGER
547 words
9 July 2010
The New York Times
NYTF
Late Edition - Final
2
English

When Procter &Gamble announced a recent recall of some Scope mouthwash with defective child-resistant caps, it disclosed the extent of the recall -- 35,000 bottles -- in a government news release.

But a unit of Johnson &Johnson that announced an expanded recall of Tylenol and other over-the-counter drugs on Thursday declined to say how many bottles of pills were involved.

"We have never given that out for any of the recalls," Bonnie Jacobs, a spokeswoman for McNeil Consumer Healthcare, the Johnson &Johnson unit, said on Thursday.

The expanded McNeil recall announced Thursday involves 21 lots of certain kinds of Tylenol, Motrin and Benadryl made at McNeil's plant in Puerto Rico. The number of bottles in a product lot can vary widely.

The company has instituted a series of recalls since last year.

The lack of specific figures released by McNeil contrasts sharply with the typical availability of public information related to other consumer product recalls. The Consumer Product Safety Commission, which oversees recalls of products like defective cribs and window blinds, negotiates with companies to make sure that they detail the number of recalled products in releases to the public, said Scott Wolfson, the director of public affairs at the commission.

Providing recall statistics is important, he said, because consumers often take action depending on the size of a recall. A larger recall that garners wide news coverage, he said, often prompts people to scour their homes for defective or unsafe products so they can throw them out or return them for a refund.

"We feel it is critically important for recalling companies to include the number of affected units so it gives the consumer a sense of scope, of importance," Mr. Wolfson said.

A spokeswoman for the Food and Drug Administration, which oversees recalls of medicines, said the agency made public the information it had on the volume of a recall. But often the agency does not "have the exact number at the time of the release and sometimes it takes a while to get the actual number from the company," Elaine Bobo, an agency spokeswoman, wrote in an e-mail message on Thursday.

Since last year, McNeil has recalled millions of bottles of Tylenol arthritis caplets,Motrin and other products made at a plant in Puerto Rico, according to information posted on the Web site of the F.D.A. The products may be contaminated with a byproduct of a chemical used to treat wooden transport pallets, causing a moldy odor in the bottles.

Earlier this year, McNeil recalled an estimated 136 million bottles of children's liquid Tylenol and other pediatric products because they might have contained a higher-than-labeled dose of the active drug ingredient, metal particles or inactive ingredients that failed quality tests, the agency said.

The F.D.A. made the volume of the children's product recall public during a Congressional hearing in May.

McNeil has a Web site, mcneilproductrecall.com, with information about the recall and how to obtain a refund.

PHOTO: McNeil Consumer Healthcare, a unit of Johnson &Johnson, has expanded a recall of Tylenol, Motrin and Benadryl. (PHOTOGRAPH BY PAUL SAKUMA/ASSOCIATED PRESS)

Document NYTF000020100709e6790002b

The New York Times

B

PILL MAKER DECLINES TO SPECIFY SIZE OF A RECALL

By NATASHA SINGER
41 words
9 July 2010
The New York Times Abstracts
NYTA
2
English

Johnson & Johnson unit McNeil Consumer Healthcare announces expanded recall of Tylenol, Motrin and Benadryl; declines to say how many bottles of pills are involved; photo (M)

Photograph

Document NYTA000020110204e6790003t

The New York Times

Business/Financial Desk; SECTB

J.&J. Unit Under Scrutiny Recalls Additional Over-the-Counter Drugs

By NATASHA SINGER

327 words
16 June 2010
The New York Times
NYTF
Late Edition - Final
3
English

The Johnson &Johnson unit whose recall of liquid children's Tylenol and other pediatric medicines is under Congressional investigation said on Tuesday evening that it was recalling additional over-the-counter drugs.

McNeil Consumer Healthcare, the Johnson &Johnson unit, said that it was recalling four lots of certain Benadryl allergy tablets and one lot of Extra Strength Tylenol gel pills. McNeil did not respond to a reporter's query about how many bottles those lots amounted to.

The company said in a statement that "the products were inadvertently omitted" from an earlier recall -- one preceding the children's drug recall -- involving medicines made at a company plant in Puerto Rico.

Since last November, McNeil has recalled about 11.7 million bottles of various Motrin products and about 6.3 million bottles of Tylenol Arthritis Pain caplets made at that Puerto Rico plant, according to the F.D.A.'s Web site. The company began the recall after receiving consumer complaints about a moldy odor emanating from some products.

The smell was caused by contamination from a chemical byproduct of a substance used to treat wooden transport pallets, the company said. Although risk of serious medical problems was remote, the company said, people should stop using the products.

Refund requests can be made using a company Web site, mcneilproductrecall.com, or toll-free number: 888-222-6036.

McNeil is already under scrutiny by the House Committee on Oversight and Government Reform over a recall in April of an estimated 136 million bottles of liquid pediatric Tylenol, Motrin, Benadryl and Zyrtec.

"Today's announcement is indication that we have more to look at when it comes to this company," Representative Edolphus Towns, a New York Democrat who is the chairman of the committee, wrote on Tuesday in an e-mail message in response to a reporter's query.

Document NYTF000020100616e66g0004d

The New York Times

B

J.&J. UNIT UNDER SCRUTINY RECALLS ADDITIONAL OVER-THE-COUNTER DRUGS

By NATASHA SINGER
50 words
16 June 2010
The New York Times Abstracts
NYTA
3
English

McNeil Consumer Healthcare, Johnson & Johnson unit whose recall of liquid children's Tylenol and other pediatric medicines is under Congressional investigation, says it is recalling additional over-the-counter drugs, including Benadryl (M)

Document NYTA000020110120e66g00018

The New York Times

B

MORE DISPUTES OVER HANDLING OF DRUG RECALL

By NATASHA SINGER
56 words
12 June 2010
The New York Times Abstracts
NYTA
3
English

House committee disputes meaning of new Johnson & Johnson documents over company's recent recalls of over-the-counter pediatric drugs; suggest documents raise prospect that McNeil Consumer Healthcare unit conducted surreptitious Motrin recall without full knowledge of Food and Drug Administration; photo (M)

Photograph

Document NYTA000020110107e66c00026

The New York Times

Business/Financial Desk; SECTB

More Disputes Over Handling Of Drug Recall

By NATASHA SINGER
609 words
12 June 2010
The New York Times
NYTF
Late Edition - Final
3
English

The feud between Johnson &Johnson and Congressional investigators over the company's recent recalls of over-the-counter medicines deepened on Friday as they disputed the meaning of company documents turned over to a House committee.

The new material sheds light on an incident in 2009 in which McNeil Consumer Healthcare, a unit of Johnson &Johnson, hired private companies to buy certain defective Motrin products from stores.

McNeil has said it did nothing wrong in removing the Motrin and that the medicine posed no safety risk. But investigators consider the documents significant because they deepen concerns about whether McNeil, responsible for a recall in April of an estimated 136 million bottles of pediatric medicines, was aboveboard in its handling of various quality-control problems.

Representative Edolphus Towns, a New York Democrat who is the chairman of the committee conducting the investigation, has suggested that the documents -- which include e-mail messages, formal correspondence and instructions to contractors -- raise the prospect that McNeil conducted a surreptitious Motrin recall in 2009 without the full knowledge of the Food and Drug Administration.

Mr. Towns, the chairman of the House Committee on Oversight and Government Reform, has repeatedly referred to the Motrin episode as a "phantom recall."

One document on McNeil letterhead instructs contractors involved in the Motrin buyback program not to alert stores about their activities.

"Do not communicate to store personnel any information about this product," the document says. A separate McNeil instruction said, "Just purchase all available product."

Mr. Towns said that document, given to the committee by McNeil this week, indicated to him that McNeil had directed surreptitious activity by its contractors.

A McNeil spokeswoman, Bonnie Jacobs, disagreed.

"Given that there was no safety risk, the objective was to remove the affected product from a unique distribution channel, mainly convenience stores and gas stations, with as little disruption and consumer confusion as possible," Ms. Jacobs said on Friday.

Earlier this week, Ms. Jacobs said that the company had nothing to do with a separate communication from a subcontractor hired to retrieve Motrin from stores.

In that document, also provided to the committee, the subcontractor instructed its employees how to behave -- "Simply 'act' like a regular customer while making these purchases. There must be no mention of this being a recall of the product!" -- when buying back the Motrin for McNeil.

On the issue of informing the F.D.A. about its activities, Ms. Jacobs said McNeil had contacted the agency after it discovered that two lots of Motrin did not dissolve properly. The company informed the agency that it planned to retrieve the products from stores and kept the agency apprised of its progress, she said.

An e-mail message from an F.D.A. official, obtained by The New York Times on Friday, suggests the agency was frustrated with McNeil's approach.

"It seems that your company is doing a recall even though you are calling it a 'retrieval,' " Neisa M. Alonso, an investigator and recall coordinator with the F.D.A. in San Juan, P.R., wrote in a message date July 16, 2009, to an executive at McNeil. "The agency's position is that your company should do a voluntary recall of the product since it appears to be that you are already doing a recall of the product."

McNeil later instituted a formal recall of the defective Motrin.

PHOTO: Representative Edolphus Towns, who heads the committee reviewing a drug recall, suggested that new documents raised the prospect that McNeil conducted a surreptitious Motrin recall. (PHOTOGRAPH BY JONATHAN ERNST/REUTERS)

Document NYTF000020100612e66c0003d

The New York Times

Business/Financial Desk; SECTB

Johnson &Johnson Seen as Uncooperative on Recall Inquiry

By NATASHA SINGER
1,341 words
11 June 2010
The New York Times
NYTF
Late Edition - Final
1
English

A Congressional investigation into a recent recall of children's Tylenol and other pediatric medicines has been stymied by the manufacturer, Johnson &Johnson, investigators say, raising the prospect that new measures -- like issuing of subpoenas to compel cooperation -- could be invoked.

The unit of Johnson &Johnson that makes the over-the-counter drugs, McNeil Consumer Healthcare, is already under scrutiny by the Food and Drug Administration for a pattern of violations in manufacturing and quality control practices that have led to a number of recent recalls. The agency said last month that it was considering criminal penalties or other actions against McNeil.

Now Representative Edolphus Towns, a New York Democrat who is the chairman of the House Committee on Oversight and Government Reform, said Johnson &Johnson had used delaying tactics in its dealings with the committee and in some instances had provided misinformation -- accusations the company denies.

Such conduct has cast Johnson &Johnson in an unusually negative light, Mr. Towns said, and might compel the committee to take more aggressive action as it looks into drug quality and safety issues raised by the recall. Other large corporations investigated recently by the committee, including Bank of America and the insurance giant A.I.G., were more forthcoming, Mr. Towns said.

"But we are not getting the kind of information and cooperation from Johnson that I would like," Mr. Towns said in a telephone interview.

A spokeswoman for McNeil offered a starkly different view of the company's dealings with the committee. The spokeswoman, Bonnie Jacobs, said Thursday that the company had provided the committee with about 20,000 pages of documents, made its executives available for interviews and answered queries in a timely manner.

"We have been very cooperative with the committee," Ms. Jacobs said.

Mr. Towns, however, said he was particularly troubled by apparent discrepancies in Johnson &Johnson's accounts of its activities. The company, he said, told members of his staff that the recall involved six million bottles of children's medicines even as it informed the F.D.A. that the recall involved more than 136 million bottles.

"It means that we didn't get a straight story from Johnson &Johnson," Mr. Towns said. "We need to know where the spin is and where the truth begins."

But Ms. Jacobs said there was a simple explanation: the numbers represented answers to two different questions from government officials. There were about six million bottles of the products in stores at the time of the recall, she said, and an estimated 136 million bottles in the hands of consumers.

The House committee opened its investigation in early May shortly after McNeil announced a voluntary recall of liquid pediatric Tylenol, Motrin, Benadryl and Zyrtec. The products, made at a company plant in Fort Washington, Pa., may have included metal particles, or too much of the active drug ingredient, or inactive ingredients that did not meet testing standards, the F.D.A. said.

McNeil said that it had rejected defective products before they reached stores and had not received reports of health problems caused by issues related to the recall. But consumers should stop using the products, the company said, even though the possibility of serious medical harm was remote.

On May 27, the committee held a public hearing, with testimony from an F.D.A. official and an executive from Johnson &Johnson, intended to shed light on the circumstances surrounding the large recall.

But, after the hearing raised new questions for legislators, the committee widened its investigation.

Mr. Towns said that the House committee was now examining a new recall of children's medicines that were made for another company by the McNeil plant involved in the Tylenol recall.

The committee has also opened an investigation into an incident last year in which McNeil hired private contractors to purchase certain defective Motrin products from stores, an event which Mr. Towns has described as a "phantom recall." After F.D.A. officials inquired about the contractors' activities, McNeil instituted an official recall.

"It was troubling to us," Dr. Joshua M. Sharfstein, the agency's principal deputy commissioner said during the Congressional hearing. "When F.D.A. found out about this, we insisted that an actual recall occur."

Ms. Jacobs of McNeil said that the company had contacted the F.D.A. after it discovered that two lots of Motrin did not dissolve properly. The company, she said, informed the agency that it planned to remove the products from stores and regularly gave the agency progress reports.

The escalating Congressional investigation, along with Mr. Towns's complaints about stalling and discrepancies from Johnson &Johnson, has the potential to fuel the F.D.A.'s own inquiry. An agency official said during the hearing that the F.D.A. had referred the McNeil case to its office of criminal investigation, the agency's law enforcement arm, which works with the Justice Department to prosecute companies accused of violating the laws governing drug manufacturing and marketing.

On Thursday, an F.D.A. spokeswoman said that the agency did not comment once it had referred a case for criminal investigation.

In a statement in late May on a company blog, McNeil said that it was undertaking comprehensive improvements in manufacturing and quality control systems.

But Mr. Towns said he found some recent actions by company managers troubling.

In particular, he faulted a company executive for implying during her sworn testimony that the "phantom recall" incident -- in which contractors bought defective Motrin products off store shelves -- was a limited and transparent transaction. Documents later provided by the company, he said, suggested more covert and larger-scale activity.

One purchase order among the evidence indicated that McNeil had hired a contractor in 2009 to visit 5,000 stores, or about 100 stores per state, for a fee of $487,500. A document from another contractor, titled "Motrin Purchase Project (June 12, 2009)," instructed employees buying Motrin to "simply 'act' like a regular customer" and make "no mention of this being a recall."

Mr. Towns said he was "troubled by the information that was given to us at the hearing versus what we are actually seeing now in the documents."

But Ms. Jacobs of McNeil said that the documents fully supported the executive's testimony. The kind of Motrin was a small-volume product for McNeil, she said, and remained on sale mainly at convenience stores and gas stations. The "Motrin Purchase Project" document was created without McNeil's knowledge by a subcontractor, she said.

But Mr. Towns cited further issues. During an interview in late May, Peter Luther, the president of McNeil, told House investigators that the Fort Washington plant involved in the Tylenol recall did not make products for other companies, Mr. Towns said.

Four days later, Blacksmith Brands, which markets PediaCare children's medicines, announced its own voluntary recall "as a precautionary step" -- because certain of its cough and cold products had been made at the same McNeil plant.

Ms. Jacobs said that McNeil had sold the PediaCare brand to Blacksmith last fall. The McNeil plant, she said, was making the PediaCare products on a temporary basis and had not fully transferred manufacturing to Blacksmith.

But Representative Eleanor Holmes Norton, a Democrat from Washington, who sits on the House oversight committee, said the company's conduct seemed to her to demonstrate a continuing lack of transparency.

"The only way for Johnson &Johnson to reclaim any measure of credibility," Ms. Norton said, "is to let it all out now."

PHOTOS: Pediatric versions of Zyrtec, Tylenol and Benadryl made at a plant in Fort Washington, Pa., were recalled in April. (PHOTOGRAPH BY TONY CENICOLA/THE NEW YORK TIMES)(B1); Representative Edolphus Towns, center, said McNeil was not forthcoming with information about a recall of over-the-counter children's medicines. (PHOTOGRAPH BY CHIP SOMODEVILLA/GETTY IMAGES); PHOTO (PHOTOGRAPH BY DANIEL ACKER/BLOOMBERG NEWS)(B4)

Document NYTF000020100623e66b0004y

The New York Times

Business/Financial Desk; SECTB

F.D.A. Weighs More Penalties In Drug Recall By J.&J. Unit

By NATASHA SINGER

1,338 words
28 May 2010
The New York Times
NYTF
Late Edition - Final
1
English

CORRECTION APPENDED

The Johnson &Johnson unit that recalled millions of bottles of liquid children's Tylenol and other pediatric medicines last month may face criminal penalties, product seizures or other sanctions, an official from the Food and Drug Administration said Thursday.

The agency is considering further actions against McNeil Consumer Healthcare, the Johnson &Johnson unit, after a pattern of violations in manufacturing and quality control practices led to a number of recent recalls, Dr. Joshua M. Sharfstein, the F.D.A.'s principal deputy commissioner, said at a Congressional hearing on Thursday.

On April 30, McNeil voluntarily recalled more than 136 million bottles of liquid pediatric Tylenol, Motrin, Benadryl and Zyrtec because they may have contained too much of the active ingredient of the drug, metal specks or inactive ingredients that failed testing requirements, the agency said. But McNeil's problems go beyond those related to last month's recall, including other forms of contamination, dating back two years.

During a session in which some committee members questioned McNeil's integrity, Dr. Sharfstein noted lengthy delays by the company in reporting problems to the agency.

And in one case, in 2008, Dr. Sharfstein said, McNeil hired a contractor to quietly remove packages of Motrin from retailers for suspected quality problems -- which he suggested was essentially an unannounced recall that was not reported to the F.D.A.

"This is something troubling to the agency," he said. "We think it reflected poorly on the company."

He said the F.D.A. was "considering additional enforcement actions against the company for its pattern of noncompliance, which may include seizures, injunction or criminal penalties."

Another agency official, Deborah M. Autor, the director of the F.D.A. Office of Compliance at the Center for Drug Evaluation and Research, told the panel that officials had referred the McNeil case to the office of criminal investigation, the agency's law enforcement arm, which works with the Justice Department to prosecute companies accused of violating the laws governing drug manufacturing and marketing.

The House Committee on Oversight and Government Reform called Thursday's hearing to examine the circumstances surrounding last month's recall and whether the F.D.A. had responded adequately. But the evidence presented indicated long-running problems.

"I have become deeply concerned about your company," Representative Edolphus Towns, the New York Democrat who is chairman of the committee, told the Johnson &Johnson executive who testified. "It paints a picture of a company that is deceptive, dishonest and willing to put the health of children at risk."

That executive, Colleen A. Goggins, the worldwide chairwoman of Johnson &Johnson's consumer group, acknowledged lapses by the McNeil unit. "The quality and process issues that we found at McNeil, those which led to the recall and others, are unacceptable," she said.

But she also defended the company's integrity. "There was never any intent to deceive or hide anything," Ms. Goggins said.

The products in the latest recall were made at a company plant in Fort Washington, Pa.

Ms. Goggins said that the risk of serious medical problems from the recalled products was remote and that there were no reports that the products had caused serious medical harm.

Earlier this week, an F.D.A. spokeswoman said that the agency had received reports of health problems associated with the recalled products, including several deaths. But she said the agency had not found evidence that the products had caused the reported health issues.

Ms. Goggins said McNeil had identified and rejected the children's medicines that contained metal particles or higher-than-normal doses before they reached the marketplace.

As part of an overhaul of its manufacturing and quality control processes, McNeil has replaced several senior executives and is making systemwide improvements, Ms. Goggins said.

McNeil posted a statement on a company Web site this week saying that it was making improvements in every part of its manufacturing and quality control operations, including organizational changes, employee training and new procedures for investigating product problems.

But Mr. Towns, the committee chairman, said McNeil's corporate conduct surrounding the recalls dating back several years raised integrity questions.

For example, Dr. Sharfstein said, in 2008, McNeil notified the F.D.A. that it had hired an outside contractor to buy samples of Motrin from retailers to determine whether problems with the drug's ability to dissolve warranted a recall.

In 2009, however, the agency received information that the contractor had been buying up inventories of the product in what seemed to be an unannounced recall, he said. McNeil later initiated a formal recall of the products after the agency questioned the company about the contractor's conduct, he said.

In answer to questions from Mr. Towns, who referred to the incident as a "phantom recall," Ms. Goggins said that McNeil had notified F.D.A. officials that it had hired a third-party contractor to determine how much of the product in question was on the market. But she said that she could not account for the contractor's actions and that she would provide the committee with further information.

Committee members also questioned the executive about other incidents cited by the F.D.A.

In 2008, for example, McNeil received several consumer complaints about a moldy smell emanating from some over-the-counter products that had been made at a company plant in Puerto Rico. Some people also reported stomach problems. But the company did not notify the agency of the issue until 2009, Dr. Sharfstein said.

"It should not have taken a year," he said. "It should have taken three days."

After hearing Dr. Sharfstein's testimony, Representative Eleanor Holmes Norton, a Democrat from the District of Columbia, asked Ms. Goggins whether the delay amounted to a "cover-up."

Ms. Goggins said that McNeil had initially tested the products for microbiological contamination and that the tests had come back negative. When the consumer complaints subsided, the company thought the problem had resolved itself, she said.

The consumer complaints picked up again in 2009. McNeil recalled products in November, December and in January after it determined that the odor was caused by contamination from a chemical, used to treat wooden transport pallets, that had leached into some products.

In an F.D.A. inspection report last month about the Fort Washington plant, the agency cited McNeil for similar issues -- failing to properly investigate 46 consumer complaints of foreign particles and unidentified black bits in some products. McNeil received that report on April 30 and announced the recall that evening. In her written testimony, Ms. Goggins said that McNeil takes each complaint and report seriously and seeks to investigate each one.

"Reports of possible serious adverse events, for example," she wrote, "are reported to the F.D.A. quickly."

Some committee members said that if Congress wanted to prevent delayed actions by drug makers on defective medicines, it should give the F.D.A. the authority to recall such products and levy civil penalties on companies. Now, the agency cannot require a recall, but pharmaceutical companies may voluntarily recall problem drugs.

Correction: May 28, 2010, Friday

This article has been revised to reflect the following correction: Because of an editing error, an article on Friday about possible criminal penalties against McNeil Consumer Healthcare, a unit of Johnson &Johnson involved in a wide recall of over-the-counter medications, quoted incorrectly from comments by Representative Edolphus Towns, who is chairman of a committee examining the recalls. Mr. Towns said the company's behavior painted a picture of a company that is "willing to put the health of children at risk." He did not say "that has risked the health of many of our citizens."

PHOTO: Dr. Joshua M. Sharfstein, left, and Michael Chappell, both of the F.D.A., appeared on Thursday before a House committee. (PHOTOGRAPH BY CHIP SOMODEVILLA/GETTY IMAGES)(B6)

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The New York Times

B

F.D.A. WEIGHS MORE PENALTIES IN DRUG RECALL BY J.&J. UNIT

By NATASHA SINGER
118 words
28 May 2010
The New York Times Abstracts
NYTA
1
English

Food and Drug Administration is considering criminal charges and other sanctions against McNeil Consumer Healthcare, unit of Johnson & Johnson that recently recalled millions of bottles of liquid children's Tylenol and other pediatric medications; say that prior to McNeil voluntarily recalling product because of potential hazards, they first hired private contractors to quietly remove some products from store shelves rather than report problems to FDA; FDA deputy commissioner Dr Joshua M Sharfstein addressed these issues and possible sanctions against McNeil during testimony before House Committee on Oversight and Government Reform hearing examining circumstances of sweeping recall; photo (M)

Photograph

Document NYTA000020100529e65s00013

The New York Times

Business/Financial Desk; SECTB

Questions For Makers On Defects In Drugs

By NATASHA SINGER
1,136 words
27 May 2010
The New York Times
NYTF
Late Edition - Final
1
English

For consumers who turned to drugstore house brands after the recall last month of liquid children's Tylenol and other medicines made by a unit of Johnson &Johnson, there is yet more unsettling news.

The recall included more than 40 varieties of liquid pediatric Tylenol, Motrin, Benadryl and Zyrtec that may have contained metal particles, too much of the active drug ingredient or inactive ingredients that did not meet testing requirements. At the time, the Food and Drug Administration recommended that consumers look for generic alternatives to these brand-name over-the-counter drugs.

But now, Perrigo, a company based in Michigan that supplies drugstore equivalents of those children's medicines to pharmacy chains like CVS and Walgreens, has received a warning letter from the F.D.A. about significant manufacturing violations of its own -- including ibuprofen tablets contaminated with metal shavings.

Although the problems cited in the warning letter did not mention children's products, the deficiencies at both Johnson &Johnson and Perrigo raise questions about why some manufacturing plants have shipped defective medicines.

"Why are these issues not being detected?" said David J. Kroll, a professor of pharmaceutical sciences at North Carolina Central University in Durham. "What is the F.D.A. planning to do about premarket quality control?"

The problems at Perrigo seem certain to focus more attention on a Congressional hearing scheduled for Thursday about the circumstances surrounding the Johnson &Johnson recall.

The House Committee on Oversight and Government Reform, which earlier this month announced an investigation into the recall, has invited officials of Johnson &Johnson and the F.D.A. to testify at the hearing.

The House committee is trying to determine the chronology and the cause of the manufacturing issues at Johnson &Johnson and whether federal regulators responded adequately.

"We feel that it's so important, when you have an agency that has jurisdiction, that they are on top of situations like this," Representative Edolphus Towns, Democrat of New York and the chairman of the committee, said Tuesday. "Were they aware of what was going on and at what point did they know?"

Mr. Towns said he also intended to ask executives if Johnson &Johnson had reduced its quality control staff at its McNeil Consumer Healthcare unit, which makes and sells the products at issue, before the recall of products manufactured at a McNeil plant in Fort Washington, Pa.

"I also want to find out if there was any shaving or cutting of staff that led to these problems," Mr. Towns said.

The McNeil unit has instituted a multipronged plan to address the quality control issues that precipitated the recall on April 30, according to a statement posted on a company blog on Tuesday. McNeil is improving "processes and employee training in every part of the manufacturing and quality operations," as well as adding new procedures for quality control investigations, the statement said. McNeil says it has also made organizational changes in management.

In response to a query from a reporter on Wednesday, a company spokeswoman declined to elaborate.

Arthur J. Shannon, a spokesman for Perrigo, the country's largest maker of store-brand over-the-counter drugs, responded to a reporter's query by saying the company was working with the F.D.A. to institute corrective actions at its plant. Different plants in the same Allegan, Mich., complex make infants' and children's products, he said.

There are some similarities in the problems at both companies. In F.D.A. documents, agency officials cited the failure of each company's quality control unit to ensure manufacturing standards.

McNeil has been beset by recent manufacturing issues. Because of quality control problems, the company made a series of recalls of popular over-the-counter medicines -- last September, November and December, and in January of this year.

Then, in April, F.D.A. inspectors observed manufacturing and quality control problems at McNeil's Fort Washington plant.

According to an F.D.A. inspection report, these included failure to investigate and take corrective action on consumer complaints regarding particle contamination in a drug, unclean equipment at the plant, failure to train employees in good manufacturing practices, and bacterial contamination of a drug ingredient. McNeil has tested some recalled products and to date has found no bacteria, according to Bonnie Jacobs, a McNeil spokeswoman.

"To our knowledge, no bacterially contaminated components were used in the manufacture of any of our recently recalled products," Ms. Jacobs wrote in an e-mail message.

McNeil shut down the plant after the inspection and recalled the liquid children's products. Even though the possibility of serious medical problems was remote, the company said, people should discontinue using the recalled products. The company has a Web site, mcneilproductrecall.com, with information about the recalled products and how to identify them.

Mr. Towns of the House committee said consumers were understandably nervous to learn of problems in products that they trusted.

"We're concerned that it could be a pattern," he said.

The F.D.A., for its part, noted a pattern of quality-control lapses at Perrigo.

The warning letter, posted on the F.D.A. Web site Tuesday, cited Perrigo for shipping defective drug products from its Allegan factory. The plant had identified certain ibuprofen tablets as being contaminated with metal shavings but had shipped a portion of the pills anyway, the letter said, before later recalling the entire lot.

Mr. Shannon of Perrigo said that the company had recalled the ibuprofen tablets cited in the letter from a retail warehouse before the pills reached retail store shelves.

In an earlier incident in 2006, Perrigo recalled about 11 million bottles of acetaminophen because it found metal particles, ranging from a speck to 8-millimeter pieces of wire, in some caplets.

The agency's recent warning does not cite any children's medications made by Perrigo. The F.D.A. stands by its recommendation that consumers look for generic alternatives to the recalled McNeil children's products, an agency spokeswoman said Wednesday.

But industry analysts said the recent quality problems at both companies raised concerns about why certain plants in the United States had not adhered to manufacturing standards.

"In a country where we are concerned about drugs being manufactured abroad, to find out that we have this lack of control at an American facility raises all sorts of questions," said Mr. Kroll, the professor of pharmaceutical sciences. "Is it possible that we could see all kinds of drug manufacturing quality issues here?"

PHOTOS: Dr. Joshua Sharfstein of the F.D.A., top, will testify Thursday. Children's Tylenol is among the drugs recalled. (PHOTOGRAPHS BY MICHAEL REYNOLDS/E.P.A.; MARIANA VASCONCELLOS/THE NEW YORK TIMES) (B5)

Document NYTF000020100527e65r0004m

The New York Times

Business/Financial Desk; SECTB

House Panel Is Investigating J.&J. Recalls

By REUTERS
204 words
7 May 2010
The New York Times
NYTF
Late Edition - Final
5
English

WASHINGTON (Reuters) -- Lawmakers requested information on Thursday from regulators about Johnson &Johnson's recall of Children's Tylenol and other over-the-counter pediatric medicines, saying the company's repeated recalls "point to a major problem" with production.

The House Committee on Oversight and Government Reform has opened an investigation after Johnson &Johnson recalled 40 widely used children's pain and allergy medications, saying some might have a higher concentration of their active ingredients, while others might be contaminated.

In an F.D.A. report issued Tuesday, inspectors said they had found thick dust, grime and contaminated ingredients at the plant that produces Children's Tylenol and dozens of other products recalled last week.

Johnson &Johnson has had four recalls of over-the-counter medicines in the last year.

"Taken together, these recalls point to a major problem in the production of McNeil products," the committee chairman, Edolphus Towns, Democrat of New York, and the panel's ranking Republican, Darrell E. Issa of California, said in a statement, referring to the company's consumer health care unit.

The McNeil unit of Johnson &Johnson declined to comment.

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The New York Times

Business/Financial Desk; SECTB

Agency Told Tylenol Maker of Many Quality Concerns

By NATASHA SINGER
798 words
5 May 2010
The New York Times
NYTF
Late Edition - Final
2
English

The Johnson &Johnson unit that voluntarily recalled certain lots of children's liquid Tylenol and Motrin over the weekend had numerous and wide-ranging quality control problems at the plant that made the products, according to a federal inspection report released Tuesday.

That unit, McNeil Consumer Healthcare, failed to adequately investigate and correct various deficiencies in its manufacturing and drugs made at its plant in Fort Washington, Pa., according to the report, posted Tuesday afternoon on the Web site of the Food and Drug Administration.

"This is yet another example of the need for companies to take full accountability for the quality of their drugs, and the serious consequences that can happen when companies do not do so," Deborah M. Autor, the director for compliance at the agency's Center for Drug Evaluation and Research, said Tuesday during a conference call with reporters.

The report, which the agency had sent to McNeil last Friday, before the recall, said the company had used raw materials with known bacterial contamination to make certain lots of infants' and children's liquid Tylenol.

Samples of finished products tested negative for bacteria, however, and the risk to consumers was remote, agency officials said.

A McNeil spokeswoman disagreed with the F.D.A.'s account of the bacteria issue. She wrote in an e-mail message that that the company had not used material that had tested positive for bacteria. She said that a supplier had rejected some drums of a material from a master lot after finding bacterial contamination. But the drums sent to McNeil's plant had tested negative for bacteria.

The F.D.A. report also said McNeil had not responded properly to several dozen consumer complaints about foreign particles found in certain medications.

McNeil said in a statement Tuesday that the company had temporarily stopped production at the Fort Washington plant. The company will not start manufacturing again until it has taken corrective actions and can assure the quality of products made there, the statement said.

The F.D.A. report concerns manufacturing deficiencies observed by federal health investigators during a routine inspection of the plant in April.

After receiving the report last Friday morning, McNeil late that evening recalled a wide range of certain lots of liquid infant's and children's Tylenol, Motrin, Benadryl and Zyrtec.

Some of these over-the-counter medicines may contain more of the active ingredient than is specified on the product label or tiny metal particles or inactive ingredients that do not meet testing standards, the company said. Although the possibility of health problems was remote, people should stop using the products, the company said.

A full list of the products can be found on the company's Web site mcneilproductrecall.com.

Consumers can also call the McNeil recall hot line at 888-222-6036 for more information about a refund or coupon to replace the recalled products.

McNeil is not disclosing the overall number of bottles involved in the recall, a company spokesman said. The F.D.A. said Tuesday that the recall involved about 1,500 product lots.

This is the fifth recall of McNeil products since last September.

In January, for example, McNeil undertook a large-scale recall of certain lots of Tylenol, Motrin, Benadryl, Rolaids and St. Joseph Aspirin after consumer complaints about moldy smells emanating from certain products. The company said that the odor had been caused by a byproduct of a chemical used to treat wooden transport pallets that had leached into the products at a company plant in Puerto Rico.

In February, F.D.A. officials met with managers from McNeil and Johnson &Johnson to express serious concerns about McNeil's manufacturing operations, the agency said Tuesday.

Since that meeting, McNeil has taken steps to improve its manufacturing processes, but F.D.A. officials said they had not yet determined whether the changes were sufficient or whether the agency would take further action against the company.

At the time of the January recall, industry analysts described the moldy smell problem at the Puerto Rico plant as a fluke and an isolated incident.

But some of the inspectors' observations about the Fort Washington plant resemble problems the agency cited at the Puerto Rico plant. These include failure to follow certain good manufacturing standards and failure to adequately investigate consumer complaints.

McNeil said it was working with the agency to resolve the matter.

"The quality issues that the F.D.A. has observed, many of which we had recently identified in our own quality reviews and communicated to the F.D.A., are unacceptable to us, and not indicative of how McNeil Consumer Healthcare intends to operate," the McNeil statement said.

Document NYTF000020100505e6550003g

The New York Times

NEWS ANALYSIS
Business/Financial Desk; SECTB
Tylenol, Generics And Trust

By NATASHA SINGER
1,039 words
3 May 2010
The New York Times
NYTF
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1
English

Is a brand-name drug synonymous with quality?

That is the question many parents were asking themselves over the weekend after they learned about a wide recall of over-the-counter liquid medicines for children from a unit of Johnson &Johnson.

McNeil Consumer Healthcare, the Johnson &Johnson unit, voluntarily had a recall because some products may have manufacturing deficiencies, the Food and Drug Administration said. It did not act because of adverse health reactions to the products, the company said in a statement.

Certain liquid infants' and children's Tylenol, Motrin, Zyrtec and Benadryl may contain too much of the active drug ingredient or tiny metal particles or inactive ingredients that do not meet testing requirements, McNeil said. Although the potential for medical problems is remote, the company said, people should stop using the products.

The recall quickly became a flashpoint for some parents on Twitter, Facebook and parenting blogs, not to mention on playgrounds and at birthday parties over the weekend. Some people said they felt frustrated in their efforts to obtain more information from the company. Others said they had lost confidence in the products. This is at least the fifth recall for consumers of McNeil products in less than a year because of quality control issues.

"Another recall for baby Tylenol!" Kevin Kowalski, a father in Illinois, wrote on Twitter on Sunday. "Well, then no more baby Tylenol, back to generic brand."

Johnson &Johnson is considered a model in the consumer products industry for its fast and adept handling of a Tylenol scare in 1982 in which seven people in Chicago died after taking capsules that had been laced with cyanide. But, in that case, the problem was not the company's fault: an outsider had tampered with the capsules. No one has ever been charged.

Now, however, Johnson &Johnson and its McNeil unit may have more difficulty wooing customers back because the latest recalls stem from problems at company plants, industry analysts said. Johnson &Johnson will have to work to counter increasing consumer skepticism about whether they should pay more for name-brand children's medicines when there are lower-cost drugstore brands available, said Michael Braun, an assistant professor of marketing at the M.I.T. Sloan School of Management.

"They are going to have to go to greater lengths," Mr. Braun said. "The greater the harm to the reputation, the more expensive it is to fix it."

But some consumers said they found the company's initial response flat-footed.

Over the weekend, some people said they had been unable to obtain clear information about how to receive a refund on mcneilproductrecall.com, a company Web site about the recalled products. Other people complained that they could not get through to customer service representatives at the company's recall hot line: (888) 222-6036. Still others complained that, when they did reach customer representatives, they were offered replacement coupons, not refunds, for the recalled products.

Mark Mandel, a father of a 21-month-old daughter in Chicago, said he felt frustrated because he had thrown out a Tylenol infants' product during a recall last year. Now, some of the replacement medicines he bought were involved in the new recall.

"It makes me question their quality control," said Mr. Mandel, a microbiologist at the Feinberg School of Medicine at Northwestern University. "It makes me wonder if they have the parents' best interest and the children's best interest at heart."

McNeil was working to respond to a higher than usual volume of consumer calls and had assigned additional resources to respond to customers, a company spokesman said Saturday. By Sunday, the company had posted clearer information on the site about how consumers may obtain either a refund or a coupon for recalled products.

McNeil has tried to address most consumer questions in the frequently asked questions section of its recall Web site, a company spokesman said Sunday. The company understands that many consumers are either not getting through on the toll-free information line or still have questions that are not answered by the site, he said.

"Responding to consumers is extremely important to us," Marc Boston, a McNeil spokesman, wrote via e-mail. "To improve our response time to consumers, we are continuing to add to these resources including adding additional information" on the Web site and increasing staffing for the hot line.

The products involved in the recall were made at a company plant in Fort Washington, Pa. McNeil is not providing information about the total number of bottles of medicine involved, Mr. Boston said. A spokeswoman for the Food and Drug Administration said that the recall involved more than 1,000 product lots.

In instituting a wide recall, Mr. Braun speculated, McNeil may have been acting out of an abundance of caution.

In January, federal health regulators cited the company for not acting quickly enough to recall a wide range of over-the-counter medicines after some consumers complained of moldy smells emanating from the products. In January, McNeil undertook a wide recall of certain kinds of Tylenol, Motrin, Benadryl and St. Joseph Aspirin.

But after the cluster of recalls, some consumers said they had lost confidence in brand-name over-the-counter medicines.

"It's very disturbing because you go to the store and buy the name brands thinking you are getting quality goods and then you find this out and you don't know who to trust now," Jennifer Perrotta, a mother of two in Massapequa, N.Y., said by phone on Sunday. "You kind of lose confidence in the brand names you have been using for years."

On Saturday, Ms. Perrotta, a speech language pathologist for the North Shore school district, told her friends via Facebook that she had emptied her medicine cabinet of children's products. She went to her local pharmacy, she said in the interview, and bought drugstore brands to replace the name-brand medicines involved in the recall.

PHOTO: Some medicines for children, including Tylenol, Benadryl and Zyrtec, have been recalled by a Johnson &Johnson unit. (PHOTOGRAPH BY MARIANA VASCONCELLOS/THE NEW YORK TIMES) (B9)

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The New York Times

AA
CHILDREN'S TYLENOL, BENADRYL AND OTHER DRUGS RECALLED

By NATASHA SINGER
63 words
2 May 2010
The New York Times Abstracts
NYTA
21
English

Food and Drug Administration reports Johnson & Johnson's McNeil Consumer Healthcare unit has begun voluntary recall of infants' and children's Tylenol, Motrin, Zyrtec and Benadryl products because of manufacturing deficiencies; medicines could have impurities and excess quantities of active ingredients; recall is not result of adverse health reactions (M)

Document NYTA000020101202e65200062

The New York Times

National Desk; SECTA
Children's Tylenol, Benadryl And Other Drugs Recalled

By NATASHA SINGER
451 words
2 May 2010
The New York Times
NYTF
Late Edition - Final
21
English

A unit of Johnson &Johnson has voluntarily begun a recall of certain children's over-the-counter liquid medicines because of manufacturing deficiencies, the Food and Drug Administration said on Saturday.

The deficiencies may affect the potency, purity or quality of the products, the agency said in a statement. It said it was investigating the plant where the products were made to make sure there were no other problems.

Consumers should stop using certain lots of infants' and children's Tylenol, Motrin, Zyrtec and Benadryl products because some of them may contain more of the active drug ingredient than specified, the Johnson &Johnson unit, McNeil Consumer Healthcare, said in a statement late Friday. Other products involved in the recall may contain foreign particles or inactive ingredients that may not meet testing requirements, the company said.

"The particles may be solidified product ingredients or manufacturing residue such as tiny metal specks," Marc Boston, a McNeil spokesman, said.

McNeil did not undertake the recall because of adverse health reactions to the products, the company said, but it advised consumers to stop using them.

Although the potential for serious medical problems is remote, McNeil said, parents and caregivers should not give the products to children.

The recall involves all unexpired lots of seven products in 43 different flavors and sizes. These include Tylenol Infants' Drops, Children's Tylenol Suspensions, Infants' Motrin Drops, Children's Zyrtec liquids in bottles and Children's Benadryl Allergy liquids.

McNeil has posted a full list of the recalled product lots on a dedicated Web site: mcneilproductrecall.com. The recall comes after federal health regulators cited McNeil on Friday morning for manufacturing violations found during a routine inspection at a company facility in Fort Washington, Pa., an F.D.A. spokeswoman said. This is the second major recall this year for McNeil. In January, after receiving reports of moldy smells emanating from over-the-counter medicines made at a plant in Puerto Rico, the company recalled several hundred lots of adult and children's products. The earlier recall involved certain lots of Benadryl, Motrin, Rolaids, Simply Sleep, St. Joseph Aspirin and Tylenol.

McNeil has a hotline, (888) 222-6036, available 8 a.m. to 10 p.m. Eastern time, Monday through Friday and on weekends from 9 a.m. to 5 p.m. But due to high call volumes, a reporter who called the hotline at different times on Saturday was unable to reach a customer service representative. A recorded message directed callers to the company's Web site and later disconnected. McNeil said it was working to respond to the high call volumes.

Document NYTF000020100502e6520009m

The New York Times

NEWS ANALYSIS
Business/Financial Desk; SECTA
Implant at Own Risk

By BARRY MEIER
1,431 words
3 April 2010
The New York Times
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Late Edition - Final
1
English

In January, William R. Morris's artificial hip, just three years old, was failing so badly that it had to be replaced during an extensive procedure that cost about $50,000.

The maker of the failed hip has since sent letters to Mr. Morris's doctor, but none offering to cover replacement expenses for the device, which typically is expected to last 15 years.

"They keep asking for the joint so they can look at it," said Mr. Morris, a 52-year-old oil industry geologist who lives in Anchorage.

When a car breaks, a computer fails or a toaster flames out, the manufacturer is often liable under the product warranty. But that is not how the multibillion-dollar orthopedics industry tends to work, according to doctors, industry experts and three of the biggest device makers.

The million or so artificial hips and knees implanted each year in the United States, they say, are normally not guaranteed. Instead, the costs of replacing implants that fail early because of design or mechanical problems -- devices that sell for as much as $15,000 each -- are largely paid by Medicare, insurance companies and patients.

Implants can fail for many reasons, but if only a small percentage of them fail prematurely because they are substandard, the costs to taxpayers, policyholders and patients can run into the tens of millions of dollars each year, health care experts estimate.

Orthopedic producers may sometimes even profit from the failures because they sell the replacements at full price.

"Companies have dumped these costs into the health care system," said Dr. Lawrence D. Dorr, an orthopedic surgeon in Los Angeles who two years ago took the unusual step of drawing attention to one problematic hip device. "They don't have any skin in the game."

The costs imposed by poorly performing medical devices were not dealt with in the landmark health care legislation that Congress passed last month. To pay for part of the overhaul, lawmakers mandated an excise tax on implant sales that is intended to bring in $20 billion over the next decade.

Patient advocates say an important opportunity was lost. Arthur Levin, the executive director of the Center for Medical Consumers, an advocacy group in New York, said it was appalling that the manufacturers did not provide warranties, given how critical such implants are for patients. By contrast, makers of another widely used and costly category of implants, heart devices like defibrillators, have issued warranties for more than 30 years and have provided free or discounted replacements when devices fail prematurely.

"Either they do not have faith in their products, or they are just saying tough luck to patients," Mr. Levin said, referring to the makers of orthopedic implants. "It borders on unethical business behavior."

Those manufacturers may cover the cost of replacement surgeries in some circumstances, as when they face lawsuits. Generally, however, patients are unaware of the industry's no-warranty policy. Three of the six major orthopedic implant manufacturers in the United States did not respond to inquiries about whether they offered warranties.

Another manufacturer, Zimmer Holdings of Warsaw, Ind., said the longevity of a hip implant depended on many factors beyond the company's control, including a surgeon's skill, a patient's weight and a patient's adherence to postoperative restrictions on activity.

"Because of the multifactorial nature of the survival of an implant in a particular patient, revision surgeries are to be expected," said Zimmer, using the medical term for a replacement operation. "Therefore, we do not provide free or discounted replacement revision products when one of Zimmer's implants needs to be revised."

The producer the implant removed from Mr. Morris this year, the DePuy Orthopaedics division of Johnson &Johnson, also said it did not guarantee its devices. "While we don't have product warranties, we evaluate and address all complaints and issues on a case-by-case basis and take actions based on the specific circumstances," the company said in a statement.

Stan Mendenhall, the editor of Orthopedic Network News, an industry publication, said he was unaware of any major producer of hips and knees that offered a warranty in this country.

As the population ages, the use of artificial hips and knees is growing fast, providing a lucrative market for device manufacturers. Sales of artificial hips and knees in this country reached an estimated $6.7 billion last year, and the devices have one of the highest profit margins of any medical product. An artificial joint can cost $3,000 to $15,000.

Many implants work well, lasting 15 years or more before they wear out and need replacing. It is impossible to know how many artificial hips and knees fail early because of design or manufacturing problems, because the United States, unlike some other countries, has no database to track such procedures. Also, implant companies and doctors say that such devices primarily fail because of issues unrelated to the product.

The makers sell implants to hospitals, rather than to patients directly. The costs are passed along to taxpayers and policyholders when hospitals recover such expenses from Medicare or private insurers. Patients with private insurance also bear a portion of the costs though co-payments.

For Mr. Morris, the procedure he underwent in January was his third hip replacement since 2006. The first one failed that same year. In mid-2006, he received another replacement. For about a year, he felt good, but then his joints became so painful and inflamed that he thought he might be dying.

"It had me thinking, 'Geez, I don't have much time,' " Mr. Morris said.

His employer's insurance covered most of his costs, but Mr. Morris estimates that his co-payments and other out-of-pocket costs were well over $10,000 for the initial replacement and the two additional surgeries.

Orthopedic specialists say that subsequent replacement procedures are typically more complex than the initial operations, and patients undergoing them face a significantly higher risk of lasting complications like nerve damage.

The type of artificial hip that Mr. Morris had taken out in January, called an ASR and made by DePuy Orthopaedics, has been particularly problematic. In early March, the company issued an alert that new data suggested the device was failing in some patients within a few years of implant.

Medical reports since 2008 have indicated that the hip might be flawed and capable of generating high levels of metallic debris, and a top DePuy consultant has said that he and company officials realized two years ago that it was particularly difficult for surgeons to implant properly; DePuy maintains that the device is safe.

The Food and Drug Administration has received about 300 reports of early replacement operations involving ASR patients since 2008. Safety experts say that the actual number of such procedures is most likely far higher, because many implant failures are not reported to the agency.

For his part, Mr. Levin, the patient advocate, says he is disturbed that orthopedic surgeons have not done more to force greater accountability on the part of manufacturers, particularly since as a profession the surgeons accept tens of millions of dollars annually in consulting fees from implant makers.

As it turns out, one manufacturer, Biomet, does offer warranties, though it may not do so in this country.

According to the Web site of its subsidiary in Britain, the company offers a 10-year warranty on some products, including certain knee, hip and shoulder implants, and provides a "free of charge replacement" if one fails. The

Biomet Web site in the United States makes no mention of warranties. Company officials declined to be interviewed and did not respond to written questions.

In a marketing brochure on the British site, the Biomet unit claims that the warranted devices are so durable that it has had just over a dozen claims since 1997, when the program began.

"We believe that all customer requirements should be met," the brochure states. It adds: "More than orthopaedic solutions, we deliver a true first-class service."

PHOTO: William R. Morris had his three-year-old artificial hip replaced in January because it was failing. It was his third hip replacement since 2006. (PHOTOGRAPH BY JOSHUA BOROUGH FOR THE NEW YORK TIMES) (A3)

CHART: Bad Hip, Big Replacement Cost: The New York Times surveyed all leading makers of artificial hips and knees to determine if they provided warranties for their products and, if not, why. Here are their responses. (Source: The companies: Wachovia (sales)) (A3)

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The New York Times

Business/Financial Desk; SECTB

Alert Follows Withdrawal Of Hip Device

By BARRY MEIER; Andrew W. Lehren contributed reporting.
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1
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A unit of Johnson &Johnson, just months after saying it was phasing out an artificial hip implant because of slowing sales, has warned doctors that the device appears to have a high early failure rate in some patients.

The action by the company, DePuy Orthopaedics, follows more than two years of reports that the hip implant, which is known as the ASR, was failing in patients only a few years after implant, requiring costly and painful replacement operations.

Some orthopedic experts have voiced dismay in recent interviews that DePuy had not halted sales of the device earlier. And some specialists said that they believed the device had a design flaw that made it difficult to implant properly, a claim disputed by DePuy officials, who had said the product had no safety problems. The director of an implant database in Australia, Dr. Stephen Graves, said the data had shown for some time that the ASR had been failing early at a significantly higher rate than some competitors' devices. In December, DePuy voluntarily withdrew the ASR from the Australian market.

DePuy, of Warsaw, Ind., also announced late last year that it planned to phase out sales of the product worldwide by the end of 2010.

"It is way too late," Dr. Graves said.

While the ASR is not widely used in the United States, DePuy officials said recently that it had been implanted in thousands of patients worldwide.

In a letter dated March 6, DePuy told doctors that recently analyzed data from Australia suggested that the ASR had a higher-than-expected failure rate when used in traditional hip replacement on certain types of patients. The letter said that the data shows that the risk is highest for patients of small stature, a group that typically includes women, and patients with weak bones.

Asked Tuesday by a reporter why the company was issuing the advisory now, even as it was winding down sales of the device, DePuy said in a statement that it believed that "this is new and important information surgeons who continue to use ASR should have to inform their clinical decision making."

The ASR, one of several hip models sold by DePuy, belongs to a category of devices known as metal-on-metal implants.

Such implants are under increasing scrutiny because they can generate large amounts of metallic debris as they wear. The debris can cause severe inflammatory responses in some patients, damaging muscles and other soft tissues, requiring a follow-up operation to replace the device soon after implant -- instead of the 15 or more years artificial hips are supposed to last.

Just last month, in an interview, DePuy officials defended the ASR's track record, saying its performance equaled that of competing devices. Those officials also said that the company was phasing out sales of the ASR for commercial reasons, not because of any safety issues.

"With declining sales of this particular product in its market segment, we are focusing on newer technologies," Sally Hunter, DePuy's worldwide vice president for regulatory affairs, said last month.

DePuy sells the ASR for use in hip "resurfacing," a popular alternative to traditional replacement. The company also separately markets an ASR component -- its hip socket, or cup -- for use in traditional hip replacement. DePuy's March 6 alert deals with that the ASR's failure rate in traditional replacements.

While the ASR resurfacing system has been used abroad, the Food and Drug Administration has not approved it for sale in the United States. In 2005, however, the F.D.A. cleared the ASR cup for use in traditional hip replacement. The device was cleared through a regulatory pathway that did not require it to undergo clinical trials.

Since the beginning of 2008, the F.D.A. has received about 300 complaints on the ASR involving patients in the United States who received it. A review of those reports indicates that a vast majority of those patients underwent an operation to have the device replaced soon after getting it.

The number of such complaints typically understates a product's problem, however, because many doctors and hospitals never bother to file reports with the F.D.A.

Ms. Hunter said that some problems with the ASR had arisen because doctors were improperly implanting the device's cup when first using it. To function properly a cup, which resembles a small hollow ball cut in half, must be positioned in the hip at the proper angle.

"With every device, there is a learning curve," Ms. Hunter said.

Some surgeons, including the ASR's co-developer, Dr. Thomas P. Schmalzried, an orthopedic specialist in Los Angeles, said they had used the device successfully in their patients. But Dr. Schmalzried said in an interview last month that he and DePuy officials realized within the last two years that the ASR cup might be more of a challenge to implant properly than competing cups.

"The window for component position that is consistent for good, long-term clinical function is smaller for the ASR," than other cups, said Dr. Schmalzried, who has received $3.4 million in payments in the last two years from DePuy for his work on the ASR and other devices. Asked last month about Dr. Schmalzried's comments, DePuy officials expressed surprise that he had made them. They said they would provide a reporter with a statement after consulting with him. But DePuy's subsequent statement did not refer to Dr. Schmalzried.

In that statement, DePuy said that while reports had cited "a theoretical potential for ASR cups to be more sensitive to component position," other data from studies and examinations of explanted devices "does not support the fact that performance is primarily related to design."

In early 2009, DePuy sent a brochure to doctors on the importance of proper cup positioning for all hip implants. But the information did not address any specific concerns about the ASR.

In its recent letter, DePuy emphasized the need to properly position the ASR.

Several orthopedic specialists said that they believed that the design of the ASR cup, which is shallower than some similar devices, was at the heart of the implant's problems. For example, Dr. Harlan C. Amstutz, an orthopedic surgeon in Los Angeles and an implant designer who is a consultant for Wright Medical Technology, a competing orthopedic company, said that he believed that the design was prone to problems.

"It may not be Toyota, but it is not good," Dr. Amstutz said.

PHOTO: A rendering of metallic debris caused by an improperly implanted hip, as shown in instructional material that stressed proper positioning of a hip socket, sent from DePuy to doctors. (PHOTOGRAPH BY DePUY ORTHOPAEDICS) (B5)

CHART: Reported Problems: Between 2006 and 2009, reports of problems with the DePuy model ASR hip replacement device rose sharply. Of the problems reported in 2009, over 90 percent required replacement.; Reports of problems with the DePuy hip model ASR* (Source: F.D.A.) (B5)

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The New York Times

NEWS ANALYSIS
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In Recall, Role Model Stumbles

By NATASHA SINGER
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English

The Harvard Business School teaches future executives the gold standard in brand crisis management. The model dictates that a company should communicate clearly with the public about a crisis, cooperate with government officials, swiftly begin its own investigation of a problem and, if necessary, quickly institute a product recall.

The template is based on Johnson &Johnson's conduct in 1982, when several people died after taking tainted Tylenol pills. The company's reaction to the crisis is widely regarded as exemplary.

But last week, Johnson &Johnson appeared to abandon its own template, stunning a few business school professors. Its conduct also drew harsh criticism from federal officials.

On Friday, McNeil Consumer Healthcare, a division of Johnson &Johnson, announced the recall of several hundred batches of popular over-the-counter medicines, including Benadryl, Motrin, Rolaids, Simply Sleep, St. Joseph Aspirin and Tylenol.

According to a federal inspection report, the response was anything but swift. The recall came 20 months after McNeil first began receiving consumer complaints about moldy-smelling bottles of Tylenol Arthritis Relief caplets, according to a warning letter sent by the Food and Drug Administration to the company on Friday. Since then, a few people have also reported temporary digestive problems like nausea, vomiting and stomach pain, the agency said.

The McNeil unit of Johnson &Johnson had recalled some batches of the arthritis drug at the end of 2009. But the company did not conduct a timely, comprehensive investigation, did not quickly identify the source of the problem, and did not notify authorities in a timely fashion, prolonging consumer exposure to the products, the warning letter said.

Analysts said the company's seemingly slow response appeared out of character for one of the most trusted corporate brands in America, the maker of beloved household products like Johnson's Baby Shampoo and Band-Aids.

And the recall, they said, had the potential to encourage consumers, who may have perceived name-brand medicines as being a higher quality worth their premium prices, to switch to less expensive drugstore brands.

"The F.D.A. comments on Friday were devastating because they make the company seem to be complacent and sloppy," said Timothy Calkins, a clinical professor of marketing at the Kellogg School of Management at Northwestern University in Evanston, Ill.

Deborah M. Autor, the director of the Office of Compliance at the F.D.A.'s Center for Drug Evaluation and Research, said on a conference call with journalists on Friday that the company should have acted faster.

"When something smells bad literally or figuratively," Ms. Autor said, "companies must aggressively investigate and take all necessary actions to solve the problem."

In response to a query from a reporter on Sunday, a spokeswoman for McNeil said that the company was working with the F.D.A. to resolve the agency's concerns.

"We're conscious of the fact that people expect more of us," the spokeswoman, Bonnie Jacobs, wrote in an e-mail message. "McNeil Consumer Healthcare has applied broad criteria to identify and remove all product lots that it believes may have the potential to be affected, even if they have not been the subject of consumer complaints."

In a statement on Friday, McNeil said the breakdown of a chemical used to treat wood pallets that transport and store product packaging was the source of the moldy smell in some products.

The company has set up a Web site, McNeilProductRecall.com, which provides the list of recalled batches, also known as lots. Consumers can also call 888-222-6036 to ask about a refund or replacement of recalled products.

Separately on Friday, the Justice Department also filed charges against Johnson &Johnson in federal court in Massachusetts, accusing the company of paying kickbacks to a nursing home pharmacy to promote several of its prescription drugs, including the antipsychotic drug Risperdal, to elderly patients. The company said on Friday that its conduct had been legal and appropriate. The company was reviewing the government's complaint and intends to respond in court, a spokeswoman said.

Mr. Calkins said the company faces even more public scrutiny with both problems coming out on the same day.

"Now you have two stories that people are connecting," Mr. Calkins said. "It is a bit of a compound fracture."

He and other analysts speculated that company managers might have underestimated the extent of the chemical contamination problem or might have underestimated the public relations issue that could ensue.

This is not the first time a multinational corporation appears to have underreacted to a limited product problem that turned into a big public relations headache, said Stephen A. Greyser, a professor emeritus of marketing at the Harvard Business School. Coca-Cola, he said, was slow to respond to reports in 1999 that several hundred people in Western Europe had become sick after drinking Coke.

Mr. Greyser said he was puzzled by Johnson &Johnson's corporate conduct in this instance.

The F.D.A.'s charges of bad behavior have not yet been proved, he said, but they were serious enough that the company should be more forthright about what its own investigations showed.

"This is an instance where behavior is more important than communications," said Mr. Greyser, who wrote Harvard's original case study on Tylenol in 1982. "Communications and good public relations can be very helpful, but it can't overcome bad behavior."

In a climate in which Americans have come to expect perfection in consumer goods, companies are better off overreacting than underreacting when product problems arise, said Michael Braun, an assistant professor of marketing at the M.I.T. Sloan School of Management.

Such an extreme measure as Johnson &Johnson's nationwide recall of Tylenol in 1982 may not have been warranted for safety reasons, he said, but it reflected well on the company.

"These kinds of actions have tremendous public relations value and that can protect a brand because it engenders trust," he said. "They probably haven't done that in this case."

Johnson &Johnson's conduct is all the more out of step, analysts said, because the drug maker had been one of the first in the pharmaceutical industry to set up its own blog, jnjbtw.com.

In 2008, for example, in an act of transparent crisis management, the blog apologized to readers for a Motrin ad that had insulted some mothers and explained that the company had pulled the ad campaign in response.

But, as of Sunday at 6 p.m., on the issue of the current recall, the blog so far has had no comment from the company.

PHOTO: Certain shipments of Motrin, Rolaids, St. Joseph Aspirin and Tylenol were recalled by a unit of Johnson &Johnson. (PHOTOGRAPH BY DANIEL ACKER/BLOOMBERG NEWS) (B2)

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Business/Financial Desk; SECT

Johnson &Johnson Widens Recall of Smelly Over-the Counter Drugs

By THE ASSOCIATED PRESS
354 words
16 January 2010
The New York Times
NYTF
The New York Times on the Web
English

The health care giant Johnson &Johnson expanded a recall of over-the-counter medications on Friday, the second time it had done so in less than a month because of a moldy smell that has made users sick.

The broadening recall includes some batches of regular and extra-strength Tylenol children's Tylenol, eight-hour Tylenol, Tylenol arthritis, Tylenol PM, children's Motrin, Motrin IB, Benadryl Rolaids, Simply Sleep and St. Joseph's aspirin. Caplet and geltab products sold in the Americas, the United Arab Emirates and Fiji were recalled.

The company's McNeil Consumer Healthcare Products unit recalled some Tylenol Arthritis Caplets in November because of the smell, which caused nausea, stomach pain, vomiting and diarrhea. Almost three weeks ago, the company expanded its recall to include Tylenol Arthritis Caplets.

A full list of the recalled products is online.

The way the company handled the recall has irked federal regulators, who say the McNeil unit did not act fast enough.

The Food and Drug Administration said McNeil knew of the problem in early 2008 but made only a limited investigation.

"When something smells bad, literally or figuratively, companies must aggressively investigate and take all necessary action to solve the problem," said Deborah Autor, the director of the F.D.A.'s Office of Compliance of the Center for Drug Evaluation and Research

About 70 people were either sickened by the odor, or noticed it, the F.D.A. said. McNeil has been sent a warning for violating manufacturing standards and failing to report and investigate the problem in a timely way, Ms. Autor said.

Johnson &Johnson has 15 days to respond. The F.D.A. said it wanted to know why the problem was not made public sooner.

Johnson &Johnson said the smell is caused by small amounts of a chemical associated with the treatment of wooden pallets. The F.D.A. said the chemical could volatilize into the air, and traced it to a plant in Las Piedras, P.R.

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Business/Financial Desk; SECTB

A Recall Is Expanded

By THE ASSOCIATED PRESS
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2
English

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